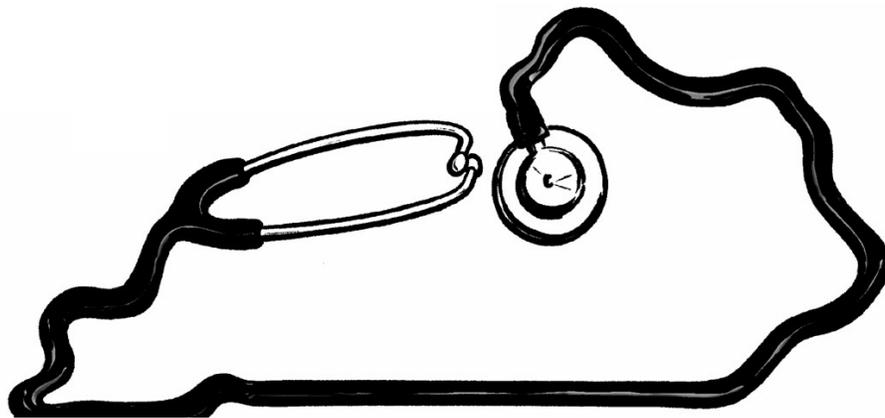




Legal Handbook for Kentucky Physicians 2017



**A service to the members of the
Kentucky Medical Association**

The material in this book is presented for informational purposes only and is not intended as legal advice. Physicians are advised to consult an attorney knowledgeable in health care law for answers to specific questions.

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Printed in the United States of America.

Legal Handbook for Kentucky Physicians

In some sections of this book, excerpts from a statute have been quoted. In other sections, the relevant material has been paraphrased. In places where portions of the Kentucky Revised Statutes are cited, the notation "KRS" is made with the appropriate statutory number following. In some instances, there are also references to Kentucky regulations, which are cited by the notation "KAR" along with the appropriate regulatory number following. Portions of federal law are also cited, although a complete review of federal laws and regulations that may affect physicians is beyond the scope of this book. Reference is also made to Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association, which has been codified as part of Kentucky law. Following the discussion of health care law, a listing of commonly used phone numbers and addresses is provided as a quick reference.

Since amendments to laws and regulations occur frequently, and excerpts can be misinterpreted when viewed in isolation, the full text of a relevant statute must sometimes be consulted. Members are advised to consult an attorney knowledgeable in health care law for answers to specific questions.

The Kentucky Medical Association hopes this book will be a ready and valuable reference for your practice.

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President 2016-2017
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Acknowledgments

This book was written, edited and assembled by the Kentucky Medical Association. Other individuals and organizations were kind enough to write material for this book or allow the KMA to reprint existing material. The following individuals and organizations contributed to this book: Peggy Appenfelden and Charles J. "Mike" Cronan, IV, JD, of the law firm of Stites & Harbison; Danna Droz, formerly of the Cabinet of Health Services/Drug Control Branch; Douglass Farnsley, JD, of the law firm of Stites & Harbison; Rob Kane of the Illinois State Medical Society; Theodore T. "Tad" Myre, JD, of the law firm of Wyatt Tarrant & Combs; Lissa Wathen, JD, of the law firm of Stites & Harbison; the Private Sector Advocacy Division of the American Medical Association; and, the Organized Medical Staff Section of the American Medical Association.

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Abandoned Infants

Any person or parent, other than an emergency medical services provider, a police officer, a firefighter, or a staff member at a participating place of worship acting in the course of his or her official duties, who leaves a “newborn infant,” which is defined as an infant who is medically determined to be less than thirty (30) days old, at an emergency room, or brings a newborn infant to an emergency room and expresses an intent to leave the infant and not return, has the right to remain anonymous and to leave at any time, and not be pursued or followed, unless there is indication of child abuse. The physician may consider the actions of leaving such an infant as implied consent for treatment. [KRS 216B.190(3)] Upon admittance, the physician or hospital administrator must immediately contact the local office of the Department for Community Based Services. [KRS 216B.190(4)]

A newborn infant that is brought to a hospital when the identity of the parents is unknown must be admitted by the hospital and provided with all necessary medical care, diagnostic tests, and medical treatment. Any person performing medical care, diagnostic testing, or medical treatment is immune from criminal or civil liability for having performed the act. That does not, however, limit any liability for negligence. [KRS 216B.190(2)]

Every emergency room must make available materials to gather health and medical information concerning the infant and the parents. The materials must be offered to the person leaving the newborn infant and it must be clearly stated that acceptance is completely voluntary and completion of the materials may be done anonymously. [KRS 216B.190(5)] ([Back](#))

Acquired Immunodeficiency Syndrome (AIDS)

Kentucky has regulated, in some respects, how physicians and other health care providers must deal with patients who have AIDS. KRS 214.625 requires that prior to a medical procedure or test to determine Human Immunodeficiency Virus Infection, a general consent form must be signed by the patient. This general consent form must instruct the patient that, as part of the medical procedures or tests, the patient may be tested for Human Immunodeficiency Virus Infection, Hepatitis, or any other blood born infectious disease if a doctor orders the test for diagnostic purposes. A separate consent form for such a test does not have to be signed by the patient, but can be part of a general consent form for the performance of medical procedures and tests. The results of such a test may only be used for diagnostic or other purposes directly related to medical treatment. Such a consent form does not have to be obtained in an emergency situation. A physician who orders the test or the attending physician is also responsible for informing the patient of the results if the test is positive for Human Immunodeficiency Virus Infection. If the test is positive, the physician must either provide information and counseling to the patient or refer the patient to an appropriate professional for such counseling. No test may be determined positive and no positive test result can be revealed to any person without collaborative or confirmatory tests being conducted.

The Cabinet for Health Services must establish a system for reporting, by the use of the person’s name, all persons who test positive for the human immunodeficiency virus (HIV) infection [KRS 214.645]. For more information on reporting patients with HIV and/or AIDS, see the “Communicable Diseases” section of this book.

If a physician has knowledge of a test result, the physician cannot be compelled to disclose the identity of any person upon whom a test is performed or the results of the test except to the following persons:

1. The patient or the patient’s authorized representative;
2. A person designated in a legally effective release;
3. A physician or other provider who has a legitimate need to know the test result in order to provide protection and to provide for the patient’s health and welfare;
4. Health care providers consulting between themselves to determine diagnosis and treatment;
5. The Cabinet for Health Services in accordance with rules controlling the spread of disease;
6. A facility that processes human body parts from a deceased person or semen provided prior to July 13, 1990 for artificial insemination;
7. Health facility staff committees for the purposes of conducting program monitoring and evaluation;
8. Authorized medical researchers who shall not further disclose such information;
9. A parent or legal guardian of a minor or a crime victim;

10. Pursuant to court order [KRS 214.625(5)(c)].

A physician shall not be civilly or criminally liable for the disclosure of otherwise confidential information under the following circumstances:

- (a) If a patient of the physician has tested positive for human immunodeficiency virus discloses to the physician the identity of a spouse or sexual partner with whom the patient has cohabitated for more than one (1) year; and
- (b) The physician recommends the patient notify the spouse or sexual partner of the positive test and refrain from engaging in sexual activity in a manner likely to transmit the virus and the patient refuses;
- (c) If, pursuant to a perceived civil duty or the ethical guidelines of the profession, the physician reasonably and in good faith advises the spouse of the patient or sexual partner with whom the patient has cohabitated for more than one (1) year of the positive test and facts concerning the transmission of the virus; and
- (d) The physician reports information about HIV status to the Cabinet for Health Services pursuant to regulation.

Notwithstanding the foregoing, a physician shall not be civilly or criminally liable for failure to disclose information relating to a positive test result for human immunodeficiency virus of a patient to a spouse [KRS 311.282].

When a public servant, a health care professional (including a physician), an employee of the health care professional, an employee of a health care facility that is licensed under the laws of the Commonwealth, or victim of a crime is bitten by, suffers a puncture wound caused by, or is exposed to the blood or body fluids of a criminal defendant, inmate, parolee, or probationer or the blood or body fluids of a criminal defendant, inmate, parolee, or probationer have come into contact with the skin or unprotected clothing of a public servant during any incident in which the public servant and the criminal defendant, inmate, parolee, or probationer are involved, the criminal defendant, inmate, parolee, or probationer must be ordered to submit to testing of the blood for human immunodeficiency virus (HIV), hepatitis B, and C, and any other disease if recommended by the Centers for Disease Control and Prevention [KRS 438.250].

Code of Medical Ethics Opinion 2.23 makes it unethical for a physician to deny treatment to HIV infected individuals because they are HIV seropositive or because they are unwilling to undergo HIV testing, except in the instance where knowledge of the patient's HIV status is vital to the appropriate treatment of the patient.

Code of Medical Ethics Opinion 5.057 mandates that physicians maintain the confidentiality of HIV status on autopsy reports to the greatest extent possible.

Code of Medical Ethics Opinion 9.131 makes it unethical for a physician to refuse to treat a patient whose condition is within the physician's current realm of competence solely because the patient is seropositive for HIV. A physician who knows that he or she is seropositive should not engage in any activity that creates an identified risk of transmission of the disease to others. A physician who has HIV disease or who is seropositive should consult colleagues as to which activities the physician can pursue without creating a risk to patients. ([Back](#))

Acupuncturist

Any person practicing, or offering to practice as an acupuncturist must be licensed by the Kentucky Board of Medical Licensure and an acupuncturist license must be renewed every two (2) years. [KRS 311.671] The Board will draft and implement regulations regarding the licensure of acupuncturists and at the time this section was written, such regulations had not yet been finalized. The requirement for licensure is not intended to limit, preclude, or otherwise interfere with the practice of other health care providers whose practices and training may include elements of the same nature as the practice of a licensed acupuncturist.

The "practice of acupuncture" means the insertion of acupuncture needles, with or without accompanying electrical or thermal stimulation, at certain acupuncture points or meridians on the surface of the human body for purposes of changing the flow of energy in the body and may include acupressure, cupping, moxibustion, or dermal friction. The practice of acupuncture may not include laser acupuncture, osteopathic manipulative treatment, chiropractic adjustments, physical therapy, or surgery. [KRS 311.672(5)] An acupuncture practitioner must use the designation "licensed acupuncturist" or "L.Ac." following his or her name in all advertisements, professional literature, and billings used in connection with his or her practice. [KRS 311.676] The license issued by the board must be conspicuously displayed in the licensed acupuncture practitioner's place of business.

An acupuncturist must obtain informed consent from each patient in a manner consistent with the acceptable and

prevailing standards of practice within Kentucky and, at a minimum, the acupuncturist must disclose to the patient the following written information prior to or during the patient's initial visit:

- The acupuncturist's qualifications, including his or her education, license information, and the definition and scope of the practice of acupuncture in ; and
- Possible outcomes of the treatment to be given, including any pain, bruising, infection, needle sickness, or other side effects that may occur. [KRS 311.678]

Every licensed acupuncturist must develop a written plan for consultation, emergency transfer, and referral to appropriate health care facilities or to other health care practitioners operating within the scope of their authorized practices, which meets the requirements contained in administrative regulations promulgated by the Board. The written plan must be filed with the Board and maintained at the acupuncturist's practice location and updated as appropriate to meet current regulatory requirements. [KRS 311.680(1)]

If, in the course of conducting an interview regarding the patient's medical history, the patient discloses that he or she suffers from one (1) of the potentially serious disorders or conditions listed below, the acupuncturist must verify that the patient is currently under the care of a physician and consult with the treating physician before providing acupuncture treatment. If the patient refuses to provide a medical history or disclose information regarding any of the conditions listed below, acupuncture treatment must not be provided. "Potentially serious disorder or condition" means:

- Hypertension and cardiac conditions;
- Acute, severe abdominal pain;
- Undiagnosed neurological changes;
- Unexplained weight loss or gain in excess of fifteen percent (15%) of the patient's body weight in less than a three (3) month period;
- Suspected fracture or dislocation;
- Suspected systemic infections;
- Serious hemorrhagic disorder;
- Acute respiratory distress without a previous history;
- Pregnancy;
- Diabetes; or
- Cancer. [KRS 311.680(3)]

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Adult Protection

KRS 209.030 requires a physician, as well as other health care providers, to report to the Cabinet for Health Services any knowledge regarding the occurrence of suspected adult abuse, neglect or exploitation. A physician can make such a report orally or in writing to the Cabinet for Health Services or local Social Services' offices. The Department for Social Services does have a reporting hotline (1-800-752-6200).

"Adult" for purposes of this requirement is defined as a person eighteen [18] years of age or older who because of mental or physical dysfunction is unable to manage his own resources or carry out the activity of daily living or protect himself from neglect, exploitation, or a hazardous or abusive situation without assistance from others, and who may be in need of protective services [KRS 209.020(4)].

"Abuse" is the infliction of injury, sexual abuse, unreasonable confinement, intimidation, or punishment that results in physical pain or injury including mental injury [KRS 209.020(8)]. "Neglect" is a situation in which an adult is unable to perform or obtain for himself the goods or services that are necessary to maintain his health or welfare, or the deprivation of services by a caretaker that are necessary to maintain the health and welfare of an adult [KRS 209.020(16)]. "Exploitation" is obtaining or using another person's resources, including funds, assets, or property, by deception, intimidation, or similar means with the intent to deprive the person of those resources [KRS 209.020(9)].

If a physician believes that an adult has suffered abuse, neglect or exploitation, the following information should be given when a report is made:

- The name and address of the adult or of any other person responsible for his care;
- The age of the adult;
- The nature and extent of the abuse, neglect or exploitation including any evidence of previous abuse, neglect or exploitation;
- The identity of the perpetrator, if known;
- The identity of the complainant if possible; and,
- Any other information the provider believes might be helpful in establishing the cause of the abuse [KRS 209.030(4)].

Federal HIPAA privacy regulations allow physicians to make reports of suspected abuse as long as the report is mandated by state law. As discussed previously, Kentucky does mandate such reports. HIPAA also requires, however, that if a report of adult abuse is made to state authorities, the patient who is the subject of the report must be informed by the physician of the report. This notice may be made orally rather than in writing, although it would be wise to document such notice.

KRS 209.050 provides immunity from civil or criminal liability for anyone who has “reasonable cause” to make a report regarding adult abuse. ([Back](#))

Advertising

Kentucky regulations set forth limits of permissible professional advertising by physicians. Physician advertising may be by any medium provided that the advertisement shall not be fraudulent, misleading or deceptive. The following may not be advertised:

- (1) Testimonials of patients as to the physician’s skill or the quality of his or her professional services;
- (2) Claims regarding the physician’s experience, competency and quality of services which imply that he or she possesses an exclusive and unique skill or remedy;
- (3) Claims which cannot be readily verified by objective standards; and,
- (4) Any representation expressly prohibited under the Medical Practice Act, such as those that deceive or defraud the public.

An advertisement may be sent to an individual addressee only if that addressee is one of a class of persons, other than a family to whom it is sent at the same time. An advertisement may not be sent to an addressee if prompted or precipitated by a specific event or occurrence involving or relating to the addressee as distinct from the general public.

A licensee may only advertise that the licensee is “board certified” if the certifying board advertised by the licensee is:

- (a) A member of the American Board of Medical Specialties (ABMS);
- (b) A member of the Bureau of Osteopathic Specialties and Board of Certification; or
- (c) A board that has been determined, by a subcommittee of the Board of Medical Licensure comprised of members appointed by the president to require:
 1. Identifiable training in the relevant specialty or subspecialty field within a program accredited by the Accreditation Council for Graduate Medical Education or its equivalent; and
 2. Satisfactory completion of a comprehensive psychometrically-validated examination in the specialty or subspecialty field. [201 KAR 9:018]

Code of Medical Ethics Opinion 5.02 provides no restrictions on advertising by physicians except those that can be specifically justified to protect the public from deceptive practices. Advertising communication may not be misleading because of the omission of necessary material information; may not contain any false or misleading statement; and, may not otherwise operate to deceive. The key issue when deciding whether physician advertisement violates the *Code of Medical Ethics* is whether advertising, regardless of format or content, is true and not materially misleading.

42 U.S.C. 1320b–10 makes it unlawful for any person to advertise using the names, abbreviations, symbols, or emblems of the Social Security Administration, Health Care Financing Administration, Department of Health and Human Services, Medicare, Medicaid or any combination or variation of such words, abbreviations, symbols or emblems in a manner that such person knows or should know would convey the false impression that the advertised item is endorsed by the named entities. For instance, a physician may not place an ad in the newspaper that reads “Dr. X is a cardiologist approved by both the Medicare and Medicaid programs.” A violation of this section may result in a penalty of up to \$5,000 (\$25,000 in the case of a broadcast or telecast) for each violation.

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Americans with Disabilities Act (ADA)

I. Introduction - Congress passed the Americans With Disabilities Act (42 USC §§12101 to 12213) in order to prevent discrimination against individuals with handicapping conditions. Physicians are cautioned about relying solely on this topical explanation of the ADA when attempting to comply with the Act’s requirements. Unfortunately, when Congress enacted this law, it left to the courts the task of defining the meaning of the Act’s provisions on a case by case basis. In effect, the ADA is a civil rights law and it should be read in conjunction with the Rehabilitation Act of 1973. That law is discussed after the ADA section in this book. The ADA applies in both the “employment” and “services” contexts even if an entity (e.g., a physician’s office) receives no federal funds. In the employment sector since July 26, 1993, the ADA has applied to employers with 15 or more employees. In the public services’ sector the ADA became effective January 26, 1992, and applies to *public accommodations* -- which specifically includes physician offices.

The general prohibition against discrimination in the *employment* sector is broad:

No covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment [§12112(a)].

In the employment setting, a *qualified individual* is someone with a disability who can perform the essential functions of a job (which the person already holds or seeks to be hired for) with or without “reasonable accommodation.” Consideration is given to the employer’s judgment as to what job functions are essential. For example, a job description is evidence of essential job functions [§12111(8)]. Employers are not required to follow affirmative action rules. Thus, they should still be free to hire only the most qualified individuals to fill job slots. (In the event that a disabled person is the most qualified and he or she is hired, then the employer, when necessary, is required to reasonably accommodate the disabled worker). Such accommodations (for all disabled workers--whether newly hired or already on the job) may include making existing facilities readily accessible, restructuring a job, offering part-time or modified work schedules (e.g., flex-time), reassignment to a vacant position, buying or modifying job-related (or facility) equipment, or even providing qualified readers or interpreters for disabled workers. Employers need not suffer undue hardship in making an accommodation such that their financial resources are strapped given their expenses, resources, size, and company type [§11211(10)].

II. Disability Definitional Considerations-The ADA defines disability three ways:

- (1) A physical or mental impairment that substantially limits one or more of the major life activities of such individual;
- (2) A record of such an impairment; or
- (3) Being regarded as having such an impairment. (Thus, this includes persons who are “perceived” to be handicapped even if they really are not.)

The law excludes from the definition of “qualified individual with a disability” any employee or applicant who is currently engaged in the illegal use of drugs, when the employer acts on the basis of such use. However, chemically impaired individuals are protected under the ADA where they:

- (1) Have successfully completed a supervised drug rehabilitation program and are no longer engaging in the illegal use of drugs, or have otherwise been rehabilitated successfully and are no longer engaging in such use;
- (2) Are participating in a supervised rehabilitation program and are no longer engaging in such use; or

- (3) Are erroneously regarded as engaging in such use, but are not engaging in such use.

It is not a violation of this law for a covered entity to adopt or administer reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual described in paragraphs (1) or (2) is no longer engaging in the illegal use of drugs.

III. Illegal Use of Drugs Under the ADA -The term *illegal use of drugs* means the use of drugs, the possession or distribution of which is unlawful under the Controlled Substances Act [21 U.S.C. §812]. Such term does not include the use of a drug taken under supervision by a licensed health care professional, or other uses authorized by the Controlled

Substances Act or other provisions of federal law. The term *drug* means a controlled substance, as defined in schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. §812].

IV. Applicant Medical Exams Under the ADA-Employers are prohibited from inquiring about, or conducting medical examinations to discover, whether an applicant is disabled. They may ask (if it is a business necessity) about the ability of an applicant to perform job-related functions. Also, employers may require a medical examination after an offer of employment has been made to a job applicant and prior to the commencement of the employment duties of such applicant, and may condition an offer of employment on the results of such examination, if-

- (A) All entering employees are subjected to such an examination regardless of disability;
- (B) Information obtained regarding the medical condition or history of the applicant is collected and maintained on separate forms and in separate medical files and is treated as a confidential medical record, except that –
 - (i) Supervisors and managers may be informed regarding necessary restrictions on the work or duties of the employee and necessary accommodations;
 - (ii) First aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment; and
 - (iii) Government officials investigating compliance with this Act shall be provided relevant information on request; and
- (C) The results of such examination are used only in accordance with (the ADA's requirements).

V. Prohibition Against Discrimination in the Service Sector - The ADA also prohibits discrimination in the provision of services by *public accommodations*. Again, the prohibition is broad:

No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation [§12182(a)].

Thus, not only does the ADA apply to entities such as bakeries, hardware stores, funeral parlors, health spas, and homeless shelters, but it also expressly includes the offices of accountants and lawyers, and facilities such as pharmacies, hospitals, and health care providers [§12181(7)]. This probably means that disabled patients cannot be denied access to health care solely on the basis of their physical or mental impairment. Physicians fall within the reach of the ADA both as health care providers and as agents of hospitals and clinics, which also fall under the “public accommodations” heading.

In this context, the ADA requires that barriers (whether they be architectural or communication) in existing facilities be removed or altered so as not to obstruct access. The litmus test is whether and to what extent a particular barrier’s removal is readily achievable. Factors to be considered are cost, the type of alteration that would have to occur, the effect on the service provider’s fiscal budget, the number of employees, and whether the service provider is owned by a larger concern and if so its financial resources. Thus, if a barrier’s removal is readily achievable then, for example, rest rooms, entrance doors, elevators, public telephones, parking lots and adjacent walkways, and other commonly used service items and areas must be made handicap accessible. Generally, the failure to modify such facilities is defined as discrimination under the Act [12182]. Not only must architectural barriers be removed or altered so that individuals with disabilities can access available services, but communication barriers that are “structural in nature” must be removed as well. These provisions are vague and at the same time complex.

VI. Auxiliary Aids and Services-There have been continuing reports of advocacy organizations for the hearing impaired demanding that physicians hire “qualified interpreters” who accompany deaf patients for treatment. In some instances, when physicians have refused to hire the interpreters, ADA discrimination lawsuits have been threatened. This troublesome position is not supported by the ADA’s language, its legislative history, or the interpretive federal regulations.

Although physicians’ offices must “furnish appropriate auxiliary aids and services where necessary to ensure effective communication with...” disabled individuals [Regulation §36.303(c)], they need not always hire the particular interpreters that the patients bring along. Instead, physicians should consult with their patients (preferably in advance of appointment dates) to find out how the patients best communicate. The American Medical Association notes that, usually, a listening

device or handwritten notes may suffice instead of hiring an interpreter. The regulations state that the auxiliary aid requirement is a flexible one: "A public accommodation can choose among various alternatives as long as the result is effective communication..." Regulation §36.303(b)(1) gives the following examples of auxiliary aids and services:

Qualified interpreters on site or through video remote interpreting (VRI) services; notetakers; real-time computer-aided transcription services; written materials, exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered materials available to individuals who are deaf or hard of hearing.

The regulations' preamble states, however, "that public accommodations must take steps to ensure that an individual with a disability will not be excluded, denied services, segregated or otherwise treated differently from other individuals because of the use of inappropriate or ineffective auxiliary aids. In those situations requiring an interpreter, the public accommodations must secure the services of a qualified interpreter, unless an undue burden would result."

In this regard, Regulation §36.104 defines "qualified interpreter" as an interpreter "who is able to interpret effectively, accurately and impartially both receptively and expressively, using any necessary specialized vocabulary." An "undue burden" is defined as involving significant difficulty or expense. The following factors are to be considered in deciding whether an action involves an undue burden for physicians' offices:

- (1) The nature and cost of the action needed under this part;
- (2) The overall financial resources of the site or sites involved in the action; the number of persons employed at the site; the effect on exposures and resources; legitimate safety requirements that are necessary for safe operation, including crime prevention measures; or the impact otherwise of the action upon the operation of the site.

Physicians may not charge patients for the provision of auxiliary aids and services [Regulation §36.301(c)] or require patients to bring their own interpreter to an office visit [Regulation §36.303(c)]. It is improper to rely on a minor to act as an interpreter, and physicians should not rely on a patient's adult companion unless all parties agree otherwise. If it is appropriate for a physician to communicate with a patient's family member or friend — and that friend or family member is deaf, hard of hearing or otherwise disabled — the physician must utilize auxiliary aids and services if they are needed to ensure effective communication.

Finally, due to recent changes in the law, if patients are offered the opportunity to use a physician's office telephone on more than an incidental convenience basis, then the office must make available a telecommunications system that allows for use by an individual who is deaf or hard of hearing. The compliance date for this requirement is March 15, 2012.

VII. Extra Help - There is a telephone hotline for answering ADA compliance questions. The service is provided by the Civil Rights Division of the United States Department of Justice. DOJ's ADA specialists will provide free legal guidance to physicians (and others) on specific ADA issues. Call (800)514-0301; M-W, F, 10 a.m. - 6 p.m. (EST), (Thurs. 1-6), (Services are menu driven.) For computer downloads call (202)514-6193. The main number is (202)514-0301.

VIII. Potential Applicability to Hospital Credentialing Process -Although hospitals generally do not employ most physician members of medical staffs, it can be argued that when Congress passed the ADA in order to prevent discrimination against individuals with handicapping conditions, Congress may have thrown the ADA net wide enough to touch hospital medical staff credentialing. Courts have not yet determined ADA applicability in this context.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), however, acknowledges the applicability of the ADA in the provision of patient care [JCAHO, Standard RI.11]. The JCAHO accreditation manual also addresses the ADA's potential applicability to physician credentialing. See JCAHO, Standards MS.2.4. to MS.2.4.1.3: "The Americans with Disabilities Act bars certain discrimination based on physical or mental impairment. Toward preventing such discrimination, the act prohibits or mandates various activities. Hospitals need to determine the applicability of the ADA to their medical staff. If applicable, the hospital should examine its privileging or credentialing procedures as to how and when it ascertains and confirms the health status of an applicant. For example, the act may prohibit inquiry as to the physical and/or mental health status of an applicant prior to making an offer of membership and privileges, but may not prohibit such inquiry after an offer is extended (contingent on the ascertainment of health status). The Act does not appear to prohibit inquiry as to the ability of the applicant (without specific reference to health matters) to perform the specific privileges requested. Thus, the inquiry may be made and confirmed as a component of the application process. The Joint Commission cannot provide legal advice to hospitals. However, the Joint Commission has and will absolutely construe MS.2.4 through MS.2.4.1.3 in such a manner as to be consistent with hospital efforts to comply with the ADA." (p. 489)

IX. The Rehabilitation Act of 1973

- A. **Introduction** - The Rehabilitation Act of 1973 (29 USC §794) is the ADA's 23 year old precursor. These laws overlap and should be considered together as a broad expansion of civil rights for persons having conditions that meet both (or either) laws' definition of *handicap* or *disability*. (AIDS is but one example of a condition covered or protected by both laws.) The Rehabilitation Act broadened the rights of employees and applicants (for employment) by prohibiting discrimination on the basis of a physical or mental handicap by any employer (such as a health care facility) that contracts with the federal government, or who otherwise receives federal funds such as Medicare. (Please note that the ADA, discussed supra, contains no such limitation.) "No otherwise qualified individual with handicaps in the United States, as defined in section 7(8) [29 USC §706(8)], shall, solely by reason of his or her handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service" [29 USC §794(a)].
- B. **Programs and Activities Defined** - (1) A *program or activity* includes all of the operations of an entire corporation, partnership, or other private organization, or an entire sole proprietorship—
- (a) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or
 - (b) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or
 - (c) Alternatively, *program or activity* includes an entire plant or other comparable, geographically separate facility to which federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship.
- C. **Reasonable Accommodation Standard** - The Act covers services and employment and sets up a reasonable accommodation standard. Thus, handicapped persons must be *reasonably accommodated* to enable them to qualify for services or employment. Persons with AIDS or HIV infection also are covered here and are considered *otherwise qualified* for employment unless they pose a *significant* transmission risk which reasonable accommodation cannot eliminate. The factors to be weighed in this determination include the nature, duration, and severity of the transmission risk.
- D. **Health Threat Exemption** - The Act defines the term *individual with handicaps* as excluding an "individual who has a currently contagious disease or infection and who, by reason of such disease or infection, would constitute a direct threat to the health or safety of other individuals or who, by reason of the currently contagious disease or infection, is unable to perform the duties of the job [29 USC §706(8)(c)]." Thus, as long as an individual, who is otherwise qualified, but who has a condition such as AIDS, does not constitute a direct threat to others and can be reasonably accommodated, he or she cannot be denied employment solely on the basis of the handicap. Importantly, discrimination cannot be justified using a theoretical possibility of transmission. Therefore, a facility may be required to allow an HIV infected health care worker to assist or perform invasive procedures if CDC guidelines are followed. ([Back](#))

Anatomical Gifts

An anatomical gift of a donor's body or part may be made during the life of the donor for the purpose of transplantation, therapy, research, or education by the donor, if the donor is an adult or if the donor is a minor and is emancipated or authorized under state law to apply for a driver's license because the donor is at least sixteen (16) years of age; an agent of the donor, unless the power of attorney for health care or other record prohibits the agent from making an anatomical gift; a parent of the donor, if the donor is an unemancipated minor; or the donor's guardian. KRS 311.1915. An agent of the donor is someone who can make health care decisions for the donor through a power of attorney for health care or is expressly to make an anatomical gift through some record signed by the donor. KRS 311.1911(2).

A donor may make an anatomical gift by authorizing a statement or symbol indicating that the donor has made an anatomical gift to be imprinted on the donor's driver's license or identification card; in a will; during a terminal illness or injury of the donor, by any form of communication addressed to at least two (2) adults, at least one (1) of whom is a disinterested witness; or a donor or other person authorized to make an anatomical gift may make a gift by a donor card or other record signed by the donor or other person making the gift or by authorizing that a statement or symbol indicating that the donor has made an anatomical gift be included on a donor registry. If the donor or other person is physically unable to sign a record, the record may be signed by another individual at the direction of the donor or other person and must be witnessed by at least two (2) adults, at least one (1) of whom is a disinterested witness, who have signed at the request of the donor or the other person; and state that it has been signed and witnessed as provided in paragraph (a) of this subsection. Revocation, suspension, expiration, or cancellation of a driver's license or identification card upon which an anatomical gift is indicated does not invalidate the gift. An anatomical gift made by will takes effect upon the donor's death whether or not the will is probated. Invalidation of the will after the donor's death does not invalidate

the gift. The making of an anatomical gift shall not under any circumstances be construed to authorize or direct the denial of health care or hydration and nourishment when the withholding or withdrawal of health care or hydration and nourishment will result in or hasten death. KRS 311.1917.

A donor or other person authorized to make an anatomical gift may amend or revoke an anatomical gift under specific circumstances set out under the law. KRS 311.1919. Individuals may also refuse to make an anatomical gift through specific written records specified under the law. KRS 311.1921.

Unless barred by other law, an anatomical gift of a decedent's body or part for purpose of transplantation, therapy, research, or education may be made by any member of the following classes of persons who is reasonably available, in the order of priority listed:

- (a) An agent of the decedent at the time of death who could have made an anatomical gift immediately before the decedent's death;
- (b) The spouse of the decedent;
- (c) Adult children of the decedent;
- (d) Parents of the decedent;
- (e) Adult siblings of the decedent;
- (f) Adult grandchildren of the decedent;
- (g) Grandparents of the decedent; and
- (h) The persons who were acting as the guardians of the person of the decedent at the time of death.

If there is more than one (1) member of a class listed in paragraph (a), (c), (d), (e), (f), (g), or (h) entitled to make an anatomical gift, an anatomical gift may be made by a member of the class unless that member or a person to which the gift may pass knows of an objection by another member of the class. If an objection is known, the gift may be made only by a majority of the members of the class who are reasonably available. A person may not make an anatomical gift if, at the time of the decedent's death, a person in a prior class is reasonably available to make or to object to the making of an anatomical gift. KRS 311.1925. A person authorized to make an anatomical gift do so by a document of gift signed by the person making the gift or by that person's oral communication that is electronically recorded or is contemporaneously reduced to a record and signed by the individual receiving the oral communication. An anatomical gift by a person may be amended or revoked orally or in a record by any member of a prior class who is reasonably available. If more than one (1) member of the prior class is reasonably available, the gift made by a person may be:

- (a) Amended only if a majority of the reasonably available members agree to the amending of the gift; or
- (b) Revoked only if a majority of the reasonably available members agree to the revoking of the gift or if they are equally divided as to whether to revoke the gift.

A revocation by a person in one of the classes above is effective only if, before an incision has been made to remove a part from the donor's body or before invasive procedures have begun to prepare the recipient, the procurement organization, transplant hospital, or physician or technician knows of the revocation. KRS 311.1927.

An anatomical gift may be made to the following persons named in the document of gift:

- (a) A hospital; accredited medical school, dental school, college, or university; organ procurement organization; or other appropriate person, for research or education;
- (b) An individual designated by the person making the anatomical gift if the individual is the recipient of the part, unless it cannot be transplanted into the individual; or
- (c) An eye bank or tissue bank.

If an anatomical gift of one (1) or more specific parts or of all parts is made in a document of gift that does not name a person but identifies the purpose for which an anatomical gift may be used, the following rules apply:

- (a) If the part is an eye and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate eye bank;
- (b) If the part is tissue and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate tissue bank;
- (c) If the part is an organ and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate organ procurement organization as custodian of the organ; or

- (d) If the part is an organ, an eye, or tissue and the gift is for the purpose of research or education, the gift passes to the appropriate procurement organization.

If there is more than one (1) purpose of an anatomical gift set forth in the document of gift but the purposes are not set forth in any priority, the gift shall be used for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education. If an anatomical gift of one (1) or more specific parts is made in a document of gift that does not name a person and does not identify the purpose of the gift, the gift may be used only for transplantation or therapy, and the gift passes by the following rules:

- (a) If the part is an eye, the gift passes to the appropriate eye bank;
- (b) If the part is tissue, the gift passes to the appropriate tissue bank, except that a tissue bank shall not receive an ovum or sperm for the purpose of creating an embryo to be used in therapy, research, or education; or
- (c) If the part is an organ, the gift passes to the appropriate organ procurement organization as custodian of the organ. KRS 311.1929

The following persons shall make a reasonable search of an individual who the person reasonably believes is dead or near death for a document of gift or other information identifying the individual as a donor or as an individual who made a refusal:

- (a) A law enforcement officer, firefighter, paramedic, or other emergency rescuer finding the individual; and
- (b) If no other source of the information is immediately available, a hospital, as soon as practical after the individual's arrival at the hospital.

If a document of gift or a refusal to make an anatomical gift is located by the search and the individual or deceased individual to whom it relates is taken to a hospital, the person responsible for conducting the search shall send the document of gift or refusal to the hospital. A person is not subject to criminal or civil liability for failing to discharge the duties imposed by this section but may be subject to administrative sanctions. KRS 311.1931

Upon or after an individual's death, a person in possession of a document of gift or a refusal to make an anatomical gift with respect to the individual shall allow examination and copying of the document of gift or refusal by a person authorized to make or object to the making of an anatomical gift with respect to the individual or by a person to which the gift could pass. KRS 311.1933(2)

When a hospital refers an individual at or near death to a procurement organization, the organization may conduct any reasonable examination of records necessary to ensure the medical suitability of a part that is or could be the subject of an anatomical gift for transplantation, therapy, research, or education from a donor or a prospective donor. During the examination period, measures necessary to ensure the medical suitability of the part may not be withdrawn unless the hospital or procurement organization knows that the individual expressed a contrary intent. Measures necessary to ensure the medical suitability of the part from a prospective donor may be administered unless it is determined that the administration of those measures would not provide the prospective donor with appropriate end-of-life care, or it can be anticipated by reasonable medical judgment that such measures would result in or hasten the prospective donor's death. Unless prohibited by law, at any time after a donor's death, the person to which a part passes may conduct any reasonable examination necessary to ensure the medical suitability of the body or part for its intended purpose. Unless prohibited by law, an examination may include an examination of all medical and dental records of the donor or prospective donor. Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent. A physician or technician may remove a donated part from the body of a donor that the physician or technician is qualified to remove. KRS 311.1935.

A person that for valuable consideration, knowingly purchases or sells a part for transplantation or therapy if removal of a part from an individual is intended to occur after the individual's death shall be imprisoned for not less than one (1) nor more than five (5) years or be fined not more than fifty thousand dollars (\$50,000), or both. A person may, however, charge a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part. KRS 311.1939. A person that, in order to obtain a financial gain, intentionally falsifies, forges, conceals, defaces, or obliterates a document of gift, an amendment or revocation of a document of gift, or a refusal shall be imprisoned in the penitentiary for not less than one (1) nor more than five (5) years or be fined not more than fifty thousand dollars (\$50,000), or both. KRS 311.1941

If a prospective donor has a declaration or advance health-care directive and the terms of the declaration or directive and the express or implied terms of a potential anatomical gift are in conflict with regard to the administration of measures necessary to ensure the medical suitability of a part for transplantation or therapy, the prospective donor's attending physician and prospective donor must confer to resolve the conflict. If the prospective donor is incapable of resolving the conflict, an agent acting under the prospective donor's declaration or directive, or, if none or the agent is not reasonably available, another person authorized by law to make health-care decisions on behalf of the prospective donor, may act for the donor to resolve the conflict. Information relevant to the resolution of the conflict may be obtained from the appropriate procurement organization and any other person authorized to make an anatomical gift for the prospective donor. Before the resolution of the conflict, measures necessary to ensure the medical suitability of the part from a prospective donor may be administered unless it is determined that the administration of those

measures would not provide the prospective donor appropriate end-of-life care, or it can be anticipated by reasonable medical judgment that such measures would result in or hasten the prospective donor's death. If the conflict is not resolved expeditiously, the direction of the declaration or advance directive controls. KRS 311.1949.

Upon request of a procurement organization, a medical examiner or coroner shall release to the procurement organization the name, contact information, and available medical and social history of a decedent whose body is under the jurisdiction of the medical examiner or coroner. If the decedent's body or part is medically suitable for transplantation or therapy, the medical examiner or coroner may release relevant postmortem examination results to the procurement organization. The procurement organization may make a subsequent disclosure of the postmortem examination results or other information received from the medical examiner or coroner only if relevant to transplantation or therapy.

The medical examiner or coroner may conduct a medicolegal investigation by reviewing all medical records, laboratory test results, X-rays, other diagnostic results, and other information that any person possesses about a donor or prospective donor whose body is under the jurisdiction of the medical examiner or coroner that the medical examiner or coroner determines may be relevant to the investigation. A person that has any information requested by a medical examiner or coroner for such purpose shall provide that information as expeditiously as possible to allow the medical examiner or coroner to conduct the medicolegal investigation within a period compatible with the preservation of parts for the purpose of transplantation or therapy. If an anatomical gift has been or might be made of a part of a decedent whose body is under the jurisdiction of the medical examiner or coroner and a postmortem examination is not required, or the medical examiner or coroner determines that a postmortem examination is required but that the recovery of the part that is the subject of an anatomical gift will not interfere with the examination, the medical examiner or coroner and the procurement organization shall cooperate in the timely removal of the part from the decedent for the purpose of transplantation or therapy. The medical examiner and procurement organizations shall enter into an agreement setting forth protocols and procedures to govern relations between the parties when an anatomical gift of a part from a decedent under the jurisdiction of the medical examiner has been or might be made, but the medical examiner believes that the recovery of the part could interfere with the postmortem investigation into the decedent's cause or manner of death. Decisions regarding the recovery of organs, tissue, and eyes from such a decedent shall be made in accordance with the agreement. In the event that the medical examiner or coroner denies recovery of an anatomical gift, the procurement organization may request the chief medical examiner to reconsider the denial and to permit the recovery to proceed. The parties shall evaluate the effectiveness of the protocols and procedures at regular intervals. If the medical examiner or coroner or designee allows recovery of a part, the procurement organization, upon request, shall cause the physician or technician who removes the part to provide the medical examiner or coroner with a record describing the condition of the part, a biopsy, a photograph, and any other information and observations that would assist in the postmortem examination. KRS 311.1953. ([Back](#))

Anti-Kickback Law

The Federal Anti-Kickback law [42 U.S.C. §1320a-7b(b)] prohibits medical providers, as well as patients, from offering, paying, soliciting or receiving "remuneration" to induce business for which payment is made under a federal health care program. In other words, no one can give or receive money to refer a person, or be referred to a provider if payment for the services is going to be made by a federal health care program. The law does not apply to payments made by private health care plans.

What is considered to be a kickback, or as the statute says, "remuneration," has been interpreted quite broadly. One federal appeals court has said: "If one purpose of the payment was to induce future referrals, the Medicare statute has been violated." See United States v. Greber, 760 F2d 68 (3rd Cir. 1985). The Departmental Appeals Board has also ruled that "remuneration" is "anything of value," which could be interpreted to mean cash, real estate, bonds, a cow or a new tee-shirt!

The use of the Anti-Kickback law by the federal government for prosecuting physicians has become more popular in the last few years. The principal reason for this is a change in the law, which now allows the government to impose Civil Money Penalties on physicians who violate the law. This means the government can make a physician pay a monetary amount without having to take the physician to court. The government will no doubt use the leverage of Civil Money Penalties against physicians and give them the option of paying the penalties or being prosecuted.

Safe Harbors

Note: The discussion below of the safe harbors to the Anti-Kickback law is not all encompassing. The safe harbors are very complicated to understand. The information provided below is only a discussion of the safe harbors and does not provide all the information necessary to apply a given situation to the law. For specific guidance, you should seek the assistance of qualified legal counsel.

The Department of Health and Human Services Office of Inspector General (OIG) has stated that referrals within a group practice are not considered a violation of this law. There are also a number of "safe harbors" with which a physician could comply and not be prosecuted. (42 CFR § 1001.952) If, however, a situation does not fit specifically into one of the "safe harbors," it does not

necessarily mean the statute has been violated. The safe harbors that may relate to physicians are discussed below.

1. Investment interests: This safe harbor applies to investment interests in what are termed “large entities” and “small entities.” To fall under the “large entity” safe harbor, a large, publicly traded company must have at least 50 million dollars in undepreciated net tangible assets. Physicians may not buy shares in a closed deal before the shares go on sale to the public and cannot swap limited partnership shares for publicly traded shares. Such transactions do not necessarily violate the law, but, are not covered under this safe harbor.

In order for an investment interest to be classified as a “small entity,” the following eight standards must be met:

1. 60/40 investor rule: No more than 40 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year by investors who are in a position to make or influence referrals to the entity.
 2. The terms of the investment interest must be no different than the terms offered to other passive investors.
 3. The terms on which an investment interest is offered must not be related to the previous or expected volume of referrals.
 4. There can be no requirement to generate referrals.
 5. The entity must not market or furnish items to passive investors differently than to non-investors.
 6. 60/40 revenue rule: No more than 40 percent of the gross revenue for the entity in the previous fiscal year may come from referrals generated from investors.
 7. The entity cannot loan or guarantee a loan to an investor in a position to provide referrals.
 8. The investment return must be directly proportional to the amount of the capital investment of that investor.
2. Space and equipment rental contracts: There must be a written agreement which specifies the premises/equipment and the payments based upon fair market value and may not vary on the volume of referrals or business generated between the parties. For purposes of equipment rental, fair market value means the value of the equipment when obtained from a manufacturer or professional distributor. “Wear and tear” clauses in equipment leases, which compensate equipment owners for the diminished value of heavily used equipment, are not protected.
 3. Personal services and management contracts: This safe harbor has similar prohibitions and requirements as the exception for space and equipment rental contracts. (ie - must be based on fair market value, etc)
 4. Sale of practice: The sale of practice safe harbor only covers sales between practitioners. The date of the first agreement pertaining to the sale and the completion of the sale cannot be more than one year and the practitioner buying the practice cannot be in a position to influence referrals.
 5. Employees: This safe harbor addresses amounts paid by an employer to an employee who has a bona fide employment agreement.

Examples of Violations

1. Some joint ventures may be created for the improper purpose of obtaining referrals from provider investors or to compensate providers for referrals. The OIG has specifically mentioned durable medical equipment and clinical laboratory joint ventures. The questionable features of a suspect joint venture include:
 1. The manner in which investors are selected and retained.
 2. The nature of the business structure of the joint venture.
 3. The financing and profit distributions.

One example of this sort of inappropriate venture may be when the amount of capital invested by a physician is disproportionately small and the return on investment is disproportionately large compared with other investors’ return on their investments.

2. If physicians forgive financial obligations for reasons other than genuine financial hardship of the patient, physicians may be unlawfully inducing patients to see them. Thus, waiver of copayments and deductibles for anyone other than financially needy individuals may constitute a “kickback” to the patient.
3. Hospital incentives to physicians have been noted by the OIG as specific violations of the Anti-Kickback law. Suspect arrangements include: (1) free or significantly discounted office space or equipment; (2) free or significantly discounted billing services; (3) income guarantees; and, (4) low interest loans.
4. Drug companies that offer physicians “valuable nonmedical benefits in exchange for selecting specific prescription drug brands” are also suspect.
5. The OIG has identified various arrangements between physicians and laboratories that may violate the law. These include:

1. Free pickup and disposal of biohazardous waste products unrelated to a laboratory's collection of specimens.
 2. Provision of free computers and fax machines unless the equipment is integral to, and exclusively used for, a laboratory's work.
 3. Provision of free laboratory testing for physicians, their families and their employees.
6. Physicians generally use one laboratory for all of their patients' needs and obtain discounts on private business as a result of referrals. There may be an issue as to whether laboratory discounts on a physician's private laboratory business can be considered a "kickback" as to the physician's Medicare laboratory referrals. No court has ruled definitively on this issue.
 7. Do small gifts from a hospital to a physician, such as a ham or pizzas for the office staff, violate the law? Here's what the OIG says. "Our endorsement of [allowing small gifts to be excepted from the law] would only serve to blur these lines and produce litigation as to what substantial, 'technical' and 'de minimus' really mean. The OIG therefore declines to adopt these concepts."
 8. Physician practice acquisitions may also present unique problems. The issue is whether a hospital's purchase of a physician practice violates the law. Six specific items have been mentioned as raising questions as to whether payment by the hospital for the practice is being made to obtain referrals:
 1. Payment for "good will."
 2. Payment for value of an ongoing business unit.
 3. Payment for covenants not to compete.
 4. Payment for exclusive dealing agreements.
 5. Payment for patient list.
 6. Payment for patient records.

The OIG has not said "good will" and other such payments are absolutely prohibited, but, may raise a "red flag."

Penalties

Penalties for violating the Anti-Kickback law include:

- Fines up to \$25,000.
- Five years in prison.
- Exclusion from Federal health care programs to be decided by the Secretary of Health and Human Services.
- Civil money penalties of up to \$50,000 and three times the amount of the remuneration.

Kentucky's Anti-Kickback Law

The state of Kentucky has its own anti-kickback law, which can be enforced by state authorities [KRS 216.2950]. This statute, at one time, went beyond federal law and prohibited payments for referrals under any health care plan--not just a government health plan. The law was changed, however, and now patterns the federal law. ([Back](#))

Any Willing Provider

"Any Willing Provider" laws have been passed by many states, including Kentucky [KRS 304.17A-270]. These laws generally require managed care organizations to accept providers that are willing to meet "terms and conditions" established by the managed care organization.

When Kentucky's law was first passed, the following written comments were made by the sponsor of the legislation: "By eliminating the ability of health plans to enter into selective or exclusive contracts with health care providers, the changes allow for patient choice of physicians, pharmacies and other providers, and guarantee access for insureds. Adequate cost controls remain because the health plan controls the criteria for participation. As long as a provider is willing to provide the service under the terms and conditions to be determined by the health plan, they are ensured that they will be able to serve the patient and receive reimbursement. Similar provisions relating to pharmacy and other services are law in thirty-four other states."

In a unanimous decision, the United States Supreme Court upheld Kentucky's Any Willing Provider law from a challenge by the Kentucky Association of Health Plans in the case of *Kentucky Association of Health Plans v. Miller*. The Kentucky Medical Association, American Medical Association, and various specialty societies participated in the case by submitting a joint *amicus* brief. ([Back](#))

Asthma - Self Administration

The board of each local public school district and the governing body of each private and parochial school or school district must permit the self-administration of medications by a student with asthma or by a student who is at risk of having anaphylaxis if the student's parent or guardian:

- (a) Provides written authorization for self-administration to the school; and
- (b) Provides a written statement from the student's health care practitioner that the student has asthma or is at risk of having anaphylaxis and has been instructed in self-administration of the student's prescribed medications to treat asthma or anaphylaxis. The statement shall also contain the following information:
 1. The name and purpose of the medications;
 2. The prescribed dosage;
 3. The time or times the medications are to be regularly administered and under what additional special circumstances the medications are to be administered; and
 4. The length of time for which the medications are prescribed.

The permission for self-administration of medications is effective for the school year in which it is granted and shall be renewed each following school year upon fulfilling the requirements of the law. Upon fulfilling the requirements of the law, a student with asthma or by a student who is at risk of having anaphylaxis may possess and use medications to treat the asthma or anaphylaxis when at school, at a school-sponsored activity, under the supervision of school personnel, or before and after normal school activities while on school properties including school-sponsored child care or after-school programs. [KRS 158.834] [\(Back\)](#)

Athletic Trainers

An athletic trainer is a person with specific qualifications who is licensed by the Kentucky Board of Medical Licensure to practice athletic training and who, upon the supervision of a physician carries out the practice of preventing, recognizing, evaluating, managing, disposing, treating, reconditioning, or rehabilitating athletic injuries. [KRS 311.900(3)] "Supervision" means advising, consenting to, and directing the activities of an athletic trainer through written or oral orders by a physician. [KRS 311.900(7)] For purposes of practicing as an athletic trainer, an "athletic injury" is defined as an injury or condition, excluding medical conditions such as internal infections, internal injuries, fractures, and spinal cord injuries except in an acute situation sustained by an athlete that affects the individual's participation or performance in sports, games, or recreation. An athletic injury is also an injury or condition that is within the scope of practice of an athletic trainer identified by a physician, a physical therapist, an occupational therapist, or a chiropractor that is likely to benefit from athletic training services that have been approved by a physician supervising the athletic trainer. [KRS 311.900(2)] For purposes of practicing as an athletic trainer, an "athlete" is an individual, referee, coach, or athletic staff member who participates in sports, games, or recreational activities requiring physical strength, agility, flexibility, range of motion, speed, or stamina, and who is associated with a sport, game, or recreational activity that is conducted in association with an educational institution or professional, amateur, or recreational sports club or organization. [KRS 311.900(1)]

An athletic trainer may use physical modalities, such as heat, light, sound, cold, or electricity, or mechanical devices and must practice only in those areas in which he or she is competent by reason of his or her training or experience. [KRS 311.900(3)] An athletic trainer may also dispense, but not prescribe, over-the-counter or prescription medications only to an adult athlete and with the supervision of a physician. The athletic trainer must maintain accurate records identifying the medication, dose, amount, directions, condition for which the medication is being used, identity of the supervising physician, lot number, and expiration date. [KRS 311.903(2)] An athletic trainer must conform to the standard of care required of an ordinary competent and careful licensed athletic trainer in exercising reasonable care for the health and safety of the athlete. [KRS 311.903(5)]

An athletic trainer may not perform the following functions:

- Use spinal or pelvic manipulations or spinal or pelvic chiropractic adjustments;
- Dispense over-the-counter or prescription medications to a minor athlete;
- Perform invasive procedures;
- Work in an industrial setting, except in the capacity of screening injuries and referring patients to an occupational

therapist, a physical therapist, a chiropractor, or a physician;

- Seek reimbursement from the federal government for physical therapy services performed by an athletic trainer;
- Seek reimbursement from the federal government for occupational therapy services performed by an athletic trainer;
- Seek reimbursement from the federal government for chiropractic services performed by an athletic trainer;
- Prescribe medications, including controlled substances; and
- Independently bill any patient or other payer for services rendered by the athletic trainer. [KRS 311.903]

[\(Back\)](#)

Autopsies and Post-Mortems

KRS 72.025 requires that a post-mortem examination be performed under certain circumstances. These circumstances include:

- (1) When the death of a human being appears to be caused by homicide or violence;
- (2) When the death of a human being appears to be the result of suicide;
- (3) When the death of a human being appears to be the result of the presence of drugs or poisons in the body;
- (4) When the death of a human being appears to be the result of a motor vehicle accident and the operator of the motor vehicle left the scene of the accident or the body was found in or near a roadway or railroad;
- (5) When the death of a human being occurs while the person is in a state mental institution or mental hospital when there is no previous medical history to explain the death, or while the person is in police custody, a jail, or penal institution, except pursuant to a sentence of death;
- (6) When the death of a human being occurs in a motor vehicle accident and when an external examination of the body does not reveal a lethal traumatic injury;
- (7) When the death of a human being appears to be the result of fire or explosion;
- (8) When the death of a child appears to indicate child abuse prior to the death;
- (9) When the manner of death appears to be other than natural;
- (10) When human skeletonized remains are found;
- (11) When post-mortem decomposition of a human corpse exists to the extent that external examination of the corpse cannot rule out injury or where the circumstances of death cannot rule out the commission of a crime;
- (12) When the death of a human being appears to be the result of drowning;
- (13) When the death of an infant appears to be caused by sudden infant death syndrome in that the infant has no previous medical history to explain the death;
- (14) When the death of a human being occurs as a result of an accident;
- (15) When the death of a human being occurs under the age of forty (40) and there is no past medical history to explain the death;
- (16) When the death of a human being occurs at the work site and there is no apparent cause of death such as an injury or when industrial toxics may have contributed to the cause of death;
- (17) When the body is to be cremated and there is no past medical history to explain the death;
- (18) When the death of a human being is sudden and unexplained; and
- (19) When the death of a human being occurs and the decedent is not receiving treatment by a licensed physician and there is no ascertainable medical history to indicate the cause of death.

In the event an autopsy is not required, consent must be obtained from the decedent, in writing, signed and acknowledged prior to death. If there is no written consent from the decedent, the spouse of the decedent may consent, and in cases where there is no spouse, the next of kin may consent. In the absence of a spouse or next of kin, the person who assumes responsibility to dispose of

the body may consent [KRS 72.425].

Unless another cause of death is clearly established, in cases requiring a post-mortem examination, the coroner or medical examiner shall take a blood sample and have it tested for the presence of any controlled substances which were in the body at the time of death. If a coroner or medical examiner determines that a drug overdose is the cause of death of a person, he or she shall provide notice of the death to:

- (a) The state registrar of vital statistics and the Department of Kentucky State Police. The notice shall include any information relating to the drug that resulted in the overdose. The state registrar of vital statistics shall not enter the information on the deceased person's death certificate unless the information is already on the death certificate; and
- (b) The licensing board for the individual who prescribed or dispensed the medication, if known. The notice shall include any information relating to the drug that resulted in the overdose, including the individual authorized by law to prescribe or dispense drugs that dispensed or prescribed the drug to the decedent.
- (c) the Commonwealth's attorney and a local law enforcement agency in the circuit where the death occurred, if the death resulted from the use of a Schedule I controlled substance [KRS 72.026]. [\(Back\)](#)

Birth Certificates

KRS 213.046 contains specific requirements regarding the registration of births and filing of birth certificates. A physician must provide medical information required for the birth certificate and certify to the fact of birth within ten days after a birth. When a birth occurs outside of an institution, the certificate must be prepared and filed by the physician at or immediately after the birth of the child. No physician may refuse to sign or delay the filing of a birth certificate. If there is no dispute as to paternity, the name of the husband of the mother must be entered on the certificate as the father of the child. If the mother claims the father of the child is not her husband and the husband agrees, a three way affidavit of paternity may be signed by the respective parties and notarized. If there is a question as to paternity, it must be settled in court. [\(Back\)](#)

Blood Tests

KRS 214.160 requires every physician who is "legally permitted to engage in attendance upon a pregnant woman" to conduct a blood test for syphilis. If the woman is in labor at the time the diagnosis of pregnancy is made, the blood test may be taken ten days after delivery. The blood specimen must be submitted to a laboratory of the Cabinet for Health Services or a laboratory approved by the Cabinet to conduct the test. The Cabinet for Health Services will publish a list of the five most frequently abused substances by pregnant women in the state.

Any physician who is "legally permitted to engage in attendance upon a pregnant woman" may perform a screening for alcohol or substance abuse on a pregnant woman. A physician may also administer a toxicology test to a pregnant woman within eight hours after delivering to determine whether there is evidence of alcohol, a controlled substance or a substance identified on the list provided by the Cabinet for Health Services. A physician may also administer to each newborn under the physician's care a toxicology test to determine whether there is evidence of prenatal exposure to alcohol, a controlled substance or a substance identified on the list provided by the Cabinet for Health Services. The circumstances surrounding any positive toxicology finding must be evaluated to determine if there has been abuse or neglect of an infant.

A physician may not conduct or cause to be conducted any toxicological test on a pregnant woman without first informing the pregnant woman of the purpose of the test.

KRS 214.170 requires every physician who takes or causes to be taken a blood specimen for syphilis testing from a woman, to identify the specimen as being from a pregnant woman submitting it for tests. The laboratory shall then report the result of the test if reactive on forms prepared and furnished by the Cabinet not later than one week after the examination is made. [\(Back\)](#)

Blood Transfusions

KRS 214.458 requires each unit of blood collected by a blood establishment for transfusion to be affixed with a Food and Drug Administration required label. Each laboratory and blood establishment must maintain for ten years from the date of collection a list containing the information on the Food and Drug required label. A physician may not transfuse into any patient unless the unit of blood has affixed to it the FDA label and the blood has tested negative for AIDS or any other blood born communicable disease. Any unit of blood not containing the required label must be destroyed by the physician.

KRS 214.464 allows untested blood to be transfused into a patient only in an emergency and when the patient provides consent or the next of kin provides consent. The consent must become part of the patient's permanent medical record.

KRS 214.466 provides immunity from civil and criminal liability for transfusion of untested blood in an emergency situation if the blood is required to save the life of the patient. ([Back](#))

Cancer

Only a licensed physician or dentist may treat or prescribe treatment for cancer [KRS 211.182]. A physician may prescribe or administer amygdalin (laetrile) in lieu of or in addition to other accepted modes of therapy in the treatment of cancer [KRS 311.956]. A patient, however, must sign a written informed request for laetrile and the physician must have made the determination that the patient is terminally ill. The written informed request for laetrile must be forwarded by the physician to the Board of Medical Licensure within three days of execution. The form to use to obtain a patient's written authorization for the use of laetrile is as follows:

WRITTEN INFORMED REQUEST FOR PRESCRIPTION
OF AMYDGALIN (Laetrile) FOR MEDICAL TREATMENT
AND RELEASE OF PHYSICIAN FROM LIABILITY

Patient's name _____

Address _____

Age _____ Sex _____

Name and address of prescribing physician:

Malignancy, disease, illness or physical condition diagnosed for medical treatment by amygdalin (laetrile):

My physician explained to me:

- (a) That the manufacture and distribution of amygdalin (laetrile) has been banned by the Federal Food and Drug Administration.
 - (b) That neither the American Cancer Society, the American Medical Association, nor the Kentucky Medical Association recommend the use of amygdalin (laetrile) in the treatment of any malignancy, disease, illness, or physical condition.
 - (c) That I am terminally ill and there are alternative recognized treatments for malignancy, disease, illness, or physical condition from which I suffer which he has offered to provide for me including: (here describe)
- _____
- _____

That notwithstanding the foregoing, I hereby request prescription and use of amygdalin (laetrile) in the medical treatment of the malignancy, disease, illness, or physical condition from which I suffer.

I hereby release the physician from any and all liability due to any deleterious consequences that may be directly attributable to

the use of amygdalin (laetrile).

Patient or person signing for patient

ATTEST:

Prescribing physician

A physician is not required to distribute laetrile or prescribe laetrile for any patient [KRS 311.954]. A physician cannot be disciplined for prescribing laetrile to a patient as long as the patient has signed a written informed request form and the physician has determined the patient to be terminally ill. A physician may not be held liable for malpractice or negligence if it is determined that a patient died from the lack of accepted therapies when the patient elected to use laetrile as the sole treatment and signed an informed request form. A physician can also not be held liable for malpractice or negligence if it is determined that a patient's medical condition deteriorated from a lack of accepted therapies when the patient elected to use laetrile [KRS 311.962].

The McDowell Cancer Network and the James Graham Brown Cancer Center submitted to the Cabinet for Health Services a summary of the advantages, disadvantages, risks and descriptions of all medically efficacious and viable alternatives for the treatment of breast cancer. This summary is printed by the Cabinet for Health Services and made available to all licensed physicians in Kentucky for distribution to patients. Any physician who treats a patient for any form of breast cancer must provide the patient with a copy of the summary [KRS 311.935].

[\(Back\)](#)

Capitation

The following discussion is taken from the American Medical Association's Model Managed Care Contract.

Capitation is a method of reimbursement that shifts the financial risk for provision of care from the managed care organization (MCO) or other payor to a physician or physician group/network by establishing a fixed amount to cover specific services for a defined patient population on a per member (ie patient) per month (PMPM) basis. In the context of managed care, the term "risk" refers to the obligation to pay for covered services, without knowing in advance what services will be needed.

Capitation is a radical shift from a fee-for-service basis or a discounted fee-for-service arrangement. When reimbursement is based on a fee-for-service basis, the cost of care is the MCO's responsibility. The physician provides medically necessary services and the MCO pays, though often at a negotiated discount.

By contrast, under a system of capitation, the physician assumes the financial risk of providing care for a population of patients. The amount of reimbursement is fixed, regardless of the number of services an individual patient may need. The theory behind capitation is that physicians will practice more "efficiently" when they are at-risk for utilization of services and will use fewer resources.

Capitation can be financially beneficial to a physician or physician group/network, and there are practices that have done well financially under capitation. However, it also can be highly risky, and there are physician groups/networks that have suffered severe financial loss under capitated agreements over the past few years. When patients use fewer services than anticipated in setting the PMPM rate, the physician practice retains the unspent funds. Healthy patients obviously use less services. However, when patients use more services than anticipated in setting the PMPM rate (and remember, healthy patients get sick), the physician practice loses money.

Therefore, entering a capitation contract requires a different approach. The physician or physician group/network must evaluate, from an actuarial standpoint, whether or not the practice is in a position to assume financial risk under the contract. Because there is no way to predict in advance how much care each patient will require, the "risk" is that the healthy patients assigned to a physician practice will balance against the sicker patients who require more services for the same set payment amount.

This involves a number of factors, including the PMPM rate, the identification of covered services, size of the patient population, an actuarial projection of cost. The practice must have the capacity to track utilization of services under a capitated contract in order to manage the risk of financial loss. While the capitation rate itself is critical, the totality of the capitation arrangement in relationship to the individual practice must be evaluated.

How do physicians manage their practices on capitation payments?

The PMPM payment for defined covered services may seem inadequate for a physician or physician group/network to accept for an individual member. For example, a capitation of \$40 PMPM for the provision of all professional services translates to \$480 a year, an amount that could be exhausted overnight by an enrollee with serious medical problems. Yet, this same PMPM capitation rate may make more sense if a physician or physician group/network has 2,000 enrollees, which translates to an annual payment of \$960,000 per year. As the number of enrollees increases, the risk associated with capitation decreases. Therefore, capitation is typically a better option for larger groups that have the infrastructure to manage the costs of health care for larger patient populations and a far riskier proposition for solo and small group practices. Regardless of the practice size, it is important to establish an actuarially sound minimum number of enrollees before the capitation rate becomes effective in order to limit risk.

It is impossible to recommend a minimum number of enrollees or appropriate capitation rates for an individual practice because every practice situation is unique. The AMA publication, *Capitation: The Physicians' Guide*, provides more detailed information on evaluating capitation rates.

What are the different types of capitation?

The different capitation arrangements relate primarily to the scope of defined services to be included. The types of capitation arrangements from greatest risk to smallest risk are:

- Full-risk capitation (also known as global risk);
- Professional risk capitation (also known as multispecialty capitation);
- Primary care capitation; and
- Specialty capitation

Full-risk or global capitation

In a full-risk capitation model, the physician or group must provide or arrange for all professional and institutional services for its assigned patients. Physicians and hospitals have shared financial incentives to control all medical utilization. Physicians accepting full-risk capitation must have a substantial infrastructure and effective practice management. The physician group must make arrangements to provide all covered services either directly, or indirectly through relationships with hospitals, other physicians, and non-physician providers. Remember that in this type of agreement, the practice is responsible for all covered services. If the practice does not perform certain services, it will be responsible for paying someone else to perform them. Administering full-risk agreements also demands sophisticated financial management, information systems, and medical management to track member eligibility, oversee referrals, process claims, and prepare reports to enable physicians to make informed decisions on a timely basis.

Percentage of premium

Percentage of premium arrangements are substantially similar to full-risk capitation. The responsibilities and duties of the physician group to provide all professional and institutional services remain the same. The critical difference is how the capitation rates are structured.

Instead of setting the capitation rate at a fixed dollar amount per member per month, the MCO pays the physician or physician group/network a percentage of the premium rate the MCO receives from the employer. The perceived benefit to the physicians is that they receive their fair portion of the premium dollar. If the MCO increases the premium it charges employers, then the physician group will receive a larger reimbursement.

Percentage of premium entails greater risk for the physician or physician group/network. If the MCO does not perform underwriting properly or decides to expand market share by lowering its premiums, then the percentage of premium received by the physicians may be insufficient to cover the cost of service that must be provided.

Professional (multispecialty capitation)

In a professional capitation model, the physician or physician group/network receives a capitation payment and agrees to provide or arrange for all primary and specialty care physician services. This differs from full-risk capitation because the physicians are not responsible for hospital or institutional services. If the physicians cannot provide a particular service, they must enter into an arrangement to pay another physician or non-physician provider to deliver the service. Because the physicians are not at risk for institutional services under a professional capitation arrangement, the MCO may structure a hospital bonus arrangement (sometimes in the form of a risk pool, discussed below) to incentivize the physicians to manage the MCO's costs for hospital utilization.

Primary care capitation

In a primary care capitation model, the physician group receives a capitation payment in exchange for the obligation to provide only primary care services for assigned patients. The specific services that are included in the primary capitation payment are defined in the contract and are frequently subject to negotiation. The physician group may also provide services not included in the capitation and receive reimbursement in accordance with a fee schedule. These services are known as "carve-outs" (see discussion below) because they are carved-out of the capitation reimbursement.

Specialty care capitation

In a specialty capitation model, the physician group receives a capitation payment in exchange for the obligation to provide specialty services for assigned patients. The specific services that are included in the specialty capitation are defined in the contract.

Physicians entering into specialty care capitation arrangements should take into account the frequency and the average cost of the service before agreeing to a specific capitation rate. The lower the frequency and the higher the cost, the larger the group of patients must be before a specialty capitation is a financially viable alternative. For example, a specialty capitation might be a viable option for a physician practice because the practice has a higher frequency and lower average cost per service. A specialty capitation might not be a viable option for a physician practice that has a lower frequency and higher average cost per service.

What is sub-capitation?

Sub-capitation refers to arrangements in which a physician group accepts capitation, but then subcontracts out some of the risks and obligations to provide certain covered services for a defined population to another group of physicians or providers. For example, a group of primary care physicians may accept professional capitation and Sub-capitate a group of cardiologists by paying them a fixed per member per month payment for the provision of cardiology-related services for the members assigned to those primary care physicians.

What is case rate reimbursement?

A case rate is the total reimbursement paid for one particular treatment or service (a “case”) with a limited duration. This term is used most often to cover all defined services related to a certain procedure, such as an outpatient surgery, maternity delivery, or organ transplant. Case rates may include the professional component only, facility component only, or both, depending on the agreement between the parties.

A case rate blends certain features of capitation and discounted fee-for-service reimbursement. It places physicians at risk for the cost of the case, but it does not place physicians at risk for the full volume of patients who may need procedures covered under these case rates.

What are “carve outs”?

Physicians may identify certain services offered by the MCO to patients that they wish to exclude from a capitation agreement, generally because they are very high cost services. These exclusions are sometimes referred to as “carve outs” because they are “carved out” of the capitation reimbursement. Any carve outs should be listed in the contract by procedural code to avoid potential payment disputes. The decision whether or not to carve out a service should be based on an analysis of the cost to provide or arrange for those services and the financial impact of potentially providing these services under a capitated payment system. Procedures that are very time consuming and expensive to perform should be carved out of the capitation rate. Examples of services commonly carved out may include pharmacy services, organ transplants, behavioral health services, and fertility services. A physician can still perform a procedure that has been carved out of the capitation arrangement. The carve out simply means that the MCO, rather than the physician group, is “at risk” to provide the service, and the physicians will be reimbursed on a fee-for-service basis.

What is “stop-loss” insurance?

“Stop-loss” insurance limits the financial liability for physicians under capitation contracts. MCOs typically offer stop-loss insurance as part of the capitation agreement. Stop loss essentially protects physician practices against the potentially devastating financial impact of a number of high cost patients not accounted for in the PMPM reimbursement methodology. There are two basic forms of stop-loss insurance. The first is specific stop-loss coverage, which bases a threshold (eg \$10,000) on an individual patient. The second is aggregate stop-loss coverage, which bases the threshold on the combined treatment costs of the entire capitated group (eg \$60,000). Once the threshold is exceeded, the MCO may pay all costs in excess of the threshold, or a percentage (eg 80%).

Stop-loss insurance is important in helping physicians effectively manage risk in capitation arrangements. Physicians should carefully analyze the price, terms of coverage, financial benefits, and appropriateness of stop-loss protection to accompany their risk-based contracts.

What are “withholds”?

Withholds are an incentive arrangement under capitation. Under a typical “withhold,” MCOs will retain a certain percentage of capitation payment due physicians, and at the end of the year, return all, some, or none of it, depending on whether certain conditions relating to utilization of medical services have been met. Common conditions for receiving withhold funds at the end of the year include achieving goals related to hospital costs, specialty costs, pharmacy utilization, and patient satisfaction. Routinely withholds may range from 10-20%.

It is critical that physicians understand before signing a contract that they may never receive a withhold payment. Therefore, it is risky to rely on that potential revenue in managing the business end of a practice. It is also critical that the practice have the ability to self-monitor progress toward meeting withhold requirements throughout the term of the contract and that the MCO

provide regular status reports on progress toward reaching the targets. One alternative to withholds is for both parties to agree that a fixed reimbursement amount will be paid, plus incentive payments, if certain agreed upon goals are met. This approach allows the practice more predictability from a business perspective.

What are “risk pools”?

“Risk pools” are another financial incentive used in capitation contracts. A risk pool is a mechanism sometimes offered to physicians to participate in any cost savings the physicians create for the MCO. Under a risk pool arrangement, funds are withheld from the physician and typically, hospitals, to cover the costs of specific services, such as prescription drugs, hospital charges, laboratory, and pathology services. The MCO may also contribute to the risk pool.

While risk pools occur in many different scenarios, the result is the same. If certain specified goals are met (for example, coming in below budget for hospital or pharmacy services), the MCO and other participants (physicians and/or hospitals) agree to share a certain portion of the savings from the budgeted expenses.

The theoretical advantage of risk pools is that physicians have access to a larger percentage of the premium dollar. However, the physician group or network (as well as the hospital) must have an infrastructure that allows it to track utilization of these specific services in order to maximize the possibility of sharing the surplus.

What are the key issues that need to be considered before accepting a capitation agreement?

Paragraph 3.3(a) of the AMA Model Managed Care Contract sets forth key issues that need to be considered before accepting a capitation arrangement. As part of the contract analysis, the physician group should consider the following questions:

1. Are the services included in the capitation rate clearly identified and understood?
2. Are there any procedures that are so expensive and time-consuming to provide that they should be “carved out” of the capitation agreement? If so, these procedures should be identified by procedure code in the contract along with their rate of reimbursement?
3. Is the amount of capitation adequate, based upon sufficient financial and actuarial analysis of relevant data?
4. Is there a minimum number of enrollees established before the capitation rate becomes effective? Is that number actuarially sound?
5. Are agreements in place to manage the risk through such mechanisms as stop loss insurance, carve outs, and sub-capitation?
6. Is the MCO’s commitment clear regarding the provision of complete, accurate, and timely financial reports and analysis?
7. Is there a mechanism, if certain conditions are met, to switch prospectively to discounted fee-for-service payments during the term of the contract and, if so, what would those terms of payment include?
8. Has the physician compensation plan been fully discussed and understood among the pertinent physicians, including analysis of best and worst case scenarios for managing capitation?
9. How realistic are the key assumptions that must be satisfied in order for the capitation payment to be adequate?
10. Has the physician or physician group/network received the appropriate professional guidance in determining that the capitation rate offered will be sufficient not only to provide all covered services but also to meet overhead?

What are the key advantages of capitation?

The key advantages of capitation are:

- *Potential increased income:* Capitation allows physicians to essentially “control” a larger share of the premium dollar. In a best-case scenario, the physicians can therefore benefit financially from reducing utilization of their own services, and in some arrangements, from reducing use of hospital and ancillary services.
- *Potential improved cash flow:* Physicians receive a fixed payment each month; therefore, capitation can improve cash flow and reduce bad debt expenses.
- *Potential budgeting benefits:* The steady cash flow generated from capitation improves physicians’ ability to manage their practices by enabling them to use well-defined budgets.
- *Relief from external utilization review:* Because physicians are at risk for overutilization, there is no external review performed by the MCO.

It is important to remember that the benefits of capitation can be illusory for many physicians because assuming risk by definition requires very sophisticated and expensive information infra-structures beyond the reach of many physician practices.

MCOs do not generally care or consider whether or not the physician or physician group/network has the capability to manage risk. This is one reason that the AMA objects strenuously to the “all products” provisions in many managed care contracts because they can force physician practices that are not equipped to handle risk into capitation contracts, with potentially dire financial consequences. Physicians and physician groups/networks should have the opportunity to review these potential advantages in the context of the realities of their practice.

What are the key disadvantages of capitation?

- *Need for complex, costly information infrastructure:* The physician or physician group/network must have in place an information infrastructure that enables tracking cost and utilization of services. It is important to remember that a number of large, sophisticated physician practice management companies have gone bankrupt because of an inability to manage risk contracts.
- *Inadequate capitation payments:* There are increasing concerns in parts of the country that MCOs are continuing to decrease capitation payments to a point that it threatens the stability of physician practices in those areas. Inadequate capitation has been cited as the primary reason for a rash of physician group practice bankruptcies in California and other parts of the country.
- *Financial risk:* No matter how careful a practice is and how carefully it manages the capitation contract, there is a possibility that the practice will lose money under a capitation contract.

Financial incentives in managed care contracts can raise complex ethical issues for physicians. For guidance, physicians can refer to AMA Council on Ethical and Judicial Affairs opinion 8.054 (available at the AMA web site www.ama-assn.org/ama). For more detailed information on capitation contracts, including evaluating capitation rates, see the AMA publication *Capitation: The Physician's Guide*. ([Back](#))

Certificate of Need

The Kentucky General Assembly has established a program for the licensure and regulation of health facilities and health services. The Legislature empowered the Cabinet for Health Services to perform “Certificate of Need” functions, as well as other functions necessary to improve quality and increase access to health care facilities, services, and providers.

A Certificate of Need is an authorization by the Cabinet to acquire, establish, offer, substantially change the bed capacity, or substantially change a health service covered under the law. No person may do any of the following without first obtaining a Certificate of Need:

- a) Establish a health facility;
- b) Obligate a capital expenditure which exceeds the capital expenditure minimum;
- c) Make a substantial change in the bed capacity of a health facility;
- d) Make a substantial change in the health service;
- e) Make a substantial change in a project;
- f) Acquire major medical equipment;
- g) Alter a geographical area or alter a specific location which has been designated on a Certificate of Need or license;
- h) Transfer an approved Certificate of Need for the establishment of a new health facility or the replacement of a licensed facility [KRS 216B.061(1)].

While the Certificate of Need requirement is quite broad, private offices and clinics of physicians, as well as office buildings built for or on behalf of a health facility for the exclusive use of physicians, are exempt from having to obtain a Certificate of Need, unless the physicians’ office requests a major medical equipment expenditure of an amount that is adjusted annually by regulation or meets the definition of an ambulatory surgical center (See [Ambulatory Surgical Center Section](#) below). [KRS 216B.020 (2)(a), KRS 216B.015(4) and KRS 216B.015(5)] In determining whether an expenditure exceeds the expenditure minimum, the cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the improvement, expansion, or replacement of any plant or any equipment with respect to which the expenditure is made must be included. Donations of equipment or facilities to a health facility which if acquired directly by the facility would be subject to review, must be considered a capital expenditure, and a transfer of the equipment or facilities for less than fair market value must be considered a capital expenditure if a transfer of the equipment or facilities at the fair market value would be subject to review [KRS 216B.015(8)].

If an office or clinic is challenged on whether it is a private office or clinic of physicians that does not require a certificate of need, hearing officers must base their findings on the following factors:

1. The practice claiming the exemption is 100 percent owned in any organizational form recognized by the Commonwealth by the individual physician, dentist, or other practitioner of the healing arts or group of physicians, dentists, or other practitioners of the healing arts claiming the exemption;
2. The practice claiming the exemption primarily provides physician services rather than services or equipment covered by the State Health Plan;
3. Services or equipment covered by the State Health Plan which are offered or provided at the office or clinic must be primarily provided to patients whose medical conditions are being treated or managed by the practice.;
4. A physician or physicians licensed to practice and practicing in Kentucky within the practice claiming the exemption is responsible for all decisions regarding the care and treatment provided to patients;
5. Patients are treated on an outpatient basis and are not maintained overnight on the premises of the office or clinic;
6. Services or equipment covered by the State Health Plan which are offered or provided at the office or clinic are related to the professional services offered to patients of the practice claiming the exemption;
7. Major medical equipment in excess of the limits set forth in regulations is not being utilized without a Certificate of Need or other statutory or regulatory exemption; and
8. Nothing shall limit or prohibit the continued operation of an office or clinic which was established and in operation prior to January 31, 2006, and operating pursuant to and in accordance with the following:
 - a. Provisions of a Certificate of Need advisory opinion issued specifically with respect to that office or clinic; or
 - b. Provisions of an Attorney General opinion issued specifically with respect to that office or clinic; or
 - c. An order issued with respect to that office or clinic by a court of competent jurisdiction in the Commonwealth of Kentucky. [900 KAR 6:050 Section 18(9)(a)]

A practice owned entirely by a radiologist or group of radiologists must demonstrate the following:

1. Compliance with paragraph (a) 1, 4, 5, and 6 above;
2. The radiologists must regularly perform physician services (e.g., test interpretations) at the location where the diagnostic tests are performed, including interpretations by or through teleradiology; and
3. The billing patterns of the practice indicate that the practice is not primarily a testing facility and that it was organized to provide the professional services of radiology.

There are extensive requirements under state law regarding a Certificate of Need for facilities other than a physician's office. If you would like information on the Certificate of Need process, contact the Cabinet for Health and Family Services.

Ambulatory Surgical Center

Under Kentucky law, an individual or individuals must obtain a certificate of need before establishing an ambulatory surgical center. [KRS 216B.061(7)] An ambulatory surgical center is defined as a health facility that is licensed by the Cabinet for Health and Family Services, provides outpatient surgical services, excluding oral or dental procedures, and seeks recognition and reimbursement as an ambulatory surgical center from any federal, state, or third-party insurer from which payment is sought. [KRS 216B.015(4)(a)] An ambulatory surgical center does not include the private offices of physicians where in-office outpatient surgical procedures are performed as long as the physician office does not seek licensure, certification, reimbursement, or recognition as an ambulatory surgical center from a federal, state, or third-party insurer without first obtaining a certificate of need or license from the Cabinet for Health and Family Services. [KRS 216B.015(4)(b) and (c); KRS 216B.020(2)(a)]

Any ambulatory surgical center licensed as of July 12, 2012, is not required to obtain a certificate of need to continue operations as a licensed health care facility, regardless of whether it obtained a certificate of need before being licensed. [KRS 216B.061(8)]

The Cabinet for Health and Family Services will grant nonsubstantive review for a certificate of need proposal to establish an ambulatory surgical center if the applicant meets the following:

1. The applicant is an ambulatory surgical center that was organized and in operation as the private office of a physician or physician group prior to October 1, 2006;
2. The cabinet's general counsel has submitted a letter to the Accreditation Association for Ambulatory Health Care

advising that the cabinet does not object to the applicant's parent company applying for and obtaining Medicare certification OR the applicant is an ambulatory surgical center that has received from the cabinet a favorable advisory opinion dated June 14, 2005, confirming that the applicant would be exempt from the certificate of need or licensure requirement;

3. The applicant's ambulatory surgical center has been inspected and accredited by the Accreditation Association for Ambulatory Health Care since December 31, 2006, and has maintained accreditation with that organization consistently since that time; and
4. The applicant was a party to litigation concerning the ambulatory surgical center and physician office issue and, prior to July 12, 2012, obtained a Court of Appeals ruling in its favor. [KRS 216B.095(7)(a)-(d)]

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Certified Surgical Assistant

"Surgical assistants" provide aid under direct supervision of a physician in exposure, hemostasis, closures, and other intraoperative technical functions that assist a physician in performing a safe operation with optimal results for the patient. [KRS 311.864(6)] "Direct supervision" means supervision by a delegating physician who is physically present and who personally directs delegated acts and remains immediately available to personally respond to any emergency until the patient is released from the operating room or care and has been transferred to the care and responsibility of another physician. [KRS 311.864(4)] Surgical assistants may not practice medicine or registered nursing. [KRS 311.888]

Surgical assistants must be certified by the Kentucky Board of Medical Licensure unless the person is a student enrolled in a surgical assistant education program approved by the board who is assisting in a surgical operation that is an integral part of the program of study; a surgical assistant employed in the service of the federal government while performing surgical assisting duties related to that employment; a health care worker, licensed or certified within this Commonwealth, acting within the scope of the person's license; a registered nurse or licensed practical nurse; a certified physician assistant; or an individual employed by a hospital who is performing the duties of a surgical assistant under the direct supervision of a registered nurse. [KRS 311.866]

An HMO, PPO or health benefit plan may not require a registered nurse or certified physician assistant to be certified as a surgical assistant as a condition for reimbursement. [KRS 311.888] [\(Back\)](#)

Charitable Work

Physicians who provide charitable health care in Kentucky must be given malpractice insurance by insurers for such work and the state must pay for such insurance. A physician who provides "charitable health care" is one who renders medical care while providing "primary care" (and performing no invasive or surgical procedures) without compensation or charge, and without expectation of compensation or charge [KRS 304.40-075(1)(a)]. This law only applies, however, to physicians performing charitable medical services who are not already covered by professional liability insurance for the charitable health care services provided [KRS 304.40-075(4)].

A charitable health care provider is anyone who is licensed or certified by the state, providing the rendering of medical care without compensation or charge, and without expectation of compensation or charge, and without payment or reimbursement from any governmental agency or insurer. Charitable health care providers only include those providing primary care and performing no invasive or surgical procedures [KRS 216.940]. [\(Back\)](#)

Child Abuse

KRS 620.030 requires any person, including a physician, to report to the county attorney or the Commonwealth's attorney, a local law enforcement agency or the Kentucky State Police, or the Cabinet for Health and Family Services or its designated

representative when there is “reasonable cause” to believe that a child is dependent, neglected or abused or a victim of human trafficking. A victim of human trafficking is someone who has been subjected to engaging in forced labor or services or commercial sexual activity through the use of force, fraud, or coercion, except that if the victim is under the age of eighteen, the commercial activity does not need to involve force, fraud, or coercion.

The report described above can be oral or written and made “by telephone or otherwise.” A physician is also required to, within 48 hours of the original report, submit a written report which must contain:

- (1) The names and addresses of the child and his or her parents or other persons exercising custodial control or supervision;
- (2) The child’s age;
- (3) The nature and extent of the child’s alleged dependency, neglect or abuse (including any previous charges of dependency, neglect or abuse) to this child or his or her siblings;
- (4) The name and address of the person allegedly responsible for the abuse or neglect; and
- (5) Any other information that the person making the report believes may be helpful.

KRS 620.030(5) requires “any agency of the state or any other agency, institution or facility providing services to the child or his or her family, such cooperation, assistance and information as will enable the [Cabinet for Health Services] to fulfill its responsibilities” regarding child abuse investigations.

The federal HIPAA privacy regulation allows physician practices to make disclosures without the authorization of the patient if the information is submitted to appropriate government authority authorized by law to receive reports of child abuse or neglect. As discussed above, a report of suspected child abuse or neglect must be made to the Commonwealth’s Attorney, County Attorney or Kentucky State Police when there is “reasonable cause” to believe that a child is dependant, neglected or abused.

KRS 620.050 provides immunity from any civil or criminal liability that may be imposed for making such a report when the person has “reasonable cause” to make the report. [\(Back\)](#)

Chiropractors

Code of Medical Ethics Opinion 3.041 states: “It is ethical for a physician to associate professionally with chiropractors provided that the physician believes that such association is in the best interests of his or her patient. A physician may refer a patient for diagnostic or therapeutic services to a chiropractor permitted by law to furnish such services whenever the physician believes that this may benefit his or her patient. Physicians may also ethically teach in recognized schools of chiropractic.”

KRS 312.017 defines the scope of practice for a chiropractor. Chiropractors cannot treat contagious or communicable diseases; treat cancer; treat by use of x-ray or radiological methods; perform surgery; treat by use of acupuncture; or, administer prescription drugs or controlled substances. [\(Back\)](#)

Closing a Medical Practice

Much of the information in this section was taken with permission from the Illinois State Medical Society’s publication A Physician’s Guide for Departing or Closing a Medical Practice. The KMA appreciates the assistance of the Illinois State Medical Society in preparing this material.

When a physician decides to change, depart, or close a medical practice, it is often a difficult and emotional decision. A practice may be closed for many reasons, but whatever the reason, it must be done carefully to protect the patients and the physician. When a physician becomes seriously ill or dies, it is often the physician’s spouse who assumes the task of dismantling and closing a solo practice. Though the family is under great emotional strain, many tasks will have to be accomplished and decisions made in a relatively short period of time.

This information is intended to assist both a physician who departs, closes, or sells a medical practice and the partners or surviving family members of a seriously ill or recently deceased physician. It is an informational document and should not be considered legal advice, nor should it be taken as such. Physicians should seek personal legal advice depending on their specific

circumstances.

Advance Planning

Physicians can partially alleviate the stress that accompanies the departure from or closure of a medical practice with good advance planning. The benefits of such planning will make the difficult task of departing or closing a practice less confusing and permit the process to be done in an organized and comprehensive fashion.

When a physician departs or closes a practice, there are numerous parties who need to be contacted and informed of the situation, documents that need to be obtained, and actions taken. The parties, materials, and activities involved will vary from physician to physician, depending greatly on the type of medicine practiced. It is in the physician's best interest to create a list of the steps needed to depart or close a practice while the medical practice is active and to update the list periodically to include or delete certain persons, documents, or entities as appropriate. Revisions should be dated. The physician should secure that his or her spouse or another trusted individual is acquainted with the important persons in the physician's professional and financial arenas so he or she will feel comfortable going to these people and asking for help if the need arises. There should also be a sufficient amount of cash available to the family at all times to deal with expenses which surface at the sudden death or illness of the physician. While important documents may be placed in a safety deposit box, it is important to keep in mind that it might be sealed after the physician's death. Following is a list of persons, organizations, agencies, and information important to a physician's practice. This list should be completed by the physician and updated regularly.

- A. Name, address, and phone number of:
 - Accountant(s)
 - Answering Service
 - Attorney(s)
 - Covering and/or referral physician(s)
 - Funeral director, location of cemetery plot, plot number, and deed
 - Insurance agent
 - Management consultant
 - Office manager
 - Receptionist
 - Stock broker
 - Trust officer
 - Other people involved with the financial and administrative management of the medical practice

- B. The location of:
 - Last executed will
 - Trust agreements
 - Codicils and other legal documents involving the practice and family
 - Lockbox keys or safe combinations
 - A listing of numbers of life and other insurance policies
 - Deeds and mortgage papers of home, office, and any other applicable real estate contracts, leases, or rental agreements
 - Birth and marriage certificates, citizenship papers, adoption papers, military discharge papers, Veterans Administration number, Social Security numbers, and other personal data
 - Stock and bond securities, other investments, and cost figures
 - The physician's taxpayer identification number
 - Names and addresses, Social Security numbers for each office employee
 - Records of accounts receivable and payable
 - Tax information for federal, state, and local taxes
 - A list of hospitals, clinics, nursing homes, etc., where physician practices
 - A list of all associations and organizations where the physician holds membership
 - A list of the state licensure agency, Medicaid, and Medicare agencies
 - All narcotics, drug records, tax stamp, etc.
 - A list of suppliers of office equipment and materials. (Have information, purchase price and date of major office equipment and likely sales outlets)
 - Receipts, unbanked cash

Notification of Patients Regarding Departure From or Closure of Practice

Every physician who changes practice settings or closes a practice should fully and clearly inform active patients of this change. Physicians should provide 60 to 90 days notice when possible to allow patients the opportunity to obtain alternative care.

When closing or departing from a practice, a physician's first and foremost duty is to the patients. *Physicians must not*

abandon his or her patients. The closure or departure should be accomplished in such a manner that allows patients sufficient time to secure the services of another physician of their choice. Formal notice of actual closure or departure from a practice should be in writing to all active patients. This notification should provide at least 60 days notice when possible to allow patients the opportunity to obtain alternative care. Patients should be advised to seek alternative care and be assured that the physician will provide necessary care until a certain date. This notification should also inform the patients of the new office telephone number and address of a physician departing practice when a physician is still available in the area to attend to local patients. In addition to individual letters, it is quite common for retiring or relocating physicians to announce the closure of their medical practice in local newspapers and other local media outlets.

LETTER FOR PHYSICIANS DISCONTINUING PRACTICE

Dear Mr. _____:

Please be advised that because of _____
(my retirement, reasons of health, etc.)

I am discontinuing the practice of medicine on _____, 20____. I shall not be able to attend you professionally after that date.

I suggest that you arrange to place yourself under the care of another physician. If you are not acquainted with another physician, I suggest that you contact the _____ Medical Society.
(local)

I shall make my records of your case available to the physician you designate. Since the records of your care are confidential, I shall require your written authorization to make them available to another physician. For this reason, I am including at the end of this letter an authorization form. Please complete the form and return it to me.

I am sorry that I cannot continue as your physician. I extend to you my best wishes for your future health and happiness.

Sincerely,

REQUEST TO TRANSFER RECORDS

Date: _____

To: _____, MD

I hereby request that you transfer or make available to _____, MD,
_____ all the records and reports relating to my case. (address)

Signed _____

Medical Records

Code of Medical Ethics Opinion 7.03 discusses what physicians should do with medical records upon retirement or departure from practice. Patients should be notified of the termination of a physician's practice and encouraged to select another physician of their choice. Patients should also be informed that upon written authorization, their records will be sent to their new physician. The notification should be made three months in advance of the termination. At that time, a physician might also want to inform the patients where the records of those who do not respond will be transferred or how those records may be accessed at some future date should the need arise.

If another physician is to receive the medical records of the patients who do not request specific transfers, it might be wise for the retiring physician to make arrangements with the patient's new physician to have access either to the records or to some facsimile or copy of those records in the event litigation is initiated at some future date which involves the retired physician's previous treatment of a patient. Records may be stored or placed on microfilm or other storage media. If stored, put them in a dry, secure attic, basement, or storage unit. For additional information on retention of medical records, review the KMA material on *Medical Records -- Retention* in the KMA Legal Handbook.

It is suggested that all regular prescription pads be destroyed in any manner that makes them illegible such as shredding or burning. In addition, wall licenses provided to the physician by the Kentucky Board of Medical Licensure to display in the office

and diplomas, certificates, and membership plaques should be stored in a secure location. These actions will help to prevent unauthorized and illegal use of the physician's licenses and prescription supplies.

DEA Registration

According to federal regulations, if a physician is registered with the Drug Enforcement Administration (DEA) and the physician discontinues or ceases his/her professional practice, the physician must notify the DEA promptly by sending in his/her DEA registration certificate and unused DEA-222 order forms to the nearest DEA office.

Physician Professional Liability Insurance

It is necessary to notify the malpractice insurance company of the departure from, or closure of, the medical practice. In the case of a physician's death, a refund of any unused premium may be requested. The insurer will need the date of the physician's death and the address where the executor can be reached.

Most physicians have an insurance policy or contract that provides either "occurrence" or "claims-made" malpractice insurance to protect them from claims and lawsuits that arise out of their medical practice. An "occurrence" policy normally covers claims and lawsuits that occurred when the policy was in effect even if the claim or lawsuit is filed many years later. Most such policies extend protection to a physician's estate. However, the policy documents should be read, or the insurance agent or company contacted to be certain that the estate is covered *after* the physician's death. A "claims-made" malpractice liability policy covers only those claims and lawsuits that are actually filed during the time the policy is in effect, regardless of the date when the alleged malpractice occurred. "Tail" coverage provides protection from all claims and lawsuits filed in subsequent years after the claims-made policy was ended. Essentially, it makes a claims-made policy into an occurrence policy.

Dissolution of a Medical Corporation

The closure of a corporation is a fairly complex matter and these materials should not be represented as an exhaustive discussion of such a situation. However, the points covered may be relevant and will enable the affected individual to discuss this situation with their legal counsel in a more informed and intelligent fashion. Some of these matters can be attended to by the individual, but this will require cooperation with either legal counsel or the appropriate accounting representative.

- A. Immediately contact the insurance agent representing the corporation to ensure that both corporate liability policies and personal liability policies are providing adequate coverage for the period after termination. The situation will vary somewhat, depending on the type of insurance carried.
- B. Contact the corporation's attorney and accountant in order to discuss economic, tax, and timely considerations attendant to various forms of corporate liquidation. There are a variety of different types of corporate liquidations, each one carries certain advantages and disadvantages. These various paths must be considered in each individual situation.
- C. Discuss with the attorney and accountant the tax considerations attendant to the various forms of distribution of any retirement plans sponsored by the corporation. This examination should include income tax consequences, state tax consequences and potential cash needs.
- D. The attorney should be consulted with respect to the various legal requirements that must be satisfied in order to successfully terminate the retirement plan and to adequately treat the rights of all plan participants.
- E. The physician's employment contracts should be examined with the attorney. There are certain benefits, such as one-time lump sum death benefits, disability, and severance pay, which may be utilized to obtain favorable tax or economic treatment.
- F. In the liquidation process, there are a number of elements, other than tax concerns, which should be attended to by the client and attorney. These include, but are not limited to, notifications of various agencies such as the Secretary of State and the Kentucky Board of Medical Licensure that the termination is occurring.
- G. The client and the attorney should examine any ongoing contracts between the corporation or the physician and a third party including healthcare plans. Steps must probably be taken in order to realize any benefits or terminate any obligations created by these agreements.
- H. Successfully collecting any existing accounts receivable may prove to be a difficult matter. There are a number of alternatives available and each should be discussed with both the attorney and the accountant.
- I. The attorney should be consulted with respect to notifying patients of the termination of the practice and the corporation. Additionally, the attorney may advise that the corporation's creditors or other persons or entities should be notified of the termination.
- J. If a physician or the professional corporation owned a medical building, attention must be directed to either leasing or selling it.

- K. Any equipment or supplies owned by the corporation must be sold or disposed of in some other fashion. There are other significant financial considerations in the disposal of such equipment.

The above mentioned items provide a brief outline of topics to be considered in the dissolution of a professional corporation. It cannot be too strongly emphasized that in such a situation, one has great need for both legal counsel and also the advice of accountants. It often takes a period of many months to satisfactorily terminate such a corporation and close attention to detail is critical in order that all items are considered and dealt with in an appropriate fashion.

Actions Following a Physician's Death

The unexpected death of a physician will leave the surviving spouse of the family with a large number of personal and financial tasks, including the needs of patients, some of whom have been dependent on the physician for years, and others who are presently in hospitals or nursing homes. Planning for the disposition and transfer of patients and their records must be carefully considered. In addition, the spouse or executor must maintain basic activities of the practice, while at the same time protecting the practice from persons who might take advantage of the situation. There are many issues to consider, including:

- Ask a colleague who has provided coverage in the past to cover the practice for a period of time to ease immediate patient needs.
- Notify the office manager, receptionist, and answering service. Keep at least one key employee on at full salary to open mail, respond to inquiries, handle collection duties, etc. Find out if there are patients in the physician's hospitals or nursing homes, who they are and how to contact them or their families.
- Notify the attorney, accountant, management consultant, etc. who have served the practice.
- Put a sign on the office door, with a referring phone number to prevent patients from contacting you at home, while helping them get the information or service needed.
- Send a death notice to the local newspaper.
- The medical staff of all hospitals and other facilities where the physician had membership and privileges should be notified, usually by writing or calling the facility administrator or medical staff secretary. The Chief of Staff may designate another physician to provide coverage for the deceased physician's hospitalized patients.
- Contact patients who may be in hospitals or nursing homes where the physician had privileges, and inform them who is covering the practice and who can answer requests for information and assistance.
- Local pharmacies should be informed so no one can use the physician's name to obtain drugs illegally.
- HMOs, PPOs, schools and any other organizations where the physician may have had contracts or was employed should be notified.
- Notify the insurance agents that have provided the physician with liability, disability, health, etc. coverage on both the office and any other facilities. Certain coverages may need to be activated or maintained for a certain period of time.
- Draft a form letter to active patients notifying them of the physician's death and provide information on who is providing coverage and how they can obtain copies of their records.
- Have furniture and equipment appraised for possible sale.
- Begin collection action on outstanding accounts receivable.
- Notify suppliers of the office and ask for final statements. Pay any outstanding bills.
- Meet with the accountant and attorney. You must determine what steps need to be taken to protect the physician's estate and how to deal with tax matters, Keogh or pension plans, employee salaries, payroll records, etc.
- Notify landlord for termination of lease, if appropriate.
- Notify utilities and telephone about discontinuing service after a certain date.
- Securely store or destroy diplomas, licenses, and medical certificates.
- County/state/national medical and specialty societies where the doctor had membership should be told of the physician's situation.
- The physician's malpractice carrier should be contacted, and if he had "claims-made" insurance, determine if he requires "tail" coverage.
- Major third-party payers should be notified, including Medicare and Medicaid.
- Notify the Post Office to ensure that all mail, especially checks, is forwarded.

- ❑ As a matter of courtesy, notify other physicians who were closely associated with the physician.

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Code of Medical Ethics

The American Medical Association publishes the “Code of Medical Ethics,” which sets forth ethical principles for physicians to follow. The AMA Code of Ethics has been incorporated into Kentucky law and is enforced by the Kentucky Board of Medical Licensure [KRS 311.597(4)]. [\(Back\)](#)

Collective Bargaining

In 1999, the KMA Changing Trends in Medicine Committee Chaired by Jim Bean, MD, issued a report on physician collective bargaining. The following discussion is taken from that report.

The antitrust laws have been interpreted to allow health plans such a high degree of leverage over physicians that an appropriate balance of interests no longer exists in the marketplace. This has caused concern among physicians and the public about the direction of our health care system since health plans now have the power to determine what kind of medical care is rendered to a patient, whereas that role was traditionally reserved to the physician. To correct the imbalance between physicians and health plans in the marketplace, physicians around the country are banding together in various ways to negotiate contract terms. The antitrust laws, however, prevent competing, independent physicians from conducting “collective bargaining,” which in many cases leaves physicians no alternative but to negotiate on their own.

In order for physicians to conduct traditional collective bargaining under federal law, physicians must be classified as “employees,” which most are not. If a physician is classified as an employee, however, the physician may also be classified as a “supervisor” or member of “management” which also could preclude the physician from collectively bargaining. There is no bright-line test as to what constitutes an “employee.” Some courts have found that physicians are supervisory employees when their decisions direct other members of the health care team, such as nurses and technicians. Other factors to consider include whether the alleged employer supplies the instrumentalities, tools, and place to work, as well as sets the work hours and pays by time period or by procedure.

Self-employed physicians are not considered “employees” eligible for collective bargaining. They are generally considered to be independent contractors, entrepreneurs, or independent businesses who do not qualify to collectively bargain. However, in recent years, physicians in independent practice have lost considerable medical decision-making authority to health plans and hospitals. In addition, health plans have enough economic leverage that physicians often feel compelled to accept many other terms of dealing.

Physicians in independent practice may join with other physicians to form certain types of “networks” which can play limited bargaining roles with insurance companies. The most common form of network is the Independent Practice Association or IPA. Three key variables determine the permissible composition and role of networks: the market power of the physician network and its physicians; whether the arrangement is exclusive (physicians may contract only through the IPA) or nonexclusive (physicians may contract with other IPAs or with payors directly); and, the type of financial risk that will be shared by the physicians through the IPA. The government has recognized a “safe harbor” for networks comprised of 20 percent or fewer of the physicians in a particular specialty with active hospital staff privileges who practice in the relevant geographic market and share substantial financial risk. An example of substantial financial risk is an agreement to provide services on a capitated basis or where the physician network provides financial incentives (such as “withholds”) for its members to achieve cost-containment goals.

Physicians can legally engage in a number of collective activities through medical associations short of the right to strike or collectively bargain. Such activities might include lobbying; providing contract reviews and information; providing other legal and regulatory information; and, providing a forum for all physicians to participate in the goals and policies of the association.

To help level the playing field in negotiations between health plans and physicians, various state and national medical associations are pushing for passage of state and federal laws that would allow physicians to collectively bargain. The American Medical Association drafted model state legislation that would allow physicians in a given state to collectively bargain, with some limitations. This legislation is based on a line of federal court cases that created an exception to the federal antitrust laws known as the “state action doctrine.” In general, the state action doctrine says that antitrust laws do not apply to action by a state, or to private conduct compelled or approved by the state. In other words, where the requirements of the state action doctrine are met, behavior

that would otherwise violate the antitrust laws will be exempt from antitrust scrutiny.

To qualify for this exemption, a private party, such as a physician, must act under a “clearly articulated and affirmatively expressed state policy” that must be spelled out in the state legislation, and the action (in this case, collective bargaining) must be subject to “active state supervision.” In other words, the state must, in practice, exercise some degree of independent judgment or control over the activity. Passive or theoretical power of a state to review private action will be insufficient to meet this standard. “Active state supervision” in negotiations between a health plan and physician *might give the state input into the negotiations themselves*. Thus, by operating under the “state action doctrine,” a certain amount of autonomy may be lost. Of course, the legislation would also allow all physicians, including self-employed physicians, the opportunity to collectively bargain with health plans.

Washington State has passed such legislation, but under its law, physicians may not collectively bargain for fees. Texas also passed legislation under the “state action doctrine” that would allow physicians to collectively bargain, and would also allow collective bargaining for fees.

The American Medical Association is also supporting legislation on the federal level that would change federal antitrust laws to allow physicians to collectively bargain. Such a law would modify the antitrust laws to allow individual physicians to engage in joint negotiations with health plans. Health plans would still have the ability to approach physicians individually and try to persuade them to contract with the plan, but the physicians could also agree that they would not contract individually unless a satisfactory contract is negotiated by the group. It is not known how such legislation would affect the bargaining position of existing IPAs.

In 1999 the AMA developed a negotiating unit within organized medicine, but without any affiliation with national trade unions, and free of antitrust constraints. Its purpose is to help all members level the playing field in negotiations with health care payers. This new labor organization is not for all physicians. Instead, it represents employed physicians and, where allowed, residents. ([Back](#))

Communicable Diseases - Reporting

KRS 214.010 requires physicians to report all diagnosed diseases designated by the Cabinet for Human Resources to the local Board of Health. 902 KAR 2:020 lists the diseases that must be reported, some of which must be reported within 24 hours, while others must be reported within one business day. Other listed diseases must be reported within five business days. The notification must be given to the local health department or the Department for Public Health. The physician must furnish the name, address, and telephone number of the patient, as well as the clinical, epidemiologic, and laboratory information pertinent to the disease. To obtain a copy of this regulation, which lists the diseases and time frame in which they must be reported, contact the Kentucky Medical Association and request a copy of 902 KAR 2:020. Failure to report these diseases as outlined in the regulations can result in a physician losing his/her medical license.

For patients with Human Immunodeficiency Virus (HIV) and/or Acquired Immunodeficiency Syndrome (AIDS) Surveillance, there are specific reporting requirements, which are outlined in 902 KAR 2:020. An HIV infection or AIDS diagnosis must be reported within five (5) business days and, if possible, on the “Adult HIV/AIDS Confidential Case Report form” or the “Pediatric HIV/AIDS Confidential Case Report form”. A report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, and Trimble Counties must be submitted to the HIV/AIDS Surveillance Program of the Jefferson County Health Department. A report for a resident of another Kentucky county must be submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, or as directed by the HIV/AIDS project coordinator.

A report for a person with HIV infection without a diagnosis of AIDS must be identified in the following order by a Unique Identifier consisting of the person’s:

- (a) Initials of last and first name;
- (b) Date of birth, using the format MMDDYY; and
- (c) Last four (4) digits of Social Security number.

The following additional information must be included with each report for a person with HIV infection without a diagnosis of AIDS:

- (a) Gender;
- (b) Race;
- (c) Risk factor, as identified by CDC;

- (d) County of residence;
- (e) Name of facility submitting report;
- (f) Date and type of HIV test performed;
- (g) Results of CD4+ cell counts and CD4+%;
- (h) Results of viral load testing;
- (i) PCR, HIV culture, HIV antigen, if performed;
- (j) Results of TB testing, if available; and
- (k) HIV status of the person's partner, spouse or children.

Reports of AIDS cases must include the patient's full name and the identifying information outlined above for patients with HIV, along with the patient's complete address, opportunistic infections diagnosed, and date of onset of illness. Reports of AIDS must be made whether or not the patient has been previously reported as having HIV infection. If the patient has not been previously reported as having HIV infection, the AIDS report will also serve as the report of HIV infection.

A physician or medical laboratory that makes an AIDS or HIV report must maintain a log with the name of the patient who tested positive and the unique identifier assigned [902 KAR 2:020(7)].

If you have questions about the proper way to report a patient with a communicable disease or HIV/AIDS, contact the Department for Public Health.

HIPAA and Public Health Reporting

The Health Insurance Portability and Accountability Act [HIPAA] Privacy Regulation mandates certain procedures that medical practices must follow prior to releasing patient information. These mandates usually involve the patient signing a form allowing for such a release. Reporting of diseases mandated by state law and regulation, however, do not have to be authorized by the patient according to HIPAA.

"Protected health information" [i.e. – patient information in a medical practice's possession] may be disclosed for the purposes of treatment, payment and health care operations without a patient authorization. For other releases of protected health information, a patient must sign a HIPAA compliant authorization form. Releases requiring authorization ordinarily involve releases to organizations outside the medical industry including a patient's employer wanting to review the results of a pre-employment physical exam; a disability insurance company wanting to review an applicant's medical history; or a school requesting a copy of a child's health information.

A physician practice may, however, disclose protected health information without obtaining an authorization from the individual in certain situations. Such disclosures include matters related to public health. According to section 164.512(b) (1)(i) of the HIPAA regulation, protected health information may be submitted without patient authorization to "a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions." Those reports that must be made to public health departments pursuant to Kentucky law or regulation, therefore, may be made without having to obtain the authorization of the individual patient. ([Back](#))

Confidentiality (Patient)

Physicians, as well as their employees, should not reveal confidential information or communications without the consent of the patient, unless required to do so by law. The federal government has issued regulations concerning the confidentiality of health information. The regulations, commonly known as "HIPAA" mandate what physician practices and other health care providers and entities must do to protect patient information, as well as what must be done prior to releasing patient information.

In addition to potential civil liability and liability under the Federal HIPAA regulations, physicians can also be disciplined by the Kentucky Board of Medical Licensure for "willfully" violating a confidential communication [KRS 311.595(16)]. Kentucky law also recognizes a patient's right of privacy in the content of a patient's record and a patient's communication with a health care provider with regard to mental health or chemical dependency [KRS 304.17A-555]. Drug or alcohol treatment records from federally supported programs are also protected. If these records are to be released, the authorization must mention these areas specifically rather than attempting to include them within the scope of an authorization to release "all the patient's records," or some similar general language.

Also, records containing reference to sexually transmitted diseases should not be released without specific authorization [KRS 214.420].

Court orders seeking the release of information about HIV test results are effective only if they comply with the law. The order must specify the persons who may have access to their information, the purpose for which it will be used, and appropriate prohibition against further disclosure. When disclosure is made, it must be accompanied by a written statement that says:

This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without specific written consent of the person to whom such information pertains, or is otherwise permitted by state law. A general authorization for the release of medical or other information is NOT sufficient for this purpose [KRS 214.625(5)(c)(10)].

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Consent

A patient must give informed consent to a physician prior to treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice [*Code of Medical Ethics* Opinion 8.08].

In any legal action brought for treating, examining, or operating on a patient when the patient's informed consent is an element of the legal action, the patient's informed consent is deemed to have been given where:

1. The action of the physician in obtaining the consent of the patient or another person authorized to give consent for the patient is in accordance with accepted standard of medical or dental practice among members of the profession with similar training and experience;
2. A reasonable individual, from the information provided by the physician, under the circumstances, would have a general understanding of the procedure and medically or dentally acceptable alternative procedures or treatments and the substantial risks and hazards inherent in the proposed treatment or procedures which are recognized among other health care providers who perform similar treatments or procedures;
3. In an emergency situation where consent of the patient cannot reasonably be obtained before providing health care services, there is no requirement that a health care provider obtain a previous consent (KRS 304.40-320).

If a physician determines that an adult patient does not have decisional capacity and the patient has not executed an advanced directive or the advanced directive does not address the decision that must be made, any one of the following responsible parties, in the following order of priority if no individual in a prior class is reasonably available, willing, and competent to act, shall be authorized to make health care decisions on behalf of the patient:

1. The judicially appointed guardian of the patient, if the guardian has been appointed and if medical decisions are within the scope of the guardianship;
2. The attorney-in-fact named in a durable power attorney, if the durable power of attorney specifically includes authority for health care decisions;
3. The spouse of the patient;
4. An adult child of the patient, or if the patient has more than one child, the majority of the adult children who are reasonably available for consultation;
5. The parents of the patient;
6. The nearest living relative of the patient, or if more than one relative of the same relation is reasonably available for consultation, a majority of the nearest living relatives.

Where a health care decision is made by one of the parties listed above, the decision must be noted in writing in the patient's medical record (KRS 311.631).

No abortion may be performed except with the voluntary and informed written consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, consent to an abortion is voluntary and informed if all of the following criteria are met:

1. The physician has verbally informed the woman of all of the following:
 - (a) The nature and purpose of the particular abortion procedure or treatment to be performed and of those medical risks and alternatives to the procedure or treatment that a reasonable patient would consider

- material to the decision of whether or not to undergo the abortion;
- (b) The probable gestational age of the embryo or fetus at the time the abortion is to be performed; and
 - (c) The medical risks associated with the pregnant woman carrying her pregnancy to term;
2. At least twenty-four (24) hours prior to the abortion, in an individual, private setting, a physician must inform the pregnant woman that:
 - (a) The Cabinet for Human Resources publishes printed materials on the subject of abortion and that she has a right to review the printed materials and that copies will be provided to her by the physician free of charge.
 - (b) Medical assistance benefits may be available for prenatal care, childbirth, and neonatal care, and that more detailed information on the availability of such assistance is contained in the printed materials published by the Cabinet; and
 - (c) The father of the fetus is liable to assist in the support of her child, even in instances where he has offered to pay for the abortion;
 3. At least twenty-four (24) hours prior to the abortion, a copy of the printed materials has been provided to the pregnant woman if she chooses to view these materials;
 4. The pregnant woman certifies in writing, prior to the performance or inducement of the abortion:
 - (c) That she has received the required information outlined above; and
 - (d) That she consents to the particular abortion voluntarily and knowingly, and she is not under the influence of any drug of abuse or alcohol; and
 - (e) Prior to the performance or inducement of the abortion, the physician who is scheduled to perform or induce the abortion or the physician's agent receives a copy of the pregnant woman's signed statement, on a form which may be provided by the physician, on which she consents to the abortion and that includes the certification outlined above [KRS 311.725].

A treating physician who provides or facilitates the use of telehealth must ensure that the informed consent of the patient, or another appropriate person with authority to make the health care treatment decision for the patient, is obtained before services are provided through telehealth. "Telehealth" is defined as the use of interactive audio, video, or other electronic media to deliver health care. It includes the use of electronic media for diagnosis, consultation, treatment, transfer of medical data, and medical education [KRS 311.5975].

There are other statutes that require the specific consent of the patient before certain procedures and tests may be performed. These include the following, all of which are discussed in other sections of this book:

- KRS 214.625 requires consent from a patient prior to an AIDS test being conducted.
- KRS 214.464 requires consent from a patient prior to untested blood being transfused into a patient.
- KRS 311.956 requires consent from a patient for the use of laetrile for cancer treatment.
- KRS 311.623 requires written consent before life support may be withheld from a patient (ie – living will).
- KRS 214.185 requires the consent of a parent before general treatment may be given to a minor.
- KRS 212.343 requires special consent and a waiting period before a sterilization procedure may be performed.

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Contact Lenses

Only a licensed physician, osteopath or optometrist may issue a contact lens prescription. Such a prescription includes a written order bearing the original signature of the licensed practitioner or an oral order issued by the practitioner to the patient. Lenses without power sold for cosmetic purposes also require a prescription [KRS 367.680].

A contact lens fitting is complete and a contact lens prescription may be written when the licensed practitioner has completed all measurements, tests, and examinations necessary to satisfy his or her professional judgment that the patient is a viable candidate to wear contact lenses and contact lenses suitable for the patient's eyes have been evaluated and fitted by the the practitioner to the patient's eyes and the practitioner is satisfied with the fitting based on the visual needs of the patient. The patient is entitled to receive a copy of the contact lens prescription until its expiration date [KRS 367.685].

A contact lens prescription must include the following:

- (a) The ophthalmic information necessary to accurately fabricate or dispense the lenses including the lens manufacturer, lens series, and the lens material if applicable;
- (b) Power and base curve;
- (c) Name, license number, telephone number, and for written orders, the signature of the prescribing optometrist, osteopath, or physician;
- (d) Patient's name and address, expiration date of the prescription, and number of refills or lenses permitted; and
- (e) The date of issuance.

The prescription may also include the diameter, axis, add power, cylinder, peripheral curve, optical zone, and center thickness [KRS 367.681].

Unless a health-related reason for the limitation is noted in the patient's medical records, contact lens prescriptions may not have an expiration date of less than twelve (12) months from the date the prescription is authorized or the last date of the contact lens evaluation, whichever date is later. In no event shall a contact lens prescription be valid twelve (12) months after the date of authorization by a licensed physician, osteopath or optometrist [KRS 367.682].

All mail order contact lens sellers and any physician, osteopath, optometrist or ophthalmic dispensers authorized to dispense contact lenses must verify the contact lens prescription by the following:

- (a) Receipt of a written or faxed valid contact lens prescription signed by the prescribing optometrist, osteopath, or physician; or
- (b) An electronic or oral affirmative communication of the complete contact lens prescription from the prescribing optometrist, osteopath, or physician [KRS 367.683].

Any person authorized to dispense contact lenses that finds it necessary to contact the prescribing optometrist, osteopath, or physician via telephone in order to verify a contact lens prescription, the following protocols must be followed:

- (a) Calls shall be made during regular business hours;
- (b) Any verification requests shall include the name, address, and telephone number of the patient;
- (c) The toll-free telephone number as required by subsection (7) of Section 8 of this Act shall be included in voice mail or messages left on answering machines;
- (d) Contact lens prescriptions shall not be mailed, sent, delivered, or dispensed before verification by the optometrist, osteopath, or physician;
- (e) Touch-tone telephone options offered by a mail order contact lens seller or any person authorized to dispense contact lenses in the Commonwealth shall not constitute verification; and
- (f) Response-time options stated by a mail order contact lens seller or any person authorized to dispense contact lenses in the Commonwealth shall not constitute verification [KRS 367.683].

No person located outside of Kentucky may ship, mail, deliver, or sell contact lenses to a patient at a Kentucky address unless registered to do so with the Attorney General of Kentucky and in possession of a valid contact lens prescription [KRS 367.686].

Anyone authorized to dispense contact lenses that fills a contact lens prescription bears the full responsibility for the accurate dispensing of the contact lenses provided under the contact lens prescription. At no time may any changes or substitutions be made including brand, type of lenses, or ophthalmic parameters without the direction of the optometrist, osteopath, or physician who issued the contact lens prescription. The optometrist, osteopath, or physician is not liable for any damages for injury resulting from the packaging, manufacturing, or dispensing of the contact lenses unless the contact lens seller and the contact lens prescriber

are the same person [KRS 367.684].

Ocular devices approved by the federal Food and Drug Administration as a drug, including but not limited to contact lenses, that contain and deliver pharmaceutical agents pursuant to a prescription from a physician, osteopath or optometrist must be fitted by an ophthalmologist or an optometrist. Ocular devices containing or delivering pharmaceutical agents may be dispensed by an ophthalmologist or an optometrist. Nothing in this law, however, should be construed to expand the prescriptive authority of an optometrist or prohibit, limit, or restrict a pharmacist from dispensing a prescription for an ocular device that contains a pharmaceutical agent [KRS 320.410]. ([Back](#))

Continuing Medical Education

Continuing Medical Education (CME) consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as with the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

All physicians who wish to maintain an active Kentucky medical or osteopathic license is required to complete 60 hours of CME every three years, with 30 hours being certified in AMA Category 1 by an organization accredited by the Accreditation Council on Continuing Medical Education. During each ten (10) year period of their practice, each licensee must complete a minimum of one (1) hour of CME in approved HIV/AIDS courses. However, this mandate expires on December 31, 2016, and from then on physicians will no longer be required to receive such training.

In addition, newly licensed physicians practicing primary care must obtain a one-time 3-hour course on domestic violence within three (3) years of the date of licensure. The course must be approved by the Kentucky Medical Association.

The 2012 House Bill 1, legislation pertaining to the prescribing and dispensing of controlled substances, also imposed certain CME requirements. For each three (3) year continuing education cycle beginning on January 1, 2015, a physician who is authorized to prescribe or dispense controlled substances in Kentucky at any time during that cycle requires 4.5 hours of approved continuing education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects. Each physician licensed to practice medicine or osteopathy within Kentucky who is authorized to prescribe or dispense controlled substances within Kentucky from July 20, 2012 through the end of the three (3) year continuing education cycle beginning January 1, 2012 and ending December 31, 2014 requires 4.5 hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects. Each physician licensed to practice medicine or osteopathy within Kentucky who is authorized to prescribe or dispense controlled substances within Kentucky during calendar years 2013 and 2014, but not 2012 requires 3.0 hours of approved Category I Credit continuing education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects. Each physician licensed to practice medicine or osteopathy within Kentucky who is authorized to prescribe or dispense controlled substances within Kentucky during calendar year 2014, but not 2012 or 2013 requires 1.5 hours of approved Category I Credit continuing education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects. Physicians may satisfy any of these CME requirements by completing a single approved program or by completing multiple approved programs [201 KAR 9:310].

Finally, current practicing pediatricians, including those certified in medicine and pediatrics, radiologists, family practitioners, and those physicians practicing in an emergency medicine or urgent care setting, must complete a one-time course of at least one (1) hour of continuing medical education approved by the board that covers the recognition and prevention of pediatric abusive head trauma, as defined in KRS 620.020, prior to December 31, 2017. Future practicing pediatricians, including those certified in medicine and pediatrics, radiologists, family practitioners, and those physicians who will practice in an emergency medicine or urgent care setting must complete this requirement within five (5) years of the date of licensure [KRS 311.601]. There are no exemptions for retired physicians who maintain an active license in Kentucky. All physicians holding a current Kentucky license are required to complete the 60 hours of CME during each three-year cycle.

The Kentucky Board of Medical Licensure is the agency empowered to regulate the CME requirements for physicians. The Board's website discusses physician CME requirements. To review the Board's requirements, log on to <http://kbml.ky.gov/Pages/Continuing-Medical-Education.aspx>. Category I CME credit can only be provided through an organization designated by the Accreditation Council on Continuing Medical Education or one of its accredited agents." ([Back](#))

Contracts – Amendments

If an insurer offering a health benefit plan makes any material change to an agreement it has entered into with a participating provider for the provision of health care services, the insurer shall provide the participating provider with at least ninety (90) days' notice of the material change. The notice of a material change must provide the proposed effective date of the change; include a description of the material change; include a statement that the participating provider has the option to either accept or reject the proposed material change; provide the name, business address, telephone number, and electronic mail address of a representative of the insurer to discuss the material change, if requested by the participating provider; provide notice of the opportunity for a meeting using real-time communication to discuss the proposed changes if requested by the participating provider ("Real-time communication" means any mode of telecommunications in which all users can exchange information instantly or with negligible latency and includes the use of traditional telephone, mobile telephone, teleconferencing, and videoconferencing. If requested by the provider, the opportunity to communicate to discuss the proposed changes may occur via electronic mail instead of real-time communication.); and provide notice that upon three (3) material changes in a twelve (12) month period, the provider may request a copy of the contract with material changes consolidated into it. The provision of the copy of the contract by the insurer shall be for informational purposes only and shall have no effect on the terms and conditions of the contract. [KRS 304-17A.235(3)]

If a material change relates to the participating provider's inclusion in any new or modified insurance products, or proposes changes to the participating provider's membership networks: the material change shall only take effect upon the acceptance of the participating provider, evidenced by a written signature; and the notice of the proposed material change shall be sent by certified mail, return receipt requested. [KRS 304-17A.235(4)]

For any other material changes that do not relate to the participating provider's inclusion in any new or modified insurance products, or proposes changes to the participating provider's membership networks, the material change will take effect on the date provided in the notice unless the participating provider objects to the change. A participating provider who objects must do so in writing and the written protest must be delivered to the insurer within thirty (30) days of the participating provider's receipt of notice of the proposed material change. Within thirty (30) days following the insurer's receipt of the written objection, the insurer and the participating provider must attempt to reach an agreement on the proposed change or any counter-proposals offered by the participating provider. If the insurer and participating provider fail to reach an agreement during the thirty (30) day negotiation period, then thirty (30) days must be allowed for the parties to unwind their relationship, provide notice to patients and other affected parties, and terminate the contract pursuant to its original terms. The insurer must send the notice of proposed material change in an orange-colored envelope with the phrase "ATTENTION! CONTRACT AMENDMENT ENCLOSED!" on the front of the envelope. [KRS 304.17A-235(5)]

If an insurer issuing a managed care plan makes a change to an agreement that changes an existing prior authorization, precertification, notification, or referral program, or changes an edit program or specific edits, the insurer must provide notice of the change to the participating provider at least fifteen (15) days prior to the change. [KRS 304.17A-235(6)]

"Material change" means a change to a contract, the occurrence and timing of which is not otherwise clearly identified in the contract, that decreases the health care provider's payment or compensation or changes the administrative procedures in a way that may reasonably be expected to significantly increase the provider's administrative expense, and includes any changes to provider network requirements, or inclusion in any new or modified insurance products. [KRS 304.17A-235(1)] [\(Back\)](#)

Contracts – Illegal Provisions

The Kentucky General Assembly has passed legislation outlawing various contract provisions in contracts between managed care companies and physicians. This section discusses these laws and provides examples of the contract provisions prohibited by such laws. Portions of the following section were taken from the American Medical Association's Model Managed Care Contract.

All Products Clauses

An "all products" provision is a clause in a managed care organization (MCO) physician contract that requires, as a condition of participating in *any* of the MCO products, that the physician participate in *all* of the MCO products, sometimes *present or future*. "All products" provisions appear to be the latest in a trend among MCOs to draft more and more onerous contracts that they present to physicians on a "take-it-or-leave-it" basis. "All products" provisions are becoming increasingly common, particularly among large MCOs that dominate markets.

Most MCOs consider the "all products" clause non-negotiable, and this has caused some larger physician networks with bargaining clout to terminate their agreements with those MCOs. Some MCOs are suggesting that they might allow physicians to opt-out of participating in all products, but that they would create a different fee schedule for those physicians who chose not

to participate in all products. While this is encouraging on one level, the AMA is very concerned that these MCOs will develop differential fee schedules that are so coercive, in the form of lower rates for physicians who do not participate in all products, that it is financially impossible for physicians to truly opt-out.

There are a number of important reasons why these clauses — particularly when they are non-negotiable — are unacceptable. MCO plan products differ substantially in operation. For example, a physician may feel comfortable participating in a PPO product, but may have very valid reasons for not wanting to participate in an HMO product, which is a dramatically different product that often requires physicians to assume insurance risk. A risk contract may not be a viable business option for smaller practices with smaller patient bases because of practice size, patient mix or other valid actuarial or business concerns. A large group may have valid concerns that the MCO does not have appropriate computer systems to provide the data needed to manage the insurance risk. “All products” provisions coerce physicians into participating in products about which they have legitimate concerns. In addition, many of these clauses require physicians to accept future contracts with unknown and unpredictable business risk.

MCOs state that they want a uniform network across product lines and that the all-products approach is intended to protect continuity of care. However, this assertion is illogical. For example, if a physician who has been participating in a PPO refuses to sign an “all products” clause, a patient who has historically chosen to see that physician through the PPO will be unable to continue under the physician’s care. As the health plan market continues to consolidate, and where plans have significant market share, the non-negotiable “all products” clauses will operate to further limit patient choice by facilitating a conscious push of patients into HMOs.

Kentucky law prohibits the use “all products” clauses in MCO contracts. An insurer that offers multiple health benefit plans cannot require a health care provider, as a condition of participation in a health benefit plan of the insurer, to participate in any of the insurer’s other health benefit plans [KRS 304.17A-150(4)].

Gag Clauses

“Gag clauses” are provisions in a contract between a health plan and a physician that limit what a physician might be able to tell a patient. Health plans argue that such provisions are used, not to limit discussion about medical treatment between physicians and patients, but to protect proprietary information and prevent physicians from airing frustrations about the changing health care market with their patients. In essence, however, these provisions are anti-competitive, interfere with the confidential physician-patient relationship, and may obstruct a physician from fully discussing all treatment options with the patient.

Many times gag clauses are inserted into a contract, but physicians would not know it if they saw it. Below are some examples of gag clauses that come from actual contract language in health plan contracts with physicians:

This contract may be immediately terminated for provider’s direct contact of plan members in regards to matters pertaining to the plan without plan’s prior written approval or provider’s making any repeated disparaging remarks at plan or expressing opinions regarding the plan or any of its affiliates that are negative in nature.

- This provision says a physician can have no “direct contact” with a patient “in regards to matters pertaining to the plan.” This statement is very broad. It prevents a physician from discussing treatment options the plan might offer, as well as other aspects of the plan. The clause also prohibits physicians from “making any repeated disparaging remarks.” If the physician tells a patient that the plan is “slow” in approving certain treatments, is that a “disparaging” statement?

Any dissatisfaction with the Specialist program should be communicated directly to the Plan rather than to patients or other physicians. Specialist Physician who engages in a pattern of derogatory remarks to patients or otherwise damages Plan’s business reputation may be suspended or terminated from participation in the Specialist program.

- This statement says that the physician must communicate with the plan if there are any problems the physician might have with the plan. If the physician believes that a service should have been approved by the plan when it was not, the physician, according to this provision, can only communicate such disagreement with the plan – not the patient.

Physician shall keep the proprietary information (payment rates, utilization review procedures, etc.) and this agreement strictly confidential.

- Such a provision could be taken to mean that physicians may not discuss with patients costly procedures or how decisions regarding medical necessity are made by the plan. Of course, this provision also contains the broad term “etc.” when describing what is not allowed to be discussed with the patient. This could mean just about anything.

Physicians shall take no action nor make any communication which undermines or could undermine the confidence of Enrollees, potential Enrollees, their employers, Plan Sponsors, or the public in [Plan] or in the quality of care which [Plan] Enrollees receive.

Physicians shall make all endeavors to make positive communication about the plan and will refrain from making any disparaging comments about the plan, or nay comment that would tend to undermine the confidence of patients in the plan.

Each physician must be supportive of the philosophy and concept of the plan.

- These provisions could mean that the physician cannot discuss anything with the patient that might make the patient think the plan is inadequate to meet his needs. Thus, a physician could not discuss the non-availability of sufficient numbers of specialists in a plan panel. Or, for patients with severe problems, alternative treatments could not be discussed because a plan may not cover them.

Provider shall use its best efforts to ensure that no employee of the PROVIDER or subcontractor of the PROVIDER makes any derogatory remarks regarding [Plan] to any member.

- This provision ensures that the “gag” applies, not only to the physician, but also to the physician’s employees “or subcontractor” (cleaning crew?).

In response to the use of such clauses, the KMA supported legislation in 1998 banning gag clauses from health plan contracts. The law states:

- (1) A managed care plan may not contract with a health care provider to limit the provider’s disclosure to an enrollee, or to another person on behalf of an enrollee, of any information relating to the enrollee’s medical condition or treatment options.
- (2) A health care provider shall not be penalized, or health care provider’s contract with a managed care plan terminated, because the provider discusses medically necessary or appropriate care with an enrollee or another person on behalf of an enrollee.
 - (a) The health care provider may not be prohibited by the plan from discussing all treatment options with the enrollee.
 - (b) Other information determined by the health care provider to be in the best interests of the enrollee may be disclosed by the provider to the enrollee, or to another person on behalf of the enrollee.
- (3)
 - (a) A health care provider shall not be penalized for discussing financial incentives and financial arrangements between the provider and the insurer with an enrollee.
 - (b) Upon request, a managed care plan shall inform its enrollees in writing of the type of financial arrangements between the plan and participating providers if those arrangements include an incentive or bonus [KRS 304.17A-530].

Some health plans, most notably “self-insured” plans, might place a gag clause in their contracts because, they argue, the federal ERISA law preempts Kentucky state law. The United States Supreme Court, however, has held that ERISA does not preempt state laws that can be characterized as an exercise of the power of “general health care regulation,” including “quality standards”. A prohibition on gag clauses is certainly designed for the regulation of general health care in the state, which has nothing to do with mandated benefits of a plan.

Some health plans might also argue that, while their contracts do contain gag clauses, the gag clauses are simply unenforceable, so there is no need to take them out. This argument, however, has no merit. Kentucky law is quite clear that contracts may not contain gag clause language that would attempt to bind a physician. There is also a Kentucky law that says no one may “knowingly and willfully transact any [insurance] contract, agreement, or investment which violates [the law]” [KRS 304.47-020(d)].

Not only are gag clauses detrimental to the physician-patient relationship, they might also create additional liability for a physician. Kentucky law makes it clear that patients must give “informed consent” to a physician for any type of service or treatment. By not discussing all available treatment options, a physician might not give enough information for the patient to provide informed consent. This might create liability for the physician. Also, if a gag clause is contained in a contract, the patient might have an argument that the physician was legally bound not to give information necessary for informed consent.

Physicians should review their contracts to determine if they contain gag clauses. If a contract does contain such a clause, the AMA suggests that the physician not just “X” out the language and send it back to the health plan. This may not be binding on the plan. Physicians should negotiate to have the language removed and Kentucky’s law banning such clauses is very good leverage for a physician to use during such negotiations. Physicians should also seek to have language put in their contracts that protects them from liability. Such language might say, “Nothing in this contract shall be construed to impede the physician’s ethical and legal duty to provide full informed consent in medical counsel to patients.”

While health plans might argue that gag clauses are meant to protect their business interests, a physician should be able to discuss all treatment options with a patient. The health of the patient should always come before the bottom-line of a managed care company.

Most Favored Nation Clause

Some managed care organizations have attempted to place “most favored nation” clauses in their contracts with physicians. Such clauses require a physician to afford the managed care company the same rates provided to other payors if such rates are more favorable. In essence, it requires a physician to charge the managed care organization the lowest rate paid to the physician by other health plans. These clauses have come under attack by the physician community over the last several years, which led to the passage of legislation in Kentucky banning such clauses from contracts except in certain circumstances. KRS 304.17A-560 states: “No insurance contract with a provider shall contain a most-favored-nation provision except where the [Commissioner of Insurance] determines that the market share of the insurer is nominal.” [\(Back\)](#)

Contracts – Model Managed Care Contract

This section is taken from a document prepared by the Private Sector Advocacy Division of the American Medical Association. It is designed to educate physicians and provide a reasonable alternative to one-sided third party payer contracts. Model contract provisions, along with an explanation of those provisions, are included in this section (the explanation is in the bold language). Physicians may want to compare the language set out in this section with the actual contract language contained in their contracts for an explanation of the language in question as well as an understanding of how the provision might affect their practices. Throughout this section, the phrase “Medical Services Entity” stands for the physician entity (eg individual, corporation, group practice, network), while the phrase “Qualified Physician” refers to an individual physician within the entity. The annotations refer more informally to “physician” or “physician group/network.” Where the contract is with an unincorporated individual physician, that physician is both a Medical Services Entity and a Qualified Physician. This model agreement is not intended for use between a physician group or network and an individual physician.

THIS AGREEMENT, made this ____ day of ____ 2000 and made effective on the ____ day of _____, 2000 (“Effective Date”) by and between [a physician] [a medical group practice] [a physician joint venture, such as a Network or IPA] _____ (“Medical Services Entity”), and _____ a [state of incorporation] Corporation (“Company”) (Medical Services Entity and Company jointly the “parties”).

Witnesseth:

This section, known as the “recitals,” will vary from arrangement-to-arrangement. The recitals describe the intentions of the parties in entering into the agreement. The recitals should be changed to fit the specific facts. Recitals generally are not an enforceable part of the contract, but they may be very important to a judge or arbitrator in interpreting the contract. Therefore, care should be taken that the recitals are set forth accurately and completely.

WHEREAS, Company offers or directly administers one or more health benefit products or plans and wishes to arrange for the provision of medical services to enrollees of such products or plans.

WHEREAS, Medical Services Entity is comprised of or contracts with one or more physicians capable of meeting the credentialing criteria of Company.

WHEREAS, Company desires to engage Medical Services Entity to deliver or arrange for the delivery of medical services to the Enrollees of its plans.

WHEREAS, Medical Services Entity is willing to deliver or arrange for the delivery of such services on the terms specified herein.

NOW, THEREFORE, in consideration of the mutual promises set forth herein, and other good and valuable consideration, the parties hereby agree as follows:

I. Definitions

Definitions matter. They are one of the most critical elements of the agreement. A right or responsibility may begin and end with the definition of a term. The difference between a liberal and narrow definition of “medically necessary” or “emergency services” could mean the difference between the MCO approving and paying for a patient’s procedure or refusing to pay. In addition, for example, an expansive definition of “Payors” may allow unscrupulous MCOs to create “silent PPOs” by “renting” discounted physician services to other entities not a party to the contract without the knowledge of physicians.

1.1 Claim. A statement of services submitted to Company by Medical Services Entity following the provision of Covered Services to an Enrollee that shall include diagnosis or diagnoses and an itemization of services and treatment provided to Enrollee.

1.2 Company Notice. A communication by Company to Medical Services Entity informing Medical Services Entity of the terms of one particular Plan, modifications to the Plan, and any other information relevant to the provision of Covered Services pursuant to this Agreement.

1.3 Company Compensation. The Total Compensation less that portion designated by the Plan as a Copayment.

1.4 Coordination of Benefits. The determination of whether Covered Services provided to an Enrollee shall be paid for, either in whole or in part, under any other private or government health benefit plan or any other legal or contractual entitlement, including, but not limited to, a private group indemnification or insurance program.

1.5 Copayment. A charge that may be collected directly by a Medical Services Entity or Medical Services Entity's designee from an Enrollee in accordance with the Plan.

1.6 Covered Services. Health care services to be delivered by or through Medical Services Entity to Enrollees pursuant to this Agreement. A description of the medical services that are covered by the applicable products or plans is attached to this Agreement as Exhibit A.

1.7 Emergency Condition. A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, that a prudent layperson would reasonably have cause to believe constitutes a condition that the absence of immediate medical attention could reasonably be expected to result in: (1) placing the health of the individual in serious jeopardy; (2) serious impairment of bodily functions; or (3) serious dysfunction of any bodily organ or part; or (4) with respect to a pregnant woman who is having contractions, a situation in which there is inadequate time to effect a safe transfer to another hospital before delivery, or a situation in which transfer may pose a threat to the health or safety of the woman or the unborn child.

The definition of emergency medical condition in managed care agreements accounts for many payment disputes, and MCOs often have denied payment based on the fact that what appeared to be a medical emergency to all parties present, was not, in fact an emergency in the view of the MCO after the fact. The "prudent layperson" standard in Section 1.7 protects patients and physicians and prevents payment disputes by acknowledging the common sense of the prudent layperson in determining whether his or her condition requires immediate medical attention. The definition of "emergency medical condition" used in this section is taken from Kentucky law [KRS 304.17A-500(4)].

1.8 Enrollees. Any individual(s) entitled to health care benefits under a Plan who presents an identification card that contains the following information: (i) the name of the Payor; (ii) the Enrollee's name; (iii) the logo of the plan or product; (iv) contact information for pre-authorization, if necessary; (v) the billing address; and (vi) the applicable Plan.

1.9 Medically Necessary/Medical Necessity. Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the convenience of the patient, physician, or other health care provider.

The definition of "medical necessity" in Section 1.9, which is AMA policy, relies on an objective "prudent physician" standard for medical necessity determinations and does not consider cost in making that determination. Generally, MCOs will not pay for care that is not "medically necessary." However, many managed care contracts allow the MCO medical director to determine what is "medically necessary" according to vague standards that allow the medical director to override the physician's clinical judgment. At the same time, the MCO disclaims any legal responsibility for these decisions. Many of these same agreements impose a "least cost" standard as well, thereby inappropriately interjecting financial considerations into a clinical decision. This definition relies on what would be believed necessary by the average, prudent physician faced with a diagnosis or condition.

1.10 Non-Covered Services. Health care services that are not Covered Services as defined herein.

1.11 Payor. The entity or organization directly responsible for the payment of Company Compensation to the Medical Services Entity under a Plan. With respect to a self-funded Plan covering the employees of one or more employers, the Payor shall be the employer(s) and/or any funding mechanism used by the employer(s) to pay Plan benefits. With respect to an insured Plan or Plan providing benefits through a health maintenance organization, the Payor shall be the insurance company or health maintenance organization, as the case may be. Under no conditions shall the parties interpret "Payor" to be, nor shall the negotiated rates herein described be accessible to, any party other than Company or an employer offering a self-funded, non-indemnity product that contracted with Company to administer such product.

The definition of "Payor" in Section 1.11 provides a reasonable amount of flexibility consistent with the reality that in some cases, the MCO will be providing an insured product, and in other cases, the MCO will be administering a product for a self-funded employer plan. In the second case, the self-funded employer is actually the payor. However, this definition makes clear that the MCO cannot "sell" or "rent" the

terms of the agreement (including the physician's discounted services) to other entities — thus preventing the creation of “silent PPOs.”

1.12 Plan. An individual set of health service delivery and compensation procedures offered as a “managed care” product by Company, or administered by Company, on behalf of a Payor for the benefit of Enrollees, as it may be modified from time to time, and all the terms, conditions, limitations, exclusions, benefits, rights, and obligations thereof to which Company and Enrollees are subject. Nothing in this Agreement shall be construed to require physicians to participate in all of Company's Plans as a condition of participating in any individual plan or plans.

Section 1.12 makes clear that the contracting physician is not required to participate in “all products” offered by the MCO. It does permit the MCO and the physician or physician group/network to enter into a single set of legal terms to govern their relationship that would apply to every product or plan included in the arrangement. However, the agreement also requires the parties to recognize separate business terms (including compensation) for each and every product and plan, which are attached as exhibits to the contract. By using this approach, the parties may terminate plans or products individually, without terminating the entire contract, by choosing to add or delete the plans or products described on Exhibit B. The AMA strongly opposes managed care contracts that require physicians to participate in “all products” as a condition of participating in any product.

1.13 Qualified Physician. A doctor of medicine or osteopathy licensed to practice medicine, who has agreed in writing, either through this Agreement or through another written instrument, to provide Covered Services to Enrollees and who has been credentialed pursuant to the rules and procedures of the Plan by the Company or a duly appointed and authorized agent to which such responsibility has been delegated.

1.14 Quality Management. The process designed to monitor and evaluate the quality and appropriateness of care, pursue opportunities to improve care, and resolve identified problems in the quality and delivery of care.

1.15 Total Compensation. The total amount payable by Payor and Enrollee for Covered Services furnished pursuant to this Agreement.

1.16 Utilization Review. The process by which Company, or a duly appointed and authorized entity (including Medical Services Entity) to which such responsibility has been delegated, determines on a prospective, concurrent, or retrospective basis the medical appropriateness of Covered Services furnished to Enrollees.

II. Delivery of Services

2.1 Covered Services. Medical Services Entity shall provide or, through its Qualified Physicians, arrange for the provision to Enrollees of those Covered Services that are identified in Exhibit A, attached hereto and made a part of this Agreement by this reference.

In many managed care contracts, the services to be covered by the MCO are either poorly defined or not defined at all. This works to the advantage of the MCO by giving it wide berth to deny requested services as “not covered.” Similarly, some capitation agreements either fail to clearly and completely articulate the set of services to be performed, or may fail to provide the list altogether, which allows the company to demand that the physician provide virtually open-ended services for the fixed capitation amount.

Section 2.1 defines the “Covered Services” for each plan or product as those specifically set forth on one or more schedules attached as Exhibit A and places the responsibility for describing covered services where it belongs: on the MCO. If the MCO fails to fulfill this responsibility, or if its terms are so unclear that it is difficult to interpret which services are covered, the company is penalized and must reimburse the physician or physician group/network using a fee schedule similar to a standard private pay or indemnity arrangement.

2.2 Full Description. Exhibit A shall be comprised of separate schedules designated as Exhibit A1, A2, etc., which shall either identify separately the Covered Services relating to each Company Plan or provide a fixed location where the Medical Services Entity can conveniently find the complete list of covered services.

2.3 Full Disclosure. Where such schedule contemplates a global or capitated arrangement requiring Covered Services not normally provided by the Qualified Physicians of Medical Services Entity, such Covered Services shall be designated in bold type on Exhibit A, and a note shall be displayed prominently stating that payment for these Covered Services shall be the Medical Service Entity's responsibility.

2.4 Administrative Responsibility. In the event Exhibit A is not attached or in the event such exhibit contains descriptions of Covered Services that are so materially lacking in specificity that the purpose of this Agreement is defeated, Company shall pay Medical Services Entity the Qualified Physician's billed charge for each service performed by a Qualified Physician for the benefit of Enrollee.

The requirement in Section 2.4 that the company pay the physician's usual and customary charge is innovative. Although MCOs are likely to strongly resist this provision, it is a fair and reasonable way to ensure that physicians receive fair payment for services when the MCO neglects to include important terms in the contract to its own financial advantage.

2.5 Medical Responsibility. All Covered Services shall be provided in accordance with generally accepted clinical

standards, consistent with medical ethics governing the Qualified Physician.

2.6 Verification of Enrollees. Except in the case of emergency, Medical Services Entity shall use the mechanism, including identification card, on-line service or telephone, chosen by Company or its agent designated for such purpose, to confirm an Enrollee's eligibility prior to rendering any Covered Service, in order to guarantee payment. If Company does not provide verification services on a twenty-four hour a day, seven-day per week basis, Medical Services Entity shall be entitled to rely on the information printed on the Enrollee's identification card as conclusive evidence of such Enrollee's eligibility. In addition, Company and Medical Services Entity agree to the following:

2.6(a) Company or Payor shall be bound by Company's confirmation of eligibility and coverage for the requested services and shall not retroactively deny payment for Covered Services rendered to individuals the Plan has confirmed as eligible using Company's designated verification mechanism.

2.6(b) If Medical Services Entity, after following Company procedure to the extent reasonably possible, is unable to verify the eligibility of a patient who holds him or herself out to be an Enrollee, Medical Services Entity shall render necessary care through its Qualified Physician, and Company shall pay for such care if the patient is an Enrollee.

2.6(c) In the event of an emergency, at the first available opportunity, Medical Services Entity shall attempt to verify eligibility. In the event Medical Services Entity makes all good faith efforts to verify eligibility, and verification is not reasonably possible given time constraints caused by the Company's action or inaction, and patient is not an Enrollee, Medical Services Entity shall attempt to collect from patient the amount due, up to the usual and customary fee of the Qualified Physician providing the service. If, after two billing cycles, Medical Services Entity or Qualified Physician has not received full payment, Company will pay Medical Services Entity the Qualified Physician's usual and customary fee, minus that which the Qualified Physician or Medical Services Entity has already collected from the patient, not to exceed the amount provided for as Total Compensation herein.

As every physician's office knows, verifying a patient's enrollment in a plan is not always an easy task, and the physician practice usually suffers for the MCO's administrative mistakes. For example, physicians sometimes are denied payment because MCOs make administrative errors in identifying Enrollees or failing to provide enough telephone access or other convenient means of communication for the physician to obtain verification in a timely fashion. This section sets forth a reasonable procedure for ensuring that a physician can verify Enrollees and allows the physician to receive payment where the physician reasonably relies on these procedures.

III. Compensation and Related Terms

Article III provides a unique and sensible approach that allows the parties to negotiate separate business terms — including compensation — for each of the company's plans and prevents the MCO from unilaterally changing those terms. It simply requires that such terms be attached as Exhibit B. In the past several years, physicians around the country have made the unpleasant discovery that they thought they had agreed to a set compensation schedule for the term of the contract, when the MCO had, in fact, reserved the right to change that schedule unilaterally and at-will. That discovery typically occurs when the physician begins receiving reduced payment for services. That dynamic would not occur under Article III.

3.1 Compensation. Medical Services Entity, or its designee, shall accept, from Company or Payor, as full payment for the provision of Covered Services, the Total Compensation identified in Exhibit B, attached hereto and made a part hereof by this reference.

3.2 Full Description. Exhibit B shall be comprised of separate schedules designated as B1, B2, etc., which shall identify separately the Total Compensation and related terms for each Payor and Plan.

3.3 Full Disclosure. The Total Compensation set forth on the Exhibit B schedule(s) shall specify for each Payor and Plan, the manner of payment (such as fee-for-service, capitation, risk withholds, global payment, or bonus arrangement) for professional services rendered pursuant to the provision of Covered Services as set forth in the counterpart schedule of Exhibit A, and shall identify the portion of the Total Compensation that shall be the Company Compensation. Exhibit B shall also identify with specificity the additional business terms negotiated by the parties related to such Total Compensation. By way of example, and with-outlimiting the requirements of this section, Exhibit B shall specify the following:

Section 3.3 requires the MCO to provide the physician or physician group/network with data needed to evaluate and manage risk contracts. The agreement requires that any compensation exhibit beyond a standard fee-for-service schedule specify in detail the precise terms of payment. Subsections (a) through (c) provide a checklist of issues to be identified and resolved in negotiating three of the alternatives to a simple fee schedule. Note that separate Exhibit B schedules are required for each plan or product, so that they can be negotiated, renewed, or terminated individually. Finally, just as with the covered services on Exhibit A, this section establishes a penalty when the company fails to articulate the precise payment terms honestly and in sufficient detail.

3.3(a) In the case of a capitation arrangement,

- i. the amount to be paid per Enrollee, per month;
- ii. the date each month that the capitation payment is due;

- iii. the manner by which Company will determine and communicate to Medical Services Entity who is an Enrollee assigned to Medical Services Entity at the beginning of each month;
- iv. the precise terms of the stop-loss arrangement offered to Medical Services Entity by Company, or a recital indicating that Medical Services Entity shall obtain stop-loss protection through other arrangements;
- v. the boundaries of the service area in which treatment of Enrollees shall be arranged by Medical Services Entity and outside of which treatment provided to Enrollees shall become the financial obligation of Company;
- vi. the fee-for-service schedule to which the parties will revert in the event the number of Enrollees assigned to Medical Services Entity falls below a designated actuarial minimum, defeating the predictability of risk that both parties rely on in the arrangement;
- vii. the number of covered lives and the fee-for-service schedule upon which Medical Services Entity will be paid for those Covered Services provided to Enrollees not specifically made a part of the capitation arrangement on Exhibit A. In the case of a capitation arrangement, Medical Services Entity shall have the right to audit, at Medical Services Entity's expense, the books and records of Company or a Payor for purposes of determining the accuracy of any capitation payment and for the purposes of determining the number of Enrollees assigned to Medical Services Entity.
- viii. the description of reports and analyses to be supplied at least monthly by the Company to enable the Medical Services Entity to manage effectively the risk it assumes under capitation arrangements.

[For answers to questions that physicians frequently ask about capitation arrangements, see the section of this book entitled "Capitation."]

3.3(b) In the case of hospital/Medical Services Entity or Payor/Medical Services Entity **risk sharing on Non-Covered Services** (ie risk pools for hospital services),

- i. the amount allocated by a Payor for Non-Covered Services including the figure used for measuring hospital inpatient days per one thousand (1,000) Enrollees assigned to Medical Services Entity and applicable hospital per diem or capitation payment;
- ii. those services that will be charged against the hospital budget, such as hospital inpatient and outpatient care, ambulance service, home health services, durable medical equipment, and the capitation payment withhold, if any, of Medical Services Entity's contribution to the hospital budget;
- iii. the monthly date upon which Company will submit to Medical Services Entity a report regarding current charges made against the hospital budget;
- iv. the amount of the hospital budget surplus to which Medical Services Entity would be entitled in the event utilization of institutional services is favorable, and the degree and scope of risk to Medical Services Entity, if any, in the event utilization of institutional services is excessive.

3.3(c) In the case of a withhold or bonus,

- i. the method by which the amount to be released or paid will be calculated and the date on which such calculation will be complete;
- ii. the records or other information on which Company will rely to calculate the release of the withhold or the payment of the bonus;
- iii. the date upon which Medical Services Entity will have access to such records or information relied on by Company in making such calculation for the purpose of verifying the accuracy thereof;
- iv. the date upon which such payment or release, if any is finally due, shall be made.

3.3(d) In the case of a discounted fee for service arrangement, Exhibit B shall contain the following:

- i. a comprehensive fee schedule that states clearly how much will be paid for each service to be rendered pursuant to the agreement or, as appropriate, sufficient information is provided to enable a fee for each service to be calculated accurately by each party;
- ii. a statement that the fee schedule cannot be changed without the consent of Medical Service Entity;
- iii. a provision stating the consequence for a Payor changing the terms of a fee schedule without consent of the Medical Service Entity, including the right to terminate the agreement and the right to recover billed charges.

3.4 Administrative Responsibility. In the event Exhibit B is not attached or contains descriptions of compensation

and related terms that are so materially lacking in specificity that the purpose of this Agreement is defeated, then Exhibit B shall be considered null and void and Company shall pay Medical Services Entity the Qualified Physician's billed charge for each service performed by a Qualified Physician hereunder. The Parties agree that the precise terms of Exhibit B, as opposed to the general description of the manner of payment, shall remain confidential between the parties and their respective attorneys.

Like Section 2.4, the concept in Section 3.4 of reverting to billed charges in the absence of sufficiently defined compensation schedules is innovative. However, allocating the administrative duty of providing information on compensation terms to the MCO is logical and fair, and reversion provides an incentive for the MCO to comply with the requirement.

3.5 Billing for Covered Services. Medical Services Entity shall submit a Claim to Company and, in the event payment is required under the terms of Exhibit B, Company shall pay Medical Services Entity for Covered Services rendered to Enrollees in accordance with the terms of this Agreement. Medical Services Entity shall arrange for all Claims for Covered Services to be submitted to Company within six (6) months after the date services were rendered. Medical Services Entity shall submit such claims electronically or on a HCFA-1500 billing form.

3.6 Coding for Bills Submitted. Company hereby agrees that claims submitted for services rendered by Medical Services Entity shall be presumed to be coded correctly. Company or Payor may rebut such presumption with evidence that a claim fails to satisfy the standards set forth on Exhibit C. Exhibit C shall include a detailed description of Company's coding standards and requirements, including, but not limited to, the rules on modifiers, multiple surgeries, evaluation and management, and bundling policies such as edits, including correct coding initiatives. Company and Payor shall not adjust the billing codes submitted by Medical Services Entity on a claim without first requesting additional documentation to satisfy the coding standards described on Exhibit C. Company or Payor must provide adequate notice if it wishes to adjust a code and must allow sufficient time for Medical Services Entity to submit additional documentation or explanation. Medical Services Entity shall have the right to appeal any adverse decision regarding the payment of claims based upon the level of coding with rights and duties as set forth in this Agreement. If Company or a Payor reduces payment of a claim in contravention of this section, such party shall be obligated to reimburse Medical Services Entity for the full amount of billed charges for the claim.

Section 3.6 prevents the practice of "bundling" and "downcoding" which are practices often used by MCOs in which multiple procedures are sometimes "bundled" together and paid as a single procedure or claims are "downcoded," meaning they are submitted to the MCO at one level but are reimbursed at a separate lower level than what was actually billed. This section is designed to require the MCO to set forth billing standards and policies to the physician or physician group/network.

3.7 Copayments to be Collected from Enrollees. When the Plan requires Enrollees to make Copayments, Medical Services Entity or one of its Qualified Physicians shall collect such Copayments from the Enrollee at the time of service. Company shall require Enrollees to make Copayments at the time of service and educate Enrollees about the amount of the Copayment and that making Copayment at the time of service is mandatory. If Copayment is not remitted to Medical Services Entity in a timely fashion, Company agrees that Medical Services Entity may discontinue seeing patient, subject to its Qualified Physician's ethical duties, and that such action will not constitute a violation of Section 4.2 by Medical Services Entity.

3.8 Coordination of Benefits. When Enrollees are covered, either fully or partially, for services provided by a Qualified Physician under any contractual or legal entitlement other than this Agreement, including, but not limited to, a private group or indemnification program, Medical Services Entity shall be entitled to keep any sums it recovers from such primary source consistent with applicable federal and state law. Except as indicated in the following sentence, Payor will pay Medical Services Entity the usual and customary fee of the Qualified Physician providing service for Medical Services Entity, less that which is obtained from any primary source. If Exhibit B contemplates a fee-for-service compensation arrangement, the sum of such payments shall not exceed the Total Compensation set forth on Exhibit B; however, in the case of Medicare beneficiaries and where the Payor is the Secondary Payor, the sum of such payments shall not be less than one hundred percent (100%) of the Medicare allowed fee schedule.

3.8(a) If Payor is deemed "primary" in accordance with applicable industry coordination of benefits ("COB") standards, the Payor shall pay Medical Services Entity in accordance with the terms of this Agreement with no delay, reduction, or offset.

3.8(b) If Payor is deemed "secondary" in accordance with applicable industry COB standards, Payor shall pay Medical Services Entity the difference between what Medical Services Entity received from the primary Payor and the amount Payor owes Medical Services Entity as Total Compensation under the terms of this Agreement.

3.8(c) Payor shall be presumed to be the primary Payor and shall make payments in accordance with this Agreement, unless such Payor can document to the satisfaction of the Medical Services Entity that

it is secondary under industry COB standards within 72 hours of receipt of a claim.

- 3.8(d)** If Payor pays a claim to Medical Services Entity in accordance with this Agreement, Medical Services Entity agrees to cooperate with the reasonable efforts of Payor to determine whether it is the primary or secondary Payor under industry COB standards.
- 3.8(e)** If it is subsequently determined that a Payor should be considered secondary under industry COB standards, then Medical Services Entity will cooperate with that Payor's reasonable efforts to seek reimbursement from the responsible primary payor.
- 3.8(f)** If Exhibit B provides a fee-for-service schedule applicable to Enrollee's Plan, Medical Services Entity shall not retain funds in excess of the Total Compensation fee schedule listed on Exhibit B, unless applicable state law regarding COB requires or imposes a different requirement.
- 3.8(g)** Secondary payors shall not be relieved of their obligation to make full payment to Medical Services Entity in the event the primary payor fails to pay Medical Services Entity properly submitted Claims within 90 days of submission.

The coordination of benefits provision in Section 3.8 deals with the question of who will pay the physician or physician group/network and how much must be paid when a person is covered by more than one insurance plan. For example, a person may be covered by both his or her employer's plan and a spouse's plan. This provision ensures that the physician or group receives full compensation without placing the patient under inappropriate financial risk.

3.9 Promptness of Payment. Each Payor shall remit to Medical Services Entity the Company Compensation within thirty (30) days of receipt of an electronic Claim or receipt of a written Claim by Medical Services Entity, as provided by Kentucky state law, that contains sufficient detail that Payor is able to reasonably determine the amount to be paid.

Delayed payment of physicians is a chronic problem in parts of the country, and most managed care contracts are silent on the issue, giving the physician no rights and the MCO no responsibilities. This section gives the physician a contractual right to prompt payment of all claims clean enough that a Payor can reasonably determine what service was performed and how much should be paid. [For more information on MCO requirements under Kentucky's new prompt payment laws, see the section of this book entitled "Prompt Payment Laws."]

- 3.9(a)** In the event that a Payor fails to make such payment in a timely fashion as specified herein, Payor shall be obligated for payment of such amounts plus interest accruing at the rate established under Kentucky state law. All payments to Medical Services Entity will be considered final unless adjustments are requested in writing by Medical Services Entity within ninety (90) days after receipt by Medical Service Entity of payment explanation from Payor.

Section 3.9(a) is designed to prevent MCOs from retrospectively auditing claims and reducing payment long after services were rendered based on the MCO's determination that certain claims should not have been paid or should have been reimbursed at a lower level. This is accomplished in Section 3.9(a) by making payments to physician or physician groups/networks final within 90 days after receipt by the physician

3.10 Sole Source of Payment. Where Enrollee is enrolled in a Plan subject to state or federal legal requirements that prohibit a physician from billing patients for Covered Services in the event the Payor fails to make such payment, Medical Services Entity agrees to look solely to that Payor for payment of all Covered Services delivered during the term of the Agreement.

- 3.10(a)** In such circumstances, Medical Services Entity shall make no charges or claims against Enrollees for Covered Services except for Copayments as authorized in the Plan covering Enrollee.
- 3.10(b)** In such circumstances, Medical Services Entity expressly agrees that during the term of this Agreement it shall not charge, assess, or claim any fees for Covered Services rendered to Enrollees from such Enrollees under any circumstances, including, but not limited to, the event of Payor's bankruptcy, insolvency, or failure to pay the Qualified Physician providing services.
- 3.10(c)** Notwithstanding the foregoing, Company shall cooperate in the processing of such claims against Payor to provide Medical Services Entity with its greatest chance to receive compensation for covered services provided, and this provision shall permit Medical Services Entity to collect payment not prohibited under state or federal law, including, but not limited to:
 - i. Covered Services delivered to an individual who is not an Enrollee at the time services were provided;
 - ii. Services provided to an Enrollee that are not Covered Services, provided that Medical Services Entity advises the Enrollee in advance that the services may not be Covered

Services; or

- iii. Services provided to any Enrollee after this Agreement is terminated.

State law strictly limits physicians' ability to charge patients for services delivered under a managed care contract, even when the MCO is in bankruptcy. However, some MCOs abuse this by effectively requiring physicians to continue to treat patients indefinitely and preventing them from making any claims against the MCO or Payor as a creditor. Section 3.10 satisfies the intent of most state statutes in protecting consumers and allows the physician or physician groups/network to pursue other remedies under the law. Section 3.10(c) also sets forth circumstances in which a physician or physician group/network can collect payment from individual patients. Non-payment of claims may be a sign of financial instability, and physicians should consider terminating in this event. Once a MCO has declared bankruptcy, the physician has limited remedies for payment.

3.11 Subrogation. In the event an Enrollee is injured by the act or omission of a third party, the right to pursue subrogation and the receipt of payments shall be as follows:

- 3.11(a)** If Exhibit B provides for a capitation payment for the Enrollee, Medical Services Entity shall retain the right of subrogation to recover reimbursement from third parties, such as automobile insurance companies, for all Covered Services for which it is at risk to provide in exchange for the capitation paid hereunder.
- 3.11(b)** If Exhibit B provides for a fee-for-service arrangement for the Enrollee, Medical Services Entity shall permit Payor to pursue all its rights to recover reimbursement from third party Payors to the extent Payor is at risk for the cost of care.
- 3.11(c)** Payor shall pay claims submitted by Medical Services Entity in accordance with this Agreement, not withstanding Payor's pursuit of subrogation rights against potentially responsible third parties who caused an injury by their act or omissions in accordance with section 3.11(b).
- 3.11(d)** Medical Services Entity shall abide by any final determination of legal responsibility for the Enrollee's injuries.
- 3.11(e)** Upon receiving payment from the responsible party, Medical Services Entity will refund the amount of payment to Payor up to the amount paid by the Payor for the services involved. Medical Services Entity shall be entitled to keep any payments received from third parties in excess of the amount paid to it by Payor.

Subrogation involves a third party's right to receive payment from a defendant in a negligence lawsuit by "stepping into the shoes" of the plaintiff. For example, if a patient is in a car accident and receives damages from the defendant or defendant's insurer, the party at risk for the medical care (the physician and/or MCO) should be afforded rights of subrogation for the cost of that care.

IV. Medical Services Entity's Obligation

Article IV sets forth the obligations of physicians or physician groups/networks that are reasonable and necessary in the managed care arrangement. They have been drafted to recognize the administrative realities that MCOs face in balancing the needs of their various Payors.

- 4.1 Licensed/Good Standing.** Medical Services Entity represents that it, or each of its Qualified Physicians, is and shall remain licensed or registered to practice medicine and, if applicable, the legal entity is registered and in good standing with the state in which it is chartered and each state in which it is doing business.
- 4.2 Nondiscrimination.** Medical Services Entity agrees that it, and each of its Qualified Physicians, shall not differentiate or discriminate in its provision of Covered Services to Enrollees because of race, color, ethnic origin, national origin, religion, sex, marital status, disability, or age. Further, Medical Services Entity agrees that its Qualified Physicians shall render Covered Services to Enrollees in the same manner, in accordance with the same standards, and within the same time availability as such services are offered to patients not associated with Company or any Plan, consistent with medical ethics and applicable legal requirements for providing continuity of care.

Section 4.2 is subject to state law, and the parties entitled to protection under Section 4.2 may be modified to be consistent with such law.

- 4.3 Standards.** Covered Services provided by or arranged for by Medical Services Entity shall be delivered by professional personnel qualified by licensure, training, or experience to discharge their responsibilities and operate their facilities in a manner that complies with generally accepted standards in the industry.
- 4.4 Cooperation in Credentialing.** Company and Medical Services Entity agree to cooperate in credentialing and re-credentialing Qualified Physicians in accordance with the process set forth on Exhibit D and consistent with Section 5.4 of this Agreement. Exhibit D shall identify with specificity the criteria for credentialing timelines and the rights and obligations of Company and the physicians during the credentialing process. By way of example, Exhibit D shall specify the following:

- 4.4(a)** The criteria to be used by Company in its decision whether or not to credential or re-credential a

physician.

- 4.4(b)** Identification of the internal process that Company will use in making credentialing decisions.
- 4.4(c)** Identification of the individual or committee that has authority to decide whether to grant or remove credentials.
- 4.4(d)** Identification of the individual or committee to whom the initial decision maker is accountable.
- 4.4(e)** Identification of how and when physicians will be notified of credentialing decisions, including a reasonable deadline by which Company must finalize credentialing decisions.
- 4.4(f)** A requirement that an adverse decision state with specificity the reason for such decision.
- 4.4(g)** A statement of the rights and duties of Medical Services Entity or a physician in an appeal of an adverse credentialing decision, including the following elements:
 - (i) The deadline for filing an appeal;
 - (ii) Whether the appeal will be in writing or a live hearing;
 - (iii) What evidence the physician may introduce;
 - (iv) The physician's right to review the material prepared by Company to support its adverse decision;
 - (v) What individuals within the Company will review the appeal and have the final authority to make a decision and a statement of that person or committee's qualifications to make credentialing decisions;
 - (vi) The deadline by which Company must make a final decision following the appeal procedure and communicate the decision to the physician; and
 - (vii) Provisions for notice and corrective action prior to an adverse credentialing decision becoming final.

4.5 Authority. Medical Services Entity shall, and hereby does, represent and warrant that it has full legal power and authority to bind its Qualified Physicians to the provisions hereof.

Physician groups/networks entering into this agreement on behalf of their physician members must have this authorization from their individual physicians under a physician agreement or employment agreement. Section 4.5 states that the authorization has been obtained. Without that authorization, the physician group/network can neither contract with a MCO nor make this representation.

4.6 Administrative Procedures. Medical Services Entity and each of its Qualified Physicians will comply with the policies and procedures established by Company or any of its Plans to the extent Medical Services Entity has received notice of same consistent with the terms of this Agreement. At the effective date hereof, the policies, rules, and procedures applicable to Medical Services Entity are contained in those manuals and other writings attached hereto on Exhibit D and incorporated by this reference. Medical Services Entity shall rely on these policies and procedures as the sole material policies and procedures of Company or its various Payors until such time as Medical Services Entity receives a Company Notice or is notified otherwise consistent with this Agreement. Neither Company nor a Payor may modify these policies and procedures in a manner that would have a material adverse effect on Medical Services Entity without Medical Services Entity's prior written consent.

Many managed care contracts allow MCOs to change their administrative policies unilaterally at any time and do not require clear communication to physicians of these policies. Section 4.6 requires reasonable written notice of policy changes and recognizes that each MCO will have certain policies and procedures on minor administrative matters that should be followed by each physician or physician group/network. All policies must be attached to the contract. Where assurances can be made that they will not be altered, they can be provided at an electronic site. In either event, the policies cannot be changed until the MCO sends a "Company Notice" pursuant to Section 5.2 thirty (30) days in advance of the policy's implementation. Most importantly, this provision prohibits the MCO or any Payor from modifying the policies and procedures in a way that would have a material adverse effect on the contract, without physician or physician group/network's written consent.

4.7 Assistance in Grievance Procedure. Medical Services Entity agrees to have each of its Qualified Physicians keep available for Enrollees explanations of the grievance procedures and grievance encounter forms relating to Plan, which shall be supplied by Company. Medical Services Entity further agrees that it and its Qualified Physicians will abide by Company's and or Plan's process for resolving Enrollee grievances, which procedures are a part of Exhibit C, consistent with this Agreement. Medical Services Entity also agrees to require each of its Qualified Physicians to participate in helping resolve the grievances described in Section 5.6 hereof.

4.8 Use of Names for Marketing. Medical Services Entity and each of its Qualified Physicians shall permit Company to include the name, address, and telephone number of it or its Qualified Physicians in its list of Medical Services Entities distributed to Enrollees; provided, however, that such rights shall not extend to the listing of such Qualified Physicians or Medical Services Entity in any newspaper, radio, or television advertising without the prior written consent of Medical Services Entity.

4.9 Provision of Covered Services. In the event Exhibit B contemplates the provision of the full range of full medical services that may be offered by a medical group on a capitated basis to a defined population of patients, Medical Services Entity agrees to provide or arrange for the provision of Covered Services on a 24 hour per day, 7 day per week, 365 day per year basis.

4.10 Noninterference with Medical Care. Nothing in this Agreement is intended to create (nor shall be construed or deemed to create) any right of Company or any Payor to intervene in any manner in the methods or means by which Medical Services Entity and its Qualified Physicians render health care services or provide health care supplies to Enrollees. Nothing herein shall be construed to require Medical Services Entity or Qualified Physicians to take any action inconsistent with professional judgment concerning the medical care and treatment to be rendered to Enrollees.

Section 4.10 clearly establishes the physician's independent role in treating the patient. While other managed care contracts often include such a provision, it can be seriously diluted by an approach to "medical necessity" which allows the MCO to override the physician's decisionmaking while avoiding any legal responsibility. In contrast, the definition of "medical necessity" in this model contract gives Section 4.10 force.

V. Company's Obligations

Article V sets forth a number of obligations that normally are, or should be, part of the obligations of the MCO. In some agreements these provisions are absent altogether. In others they are set forth in a way that either makes the obligations meaningless or subject to the MCO's sole interpretation.

5.1 List of Payors. Company shall include as part of Exhibit C a list of each Payor and shall promptly update Exhibit C upon the addition or deletion of Payors. The parties acknowledge that the intent of Sections 1.11, 3.1, and this Section 5.1 is to provide a mechanism for assuring that "networks," "silent PPOs," and similar arrangements between entities similar to Company and Payors do not accede to this Agreement or avail themselves of the discounts and arrangements established by the Parties through this Agreement.

Section 5.1, read in concert with Section 1.11, prevents MCOs from "renting" their physician networks to third parties who are not party to this agreement. It is designed to prevent the practice of "silent PPOs."

5.2 Deemed Notification. Company shall notify Medical Services Entity in writing of all policies, procedures, rules, regulations, schedules, in addition to those attached as Exhibit C, that Company considers material to the performance of this Agreement, as well as any amendments thereto. Medical Services Entity shall be deemed notified of such policies, procedures, rules, or regulations, or any amendment thereto, or any Company Notice ninety (90) days after receipt of written notice of same is delivered to Medical Services Entity consistent with the notice provisions of this Agreement. Neither Company nor a Payor may modify its policies and procedures in a manner that would have a material adverse effect on Medical Services Entity without Medical Services Entity's prior written consent.

The "deemed notification" provision in Section 5.2 sets forth a rational approach to the policy changes a MCO may make from time-to-time by requiring the MCO to provide the physician or physician group/network with written notice of changes in policies at least ninety (90) days in advance of the change. This requirement prohibits the MCO from making changes to policies or procedures that would have a material effect on the physician or physician group/network without its prior consent.

5.3 Adverse UR/QM Decisions. Notwithstanding anything to the contrary contained in the policies, procedures, rules, or regulations of Company, Company shall grant Medical Services Entity or Qualified Physician a right and a mechanism to appeal any Utilization Review or Quality Management decision made by Company on behalf of a Payor. Such appeal shall be coordinated with any related appeal by the Enrollee filed at or prior to the time of the Medical Services Entity appeal. The appeal procedure shall be as follows:

Section 5.3 is designed to link existing MCO procedures with due process protections. Adverse decisions on medical utilization review or medical quality matters are subject to a due process review that is ultimately decided by independent peers, rather than by the MCO in its sole discretion. The utilization review and quality management procedures in this agreement closely resemble the peer review process traditionally found in hospital medical staff rules and are supported by AMA policy. These procedures can be complex and vary widely from plan-to-plan. They also must be consistent with the laws of the states in which services are provided. For an in-depth discussion of Kentucky state law requirements for utilization review, including independent external review, see the "Utilization Review" section of this book.

5.4 Administration. With respect to each Plan it offers or administers, Company shall promptly and diligently perform

all necessary administrative, accounting, enrollment, and other functions including, but not limited to, eligibility determination, claims review, data collection and evaluation and, if applicable, maintenance of medical, ancillary, and hospital group risk pools.

5.4(a) With respect to each Plan, Company shall issue a Company Notice to Medical Services Entity identifying the manner in which rules, regulations, or policies relating to a particular Plan are at variance with the general rules, regulations, or policies of the Company upon which Medical Services Entity generally relies.

5.4(b) In the credentialing of Qualified Physicians, Company agrees that neither it nor its agents to whom such duties have been delegated shall request that Qualified Physicians sign an information release broader than necessary to obtain the specific credentialing information sought, and Company shall limit such request to that which is reasonable and necessary to achieving valid credentialing purposes.

Section 5.4 provides general, minimum administrative requirements. Depending on the needs of the physician or physician group/network, or its concerns about the MCO, this list could be significantly expanded. The administrative requirements in Section 5.4 go to the heart of what a MCO is in business to provide.

5.5 Payment by Parties other than Company. In the event Company contemplates that payment for services provided hereunder is to be made by a Payor other than Company, and in the event that such payment is not received by Medical Services Entity within the time and under the conditions set forth in Section 3.5, Company, within five (5) days of the receipt of written notice from Medical Services Entity, shall make a written demand to Payor on behalf of such Medical Services Entity for payment.

Section 5.5 protects the physician or physician group/network no matter who is obligated to pay. Many managed care contracts do not require the MCO to make payment. Instead, they require the payor, (who may be, for example, an employer under an employer-funded plan) to make such payment. While this is virtually unavoidable in the managed care arrangement, it presents a significant problem for physicians. Because there may be no direct relationship between the physician and the party who has the obligation to pay, the physician does not have a direct remedy in the event the payor does not make payment. This provision is a businesslike approach to granting physicians or physician groups/networks the right to pursue the appropriate party, if necessary, in court.

5.5(a) In the event a Payor fails to make payment within sixty (60) days after receipt of such notice, Company shall either: (i) make such payment on behalf of the Payor; (ii) initiate legal action to recover such payment on behalf of Medical Services Entity; or (iii) assign the right to initiate such action to Medical Services Entity.

5.5(b) In the event of an occurrence described in Section 5.5(a)(ii) or (iii) of this Section, Company shall tender to Medical Services Entity a copy of the agreement that governs the relationship between Company and Payor and upon which Medical Services Entity may rely in prosecuting such action and shall release Medical Services Entity, at Medical Services Entity's option, from any further obligation under this Agreement to provide services to Enrollees of Payor.

5.5(c) Company shall notify Payor of the provisions hereof and obligate Payor with respect to such provisions.

5.6 Physician Grievances. Company shall establish and maintain systems to process and resolve a grievance by a Qualified Physician toward Company or a Payor. Such process shall be set forth in the procedures which are a part of Exhibit C and any Company Notice amending such process. In connection with such grievances, to the extent that confidential patient information is discussed or made part of the record, or confidential patient records are submitted to Company, Company shall either abstract such information or shall remove the name of the patient such that none of the information or records would allow a third party to identify the patient involved. Notwithstanding anything in Company's policies, procedures, or rules to the contrary, the internal procedure for resolving such grievance will be conclusively presumed concluded in the event such grievance is not resolved to the parties' satisfaction within forty-five (45) days of the submission of such grievance and will allow either party resort to the dispute remedies of Article IX.

The type of grievance system outlined in Section 5.6 is supported by AMA policy and should be an integral part of the managed care relationship. Each MCO should maintain a system to process and resolve grievances brought by both physicians and patients. This provision protects patients by limiting the use of patient record information and protects physicians by providing a clear point in time when the MCO's internal grievance procedures have been exhausted and the matter may be resolved by arbitration. Many managed care grievance procedures allow the MCO to delay resolving grievances, preventing physicians from taking up the matter in another forum.

5.7 Benefit Information. Company shall advise and counsel its Enrollees and Medical Services Entity on the type, scope, and duration of benefits and services to which Enrollees are entitled pursuant to the applicable agreement between Company or a Payor and Enrollees.

Section 5.7 places the responsibility to inform Enrollees of their benefits where it belongs: on the MCO. Often, the physician and his or her office staff are left to explain the details of MCO to patients. This provision makes such explanations the clear duty of the MCO.

5.8 Cooperation on Care Review and Management. In the event that Medical Services Entity is responsible for utilization review and quality management activities, Company shall assist and cooperate with Medical Services Entity in the development and initial implementation of such activities that are necessary to carry out the terms of this Agreement. In the event that utilization review and quality management activities are the sole responsibility of Company, Company shall fully advise Medical Services Entity of the methods used and underlying information relied on to develop, implement, and manage or monitor utilization and quality on an ongoing basis, and shall develop a mechanism to allow Qualified Physicians to participate in the development of utilization review and quality management ongoing assessment and evaluation.

Many MCOs do not provide any mechanism for practicing physician input into utilization review and quality management programs, nor do they provide for adequate communications of these policies. Section 5.8 requires the MCO to actively assist or fully advise physicians on the “management” portion of managed care and most importantly, requires practicing physician input into the process.

5.9 Context of Company/Payor Obligations. To the extent Company is also a Payor under this Agreement, it shall perform and satisfy all duties and obligations of the Payor under this Agreement. To the extent Company is not a Payor under this Agreement, this agreement shall be construed to require Company to use its best efforts to cause the Payor to perform and satisfy the Payor’s duties and obligations under this Agreement.

5.10 Provision of Financial Information. Company shall provide to Medical Services Entity, no less frequently than quarterly, a balance sheet and income statement (collectively, “Financial Statements”) accurately depicting the financial condition of Company. Such Financial Statements shall be prepared in accordance with generally accepted accounting principles and shall be provided on an audited basis to the extent available. Medical Services Entity acknowledges the confidentiality of such Financial Statements and shall not: (a) use such Financial Statements for any purpose other than evaluating the financial condition of Company; or (b) disclose the Financial Statements, or any non-public information contained therein, to any third party, other than Medical Services Entity’s attorneys or accountants, without the prior written consent of Company. The obligations of Medical Services Entity under the immediately preceding sentence shall survive termination of this Agreement.

Section 5.10 is important for protecting physicians and physician groups/networks from financially troubled MCOs by granting physicians and physician groups the right to review the MCO’s quarterly balance sheet and income statement. Physicians also might consider including an additional requirement that the MCO notify the physician or physician group/network when the Payor is unable to pay its debts as they come due or when it does not have capital sufficient to carry on its business. As noted in Section 3.9, there is suspicion that one reason some MCOs pay claims slowly or reject an excessive number of claims as not being “clean” is to improve their financial reporting when they are short on capital — a clear sign of financial instability. Physicians need to be alert to this possibility. Taken together with Section 8.5, Section 5.10 gives the physician the greatest protection possible, short of prepayment for services, in the event of a MCO’s financial failure.

VI. Records and Confidentiality

6.1 Confidential Medical Records. All medical records of Enrollees shall be maintained as confidential in accordance with applicable state and federal laws. All medical records shall belong to Medical Services Entity’s Qualified Physicians consistent with the dictates of medical ethics. The release, disclosure, removal, or transfer of such records shall be governed by state and federal law and by the Medical Services Entity’s established policies and procedures. Prior to the release of copies of any medical records to Company or other third parties, Company shall obtain from the subject Enrollee (or the Enrollee’s legal representative) and present to Medical Services Entity an effective written consent or release that satisfies ethical constraints and applicable laws and is narrowly tailored to accomplish the sole purpose of such release, which the parties agree is to determine whether care was properly and efficiently rendered. The cost associated with copying medical records or any other records referred to in this Article VI shall be paid by Company. In handling all medical records, Company agrees to comply with all applicable state and federal laws and with any requirements or limitations described in the written consent or release. Company agrees it shall not release such information to other parties without written consent of the Enrollee and shall share such information internally only with the narrowest circle of Company’s agents necessary to effectuate the specific purpose for which the MCO seeks the information. Company shall counsel such agents on their obligations to ensure such information remains confidential.

6.2 Records. All data and information obtained, created, or collected by Medical Services Entity relating to services provided to Enrollees that is not a part of the medical record shall be freely shared by Medical Services Entity with Company. Such information may be obtained by Company upon written request to Medical Services Entity without a requirement for obtaining the written release by Enrollee.

6.3 Access to Records. During normal business hours, each party shall have access to and the right to examine records of the other which relate to a Covered Services or payment provided for a Covered Service. However, any review of the medical record must be narrowly tailored to the specific purpose for which the Company seeks the information. Upon written request of Company or Medical Services Entity, such access shall be extended beyond normal business hours with respect to any records which are identified in such written request as the actual or potential subject of an

investigation or litigation.

Sections 6.1 - 6.3 are designed to protect medical information from unauthorized use or disclosure. Many managed care agreements make little distinction between non-confidential information and confidential medical records that are part of the patient-physician relationship; they simply grant the MCO unlimited access to all records. To the extent that they recognize patient confidentiality at all, many managed care agreements place the responsibility to obtain patient consent or releases on the physician or physician group/network. This provision acknowledges the patient's expectation of confidentiality. When medical records are relevant, the MCO, not the physician, must obtain a consent from the patient that is narrowly tailored to accomplish the MCO's purposes. The MCO also must counsel its employees to keep medical information confidential. These concepts are increasingly important in an age of electronic medical records.

6.4 Other Confidential Information. Generally, the parties agree that the sole items of information subject to confidentiality under this Agreement are: (i) medical information relating to individual Enrollees, so as to protect the patient's medical record as required by medical ethics and law; and (ii) the precise schedule of compensation to be paid to Medical Services Entity pursuant to Exhibit B. Otherwise, all other information, including the general manner by which Medical Services Entity is paid under this Agreement and the general terms and conditions of this Agreement, may be shared with non-parties in the reasonable and prudent judgment of the Parties to this Agreement or Qualified Physicians. In addition, the Parties agree that:

Section 6.4 protects patient-physician communication, and clarifies that, except for a limited number of matters that are proprietary to both the MCO and physician or physician group/network, there are no inhibitions on free communication between the physician and the patient or any other parties. While some plans have eliminated so-called "gag clauses" from their contracts and a number of states have outlawed them, the AMA has found that some MCOs continue to find ways to constrain patient-physician communication through the contract. Section 6.4 eliminates this possibility.

6.4(a) Any financial or utilization information provided by Medical Services Entity to Company or a Payor (including the Compensation schedule(s) set forth in Exhibit B) shall be maintained in strict confidence by Company and each Payor and may not be disclosed by Company or Payor to any third party or used by Payor for any purpose, other than: (i) to satisfy mandatory governmental or regulatory reporting requirements; (ii) to compare cost, quality, and service among providers with whom Company has contracted; (iii) for premium setting purposes; (iv) for HEDIS reporting; or (v) to perform any of Company's obligations under this Agreement.

6.4(b) Notwithstanding the foregoing, Company shall be permitted to prepare and disclose to a third party a report of "Medical Services Entity Quality Data." For purposes of this subsection, Medical Services Entity Quality Data shall be limited to: (i) utilization data of all contracted Medical Services Entities in the aggregate; (ii) HEDIS data production and performance evaluation; (iii) Enrollee satisfaction data; (iv) overall compliance with NCQA or other comparable quality standards; and (v) Payor disenrollment data; provided, however, that Medical Services Entity Quality Data shall not include any information that identifies an individual Enrollee or an individual Qualified Physician or information that is privileged or confidential under applicable peer review or patient confidentiality laws.

6.4(c) At least thirty (30) days prior to providing Medical Services Entity Quality Data to a third party, the third party shall provide such Medical Services Entity Quality Data to Medical Services Entity so that Medical Services Entity may confirm the accuracy, completeness, or validity of the data and prepare a written response to such data to the extent Medical Services Entity deems appropriate.

6.4(d) To the extent Medical Services Entity believes that all or any portion of the Medical Services Entity Quality Data is inaccurate or incomplete, Medical Services Entity and Company shall negotiate in good faith to correct such inaccuracies or to make such data complete prior to its submission to the third party. If such inaccuracies or deficiencies are not corrected to the satisfaction of Medical Services Entity, Company shall submit, at the time the Medical Services Entity Quality Data is provided to the third party, any written response to such Medical Services Entity Quality Data prepared by Medical Services Entity.

VII. Insurance

7.1 Medical Services Entity Insurance. Medical Services Entity shall require each Qualified Physician to maintain, at all times, in limits and amounts standard in the community, a professional liability insurance policy and other insurance as shall be necessary to insure such Qualified Physician against any claim for damages arising directly or indirectly in connection with the performance or non-performance of any services furnished to Enrollees by such Qualified Physician. In the event that Medical Services Entity discovers that such insurance coverage is not maintained, Medical Services Entity shall immediately upon making such discovery ensure that such Qualified Physician discontinues the delivery of Covered Services to Enrollees until such insurance is obtained. Evidence of such coverage shall be tendered to Company by Medical Services Entity upon Company's request.

VIII. Term and Termination

Article VIII avoids the yearly “renewal” approach in favor of a defined beginning and ending date based on an event (eg notice of termination). However, certain terms and provisions may be renegotiated at the initiative of either party on an annual basis (see Section 8.2). State law should be consulted to assure that a failure to state a term of years does not convert the agreement to be one terminable at-will.

8.1 Term. This Agreement shall commence on the Effective Date and extend until terminated pursuant to this Article VIII.

8.2 Negotiation of Renewal of Exhibits A and B. Not later than ninety (90) days prior to each anniversary of the Effective Date hereof, a Party wishing to revise Exhibits A or B or any of the schedules affixed thereto shall serve notice in writing of such intention to the other Party, along with the new terms proposed. Within sixty (60) days thereafter, the Parties shall agree to a new Exhibit A and Exhibit B. In the event the Parties are unable to come to such agreement, either Party may notify the other within ten (10) days following the deadline for such agreement that it intends to terminate the Agreement entirely or with respect to one or more specific Plans reflected on a schedule. In such event, this Agreement (in the case of termination of all Plans) or the Agreement with respect to a particular Plan or Plans, shall be terminated sixty (60) days after such notice.

Section 8.2 furthers two purposes. First, it allows either party to renegotiate the business terms of the contract (Exhibits A and B) annually, provided that the party gives notice 90 days before the anniversary. Second, it also allows physician or physician group/network to drop a single product or plan without terminating every product subject to the agreement by providing an administratively convenient method for the physician or group/network to end participation in one product while continuing the legal relationship on other products uninterrupted. Even when an agreement does not overtly require the physician to service “all products,” most managed care contracts effectively do just that by requiring the physician or physician group/network that wishes to discontinue only certain plans or products to terminate the entire contract and re-enter a new contract that excludes the product rejected.

8.3 Termination for Cause. In the event either Party shall fail to keep, observe, or perform any covenant, term, or provision of this Agreement applicable to such Party, the other Party shall give the defaulting party notice that specifies the nature of such default. If the defaulting Party shall have failed to cure such default within thirty (30) days after the giving of such notice, the non-defaulting Party may terminate this Agreement upon five (5) days notice; provided, however, that it shall be grounds for immediate termination if Company should lose its license to underwrite or administer Plans; or if any Qualified Physician suffers a loss or suspension of medical license, a final unappealable loss of hospital medical staff privileges for reasons that would require reporting to the National Practitioner Data Bank pursuant to the requirements of the Health Care Quality Improvement Act of 1986, a conviction of a felony, or a loss of credentials for stated quality reasons under a Plan, and upon notice to Medical Services Entity, Medical Services Entity fails to immediately terminate such Qualified Physician from the provision of services to Enrollees.

8.4 Voluntary Termination. Either Party may terminate this Agreement or Medical Services Entity participation in any Plan with or without cause upon one hundred twenty (120) days written notice to the other Party specifying whether the termination relates to a specific Plan or to the Agreement generally. The terminating Party shall state the reason for such termination. In the event of a voluntary termination hereunder, neither party shall be foreclosed from participation in the dispute resolution procedures described in Article IX.

Section 8.4 protects the integrity of the termination process for both parties. Many managed care agreements provide the illusion of running for a full year prior to renewal, when in fact, the termination clauses allow the company to terminate the agreement upon ninety (90) days notice. The AMA Model Managed Care Contract rejects that approach. Instead, it separates all terms unrelated to the definition of covered services and the fee schedules from other legal terms. The legal terms are binding throughout the relationship of the parties. The list of covered services and fee schedules for each plan or product, as set forth in Exhibits A and B, are to be renegotiated annually and renewed or rejected individually. However, under Section 8.3, either party may terminate the entire contract on thirty (30) days notice or less upon the occurrence of a default or breach under the contract. Otherwise, Section 8.4 provides that either party must give one hundred twenty (120) days notice of termination. Most importantly, a party that wishes to terminate the agreement must state in writing the reason for the termination. Often, physicians are the subject of unfair discrimination when a MCO terminates a contract even though the initial termination may have been strictly for business or administrative reasons. Requiring the terminating party to state reasons for termination may provide the physician with increased ability to obtain and maintain relationships with other companies. The requirement of a written reason for termination also provides some protection for a physician who suspects that the termination is premised on violation of the MCO’s informal “gag” policy or other illegal reasons. Finally, this provision allows the physician or MCO to ensure that terminations are not based on mistakes of fact. The dispute resolution procedures of mediation and arbitration in Article IX are available to either party in the event of termination.

8.5 Termination for Failure to Satisfy Financial Obligations. This Agreement may be terminated in its entirety or with respect to a Payor by either party upon five (5) days written notice if either party, or in the case of termination by Medical Services Entity, a Payor is: (a) more than sixty (60) days behind its financial obligations to its creditors; (b) is declared insolvent; or (c) files in any court of competent jurisdiction: (i) a petition in bankruptcy; (ii) a petition for protection against creditors; or (iii) an assignment in favor of creditors or has such a petition filed against it that is not discharged within ninety (90) days.

8.6 Effect of Termination. This Agreement shall remain in full force and effect during the period between the date that notice of termination is given and the effective date of such termination. As of the date of termination of this Agreement, and except as provided by Section 10.14, this Agreement shall be of no further force and effect, and each of the Parties shall be discharged from all rights, duties, and obligations under this Agreement, except that Company shall remain liable for Covered Services then being rendered by Qualified Physicians to Enrollees who retain eligibility under the applicable Plan or by operation of law until the episode of illness then being treated is completed and the obligation of Company to pay for Covered Services rendered pursuant to this Agreement is discharged. Payment for such services shall be made pursuant to the fee schedule contained on Exhibit B or, if Exhibit B does not contain a fee schedule, at the usual and customary charge of the Qualified Physician performing the service.

IX. Dispute Resolution

Article IX requires mediation and binding arbitration unless one party has already filed a lawsuit. Many MCOs rely on the twin strategies of disenfranchising physicians from legal rights in the text of the agreement, and if the matter is taken to a court of law, relying on the likelihood that the physician will have insufficient resources to pursue a lawsuit against the MCO. When done properly, alternative dispute resolution can level the legal playing field. Mediation is the first step in the alternative dispute resolution process and often helps two parties with a misunderstanding to settle their differences. Under Article IX, when mediation is unsuccessful (and presuming one party has not first filed suit), the parties can move to arbitration, which involves an expedited trial-like proceeding. At the end of the arbitration process, the parties reach a final, legal, and binding resolution in much less time and at much less expense than otherwise would be associated with a lawsuit. These dispute resolution procedures may greatly enhance both sides' attention to the nature of their relationship and need to settle differences fairly, impartially, and quickly.

9.1 Initial Mediation of Dispute. In the event of a dispute regarding this Agreement between the Parties to this Agreement, the following procedure shall be used to resolve the dispute prior to either party pursuing other remedies:

9.1(a) A meeting shall be held within seven (7) days of receipt by one Party of the disputing Party's written notice. All Parties shall be present or represented by individuals with full decision making authority regarding the matters in dispute (the "Initial Meeting").

9.1(b) If, within thirty (30) days following the Initial Meeting, the Parties have not resolved the dispute, the dispute shall be submitted to mediation directed by a mediator mutually agreeable to the Parties and not regularly contracted or employed by either of the Parties ("Mediation"). Each Party shall bear its proportionate share of the costs of Mediation, including the mediator's fee.

9.1(c) The Parties agree to negotiate in good faith in the Initial Meeting and in Mediation.

9.1(d) If, after a period of sixty (60) days following commencement of Mediation, the Parties are unable to resolve the dispute, either Party may submit the dispute to binding arbitration in accordance with Section 9.2 upon ten (10) days prior written notice to the other Party.

9.2 Binding Arbitration. Unless one Party has previously filed suit in a court of competent jurisdiction regarding the same subject matter, either Party may submit any dispute arising out of this Agreement that is not resolved through Mediation to final and binding arbitration. Any such arbitration shall be held in the state where the services at issue in the dispute were or are to be performed and shall be conducted pursuant to either the rules of the American Arbitration Association or the American Health Lawyers Association Alternative Dispute Resolution Project. Each Party shall be responsible for its own costs and expenses related to the arbitration, including attorneys' fees, and shall bear its proportionate share of the arbitrator's fees. The arbitrator shall be selected on the mutual agreement of both Parties and shall be an attorney and member of the National Academy of Arbitrators or the American Health Lawyers Association.

X. Additional Provisions as Required by State Law

Kentucky state law requires the following language to be included in a medical services or "provider" agreement.

10.1 Hold Harmless. Physician may not, under any circumstance, including (1) nonpayment of moneys due the providers by the managed care plan; (2) insolvency of the managed care plan; or (3) breach of the agreement, bill, charge, collect a deposit, seek compensation, remuneration, or reimbursement from, or have any recourse against the subscriber, dependent of subscriber, enrollee, or any persons acting on their behalf, for services provided in accordance with the provider agreement. This provision shall not prohibit collection of deductible amounts, copayment amounts, coinsurance amounts, and amounts for noncovered services.

10.2 Continuity of Care. If this agreement is terminated for any reason, other than a quality of care issue or fraud, the provider shall continue to provide services and reimburse the provider in accordance with the agreement until the subscriber, dependent of the subscriber, or the enrollee is discharged from an inpatient facility, or the active course of treatment is completed, whichever time is greater, and in the case of a pregnant woman, services shall continue

to be provided through the end of the post-partum period if the pregnant woman is in her fourth or later month of pregnancy.

10.3 Survivorship. The hold harmless clause and continuity of care clause shall survive the termination of this agreement.

10.4 Subcontracts. If a provider enters into any subcontract agreement with another provider to provide health care services to the subscriber, dependent of the subscriber, or enrollee of a managed care plan the subcontract agreement must meet all requirements of Kentucky state law and that all such subcontract agreements shall be filed with the insurance commissioner in accordance with the law.

XI. Miscellaneous

11.1 Nature of Medical Services Entity. In the performance of the work, duties, and obligations of Medical Services Entity under this Agreement, it is mutually understood and agreed that Medical Services Entity and each of its Qualified Physicians are at all times acting and performing as independent contractors, practicing medicine, or providing for the delivery of medical services.

11.2 Additional Assurances. The provisions of this Agreement shall be self-operative and shall require no further agreement by the Parties except as may be specifically provided in this Agreement. However, at the request of either Party, the other Party shall execute such additional instruments and take such additional acts as may be reasonably requested in order to effectuate this Agreement.

11.3 Governing Law. This Agreement shall be governed by and construed in accordance with the applicable federal laws and regulations and the laws of the state in which the subject services are primarily performed by or through Medical Services Entity.

11.4 Assignment. This Agreement shall inure to the benefit of and be binding upon the Parties hereto and their respective legal representatives, successors, and assigns. Company may not assign this Agreement without Medical Services Entity's prior written consent, except that Company may assign this Agreement to an entity related to Company by ownership or control or to any successor organization without Medical Services Entity's prior written consent. Medical Services Entity may not assign this Agreement without Company's prior written consent, except that Medical Services Entity may assign this Agreement to an entity related to Medical Services Entity by ownership or control or to any successor organization without Company's prior written consent.

The assignment provision in 11.4 is mutual, unlike many managed care contracts, which limit the right of assignment to the MCO. Section 11.4 allows the assignment of the contract only to closely connected entities without requiring the consent of the other party. The automatic assignment will assist the parties administratively in the event of a change in ownership or control.

11.5 Waiver. No waiver by either Party of any breach or violation of any provision of this Agreement shall operate as, or be construed to be, a waiver of any subsequent breach of the same or any other provisions.

11.6 Force Majeure. Neither Party shall be liable for nor deemed to be in default for any delay or failure to perform under this Agreement deemed to result, directly or indirectly, from acts of God, civil or military authority, acts of public enemy, war, accidents, fires, explosions, earthquake, flood, failure of transportation, strikes or other work interruptions by either Party's employees, or any other cause beyond the reasonable control of either party.

11.7 Time is of the Essence. Time is of the essence in this Agreement. The Parties shall perform their obligations within the time specified.

11.8 Notices. Any notice, demand, or communication required, permitted, or desired to be given hereunder shall be deemed effectively given when personally delivered or sent by fax with a copy sent by overnight courier, addressed as follows:

If to Company:

If to Medical Services Entity:

or to such other address, and to the attention of such other person or officer as either Party may designate in writing.

11.9 Severability. In the event any portion of this Agreement is found to be void, illegal, or unenforceable, the validity or enforceability of any other portion shall not be affected.

11.10 Third-Party Rights. This Agreement is entered into by and between the Parties hereto and for their benefit. There is no intent by either Party to create or establish a third-party beneficiary status or rights in a third party to this Agreement, except for Enrollees or as such rights are expressly created and as set forth in this Agreement. Except for such parties, no such third party shall have any right to enforce or any right to enjoy any benefit created or established under this Agreement.

Unlike virtually every managed care agreement, this contract recognizes that the patient may have a legally recognizable right to benefit from the relationship between the physician and the MCO entity.

11.11 Entire Agreement. This Agreement supersedes any prior agreements, promises, negotiation, or representations, either oral or written, relating to the subject matter of this Agreement.

11.12 Notification of Legal Matters. If any action is instituted against either Party relating to this Agreement or any services provided hereunder, or in the event such Party becomes aware of facts or circumstances which indicate a reasonable possibility of litigation with any Payor utilizing Medical Services Entity, any Enrollee, or any other third person or entity, relevant to the rights, obligations, responsibilities, or duties of the other Party under this Agreement, such Party shall provide timely notice to the other, and the other Party shall cooperate with the first Party in connection with the defense of any such action by furnishing such material or information as is in the possession and control of the other Party relevant to such action.

11.13 Amendment. This Agreement may not be modified without the express written approval of both parties.

Many managed care contracts allow the MCO to unilaterally amend most of the terms and provisions at any point during the life of the contract. Section 11.13 ensures that neither side can amend the agreement without authorization.

11.14 Survival. Notwithstanding any provisions contained herein to the contrary, the obligations of the Parties under Articles III, VI, and IX shall survive termination of this Agreement.

Even after the contract is terminated, this provision ensures that the compensation, confidentiality and dispute resolution provisions remain in effect.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in their names by the undersigned officers, the same being duly authorized to do so.

MEDICAL SERVICES ENTITIY

By: _____

Title: _____

COMPANY

By: _____

Title: _____

Exhibits that must be attached to AMA Managed Care Contract

**Exhibit A
Covered Services**

**Exhibit B
Fee Schedules/Capitation/Withhold Schedule**

**Exhibit C
Coding Standards and Requirements**

**Exhibit D
Credentialing Criteria and Process**

[\(Back\)](#)

Contracts – Noncompete Statute

Many contracts between physicians and entities that employ them contain a provision known as a “noncompete clause.” This provision provides that a physician who is employed by an entity may not, upon terminating his or her employment with the entity, practice in the geographic area serviced by the entity for a number of years. These provisions are designed to prevent physicians who are employed by an entity from building up a patient base, then simply quit and open up an office across the street from the entity.

Kentucky law used to provide that such provisions could not exceed one year in length. That law, however, has been repealed, so entities may now include such provisions in contracts for terms greater than one year. The only limitation on such a provision is a court-imposed limitation that the geographic area described, as well as the duration of the provision, must be “reasonable.”

Of course, physicians who employ other practitioners may also put such a provision in an employment agreement, limiting the employee from opening up a practice in the same location as the physician. The *Code of Medical Ethics*, however, discourages such agreements between physicians. Opinion 9.02 states: “The Council on Ethical and Judicial Affairs discourages any agreement between physicians which restricts the right of a physician to practice medicine for a specified period of time or in a specified area upon termination of employment or a partnership or a corporate agreement.” It is important to remember that the *Code of Medical Ethics* has been incorporated into Kentucky’s Medical Practice Act so physicians may be unable to enforce such a provision against other physicians. The Board of Medical Licensure has indicated it will review such matters on a case-by-case basis. ([Back](#))

Contracts – Required Filing

An insurer must file with the Department of Insurance sample copies of any agreements it enters into with medical providers [304.17A-527(1)]. An insurer that offers a health benefit plan that enters into any risk-sharing arrangement or subcontract agreement must file a copy of the arrangement with the Department of Insurance. The insurer must also file the following information regarding the risk-sharing arrangement:

1. The number of enrollees affected by the risk-sharing arrangement;
2. The health care services to be provided to an enrollee under the risk-sharing arrangement;
3. The nature of the financial risk to be shared between the insurer and entity or provider, including, but not limited to, the method of compensation;

4. Any administrative functions delegated by the insurer to the entity or provider; and
5. The insurer’s oversight and compliance plan regarding the standards and method of review [KRS 304.17A-527(2)].

Nothing requires an insurer to submit the actual financial information agreed to between the insurer and the entity or provider [KRS 304.17A-527(3)]. ([Back](#))

Contracts – Required Provisions

All agreements between providers and managed care plans must include the following provisions:

A hold harmless clause that states that the provider may not, under any circumstance, bill or have any recourse against the subscriber for services provided in accordance with the provider agreement.

A continuity of care clause that states that if an agreement between the provider and the managed care plan is terminated for any reason the provider must continue to provide services and the plan shall continue to reimburse the provider in accordance with the agreement until the patient is discharged from an inpatient facility, or the active course of treatment is completed. In the case of a pregnant woman, services must continue to be provided through the end of the post-partum period if the pregnant woman is in her fourth or later month of pregnancy at the time the agreement is terminated.

A survivorship clause that states the hold harmless clause and continuity of care clause survives the termination of the agreement between the provider and the managed care plan.

A clause stating that upon request the insurer will provide or make available to a participating provider, when contracting

or renewing an existing contract with such provider, the payment or fee schedules or other information sufficient to enable the provider to determine the manner and amount of payments under the contract for the provider's services prior to the final execution or renewal of the contract and shall provide any change in such schedules at least ninety (90) days prior to the effective date of amendment.

A clause requiring that if a provider enters into any subcontract agreement with another provider to provide their licensed health care services to the subscriber, dependent of the subscriber, or enrollee of a managed care plan where the subcontracted provider will bill the managed care plan or subscriber or enrollee directly for the subcontracted services, the subcontract agreement must meet all requirements of the law. All such subcontract agreements must be filed with the Department of Insurance [KRS 304.17A-527(1)]. [\(Back\)](#)

Corporate Compliance Plan

The following discussion is taken from a federal government publication entitled OIG Compliance Program for Individual and Small Group Physician Practices. The Medicare Office of Inspector General (OIG) drafted this model compliance plan to assist physicians in preventing the submission of erroneous claims or engaging in unlawful conduct involving federal health care programs. While the publication of this information has created controversy, most of it is reprinted here in order for physicians to read what the government advises. The OIG says the following about these guidelines:

"[T]he guidance emphasizes a step by step approach to follow in developing and implementing a voluntary compliance program. This...is in recognition of the financial and staffing resource constraints faced by physician practices. The guidance should not be viewed as mandatory or as an all-inclusive discussion of the advisable components of a compliance program. Rather, the document is intended to present guidance to assist physician practices that voluntarily choose to develop a compliance program.

I. Introduction

This compliance program guidance is intended to assist individual and small group physician practices ("physician practices") in developing a voluntary compliance program that promotes adherence to statutes and regulations applicable to the Federal health care programs ("Federal health care program requirements"). The goal of voluntary compliance programs is to provide a tool to strengthen the efforts of health care providers to prevent and reduce improper conduct. These programs can also benefit physician practices by helping to streamline business operations.

Many physicians have expressed an interest in better protecting their practices from the potential for erroneous or fraudulent conduct through the implementation of voluntary compliance programs. The Office of Inspector General (OIG) believes that the great majority of physicians are honest and share our goal of protecting the integrity of Medicare and other Federal health care programs. To that end, all health care providers have a duty to ensure that the claims submitted to Federal health care programs are true and accurate. The development of voluntary compliance programs and the active application of compliance principles in physician practices will go a long way toward achieving this goal.

Through this document, the OIG provides its views on the fundamental components of physician practice compliance programs, as well as the principles that a physician practice might consider when developing and implementing a voluntary compliance program. While this document presents basic procedural and structural guidance for designing a voluntary compliance program, it is not in and of itself a compliance program. Indeed, as recognized by the OIG and the health care industry, there is no "one size fits all" compliance program, especially for physician practices. Rather, it is a set of guidelines that physician practices can consider if they choose to develop and implement a compliance program.

As with the OIG's previous guidance, these guidelines are not mandatory. Nor do they represent an all-inclusive document containing all components of a compliance program. Other OIG outreach efforts, as well as other Federal agency efforts to promote compliance, can also be used in developing a compliance program. However, as explained later, if a physician practice adopts a voluntary and active compliance program, it may well lead to benefits for the physician practice.

A. Scope of the Voluntary Compliance Program Guidance

This guidance focuses on voluntary compliance measures related to claims submitted to the Federal health care programs. Issues related to private payor claims may also be covered by a compliance plan if the physician practice so desires.

The guidance is also limited in scope by focusing on the development of voluntary compliance programs for individual and small group physician practices. The difference between a small practice and a large practice cannot be determined by stating a particular number of physicians. Instead, our intent in narrowing the guidance to the small practices subset was to provide guidance to those physician practices whose financial or staffing resources would not allow them to implement a full scale, institutionally structured compliance program as set forth in the Third Party Medical Billing Guidance or other previously released OIG guidance. A

compliance program can be an important tool for physician practices of all sizes and does not have to be costly, resource-intensive or time-intensive.

B. Benefits of a Voluntary Compliance Program

The OIG acknowledges that patient care is, and should be, the first priority of a physician practice. However, a practice's focus on patient care can be enhanced by the adoption of a voluntary compliance program. For example, the increased accuracy of documentation that may result from a compliance program will actually assist in enhancing patient care. The OIG believes that physician practices can realize numerous other benefits by implementing a compliance program. A well-designed compliance program can:

- Speed and optimize proper payment of claims;
- Minimize billing mistakes;
- Reduce the chances that an audit will be conducted by HCFA or the OIG; and
- Avoid conflicts with the self-referral and anti-kickback statutes.

The incorporation of compliance measures into a physician practice should not be at the expense of patient care, but instead should augment the ability of the physician practice to provide quality patient care.

Voluntary compliance programs also provide benefits by not only helping to prevent erroneous or fraudulent claims, but also by showing that the physician practice is making additional good faith efforts to submit claims appropriately. Physicians should view compliance programs as analogous to practicing preventive medicine for their practice. Practices that embrace the active application of compliance principles in their practice culture and put efforts towards compliance on a continued basis can help to prevent problems from occurring in the future.

A compliance program also sends an important message to a physician practice's employees that while the practice recognizes that mistakes will occur, employees have an affirmative, ethical duty to come forward and report erroneous or fraudulent conduct, so that it may be corrected.

C. Application of Voluntary Compliance Program Guidance

The applicability of these recommendations will depend on the circumstances and resources of the particular physician practice.

Each physician practice can undertake reasonable steps to implement compliance measures, depending on the size and resources of that practice. Physician practices can rely, at least in part, upon standard protocols and current practice procedures to develop an appropriate compliance program for that practice. In fact, many physician practices already have established the framework of a compliance program without referring to it as such.

D. The Difference Between "Erroneous" and "Fraudulent" Claims To Federal Health Programs

There appear to be significant misunderstandings within the physician community regarding the critical differences between what the Government views as innocent "erroneous" claims on the one hand and "fraudulent" (intentionally or recklessly false) health care claims on the other. Some physicians feel that Federal law enforcement agencies have maligned medical professionals, in part, by a perceived focus on innocent billing errors. These physicians are under the impression that innocent billing errors can subject them to civil penalties, or even jail. These impressions are mistaken.

To address these concerns, the OIG would like to emphasize the following points. First, the OIG does not disparage physicians, other medical professionals or medical enterprises. In our view, the great majority of physicians are working ethically to render high quality medical care and to submit proper claims.

Second, under the law, physicians are not subject to criminal, civil or administrative penalties for innocent errors, or even negligence. The Government's primary enforcement tool, the civil False Claims Act, covers only offenses that are committed with actual knowledge of the falsity of the claim, reckless disregard, or deliberate ignorance of the falsity of the claim. The False Claims Act does not encompass mistakes, errors, or negligence. The Civil Monetary Penalties Law, an administrative remedy, similar in scope and effect to the False Claims Act, has exactly the same standard of proof. The OIG is very mindful of the difference between innocent errors ("erroneous claims") on one hand, and reckless or intentional conduct ("fraudulent claims") on the other. For criminal penalties, the standard is even higher—criminal intent to defraud must be proved beyond a reasonable doubt.

Third, even ethical physicians (and their staffs) make billing mistakes and errors through inadvertence or negligence. When physicians discover that their billing errors, honest mistakes, or negligence result in erroneous claims, the physician practice should return the funds erroneously claimed, but without penalties. In other words, absent a violation of a civil, criminal or administrative law, erroneous claims result only in the return of funds claimed in error.

Fourth, innocent billing errors are a significant drain on the Federal health care programs. All parties (physicians, providers, carriers, fiscal intermediaries, Government agencies, and beneficiaries) need to work cooperatively to reduce the overall error rate.

Finally, it is reasonable for physicians (and other providers) to ask: what duty do they owe the Federal health care programs? The answer is that all health care providers have a duty to reasonably ensure that the claims submitted to Medicare and other Federal health care programs are true and accurate. The OIG continues to engage the provider community in an extensive, good faith effort to work cooperatively on voluntary compliance to minimize errors and to prevent potential penalties for improper billings before they occur. We encourage all physicians and other providers to join in this effort.

II. Developing a Voluntary Compliance Program

A. The Seven Basic Components of a Voluntary Compliance Program

The OIG believes that a basic framework for any voluntary compliance program begins with a review of the seven basic components of an effective compliance program. A review of these components provides physician practices with an overview of the scope of a fully developed and implemented compliance program. The following list of components, as set forth in previous OIG compliance program guidances, can form the basis of a voluntary compliance program for a physician practice:

1. Conducting internal monitoring and auditing through the performance of periodic audits;
2. Implementing compliance and practice standards through the development of written standards and procedures;
3. Designating a compliance officer or contact(s) to monitor compliance efforts and enforce practice standards;
4. Conducting appropriate training and education on practice standards and procedures;
5. Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate Government entities;
6. Developing open lines of communication, such as (1) discussions at staff meetings regarding how to avoid erroneous or fraudulent conduct and (2) community bulletin boards, to keep practice employees updated regarding compliance activities; and
7. Enforcing disciplinary standards through well-publicized guidelines.

These seven components provide a solid basis upon which a physician practice can create a compliance program. The OIG acknowledges that full implementation of all components may not be feasible for all physician practices. Some physician practices may never fully implement all of the components. However, as a first step, physician practices can begin by adopting only those components which, based on a practice's specific history with billing problems and other compliance issues, are most likely to provide an identifiable benefit.

The extent of implementation will depend on the size and resources of the practice. Smaller physician practices may incorporate each of the components in a manner that best suits the practice. By contrast, larger physician practices often have the means to incorporate the components in a more systematic manner. For example, larger physician practices can use both this guidance and the Third-Party Medical Billing Compliance Program Guidance, which provides a more detailed compliance program structure, to create a compliance program unique to the practice.

The OIG recognizes that physician practices need to find the best way to achieve compliance for their given circumstances. Specifically, the OIG encourages physician practices to participate in other provider's compliance programs, such as the compliance programs of the hospitals or other settings in which the physicians practice. Physician Practice Management companies also may serve as a source of compliance program guidance. A physician practice's participation in such compliance programs could be a way, at least partly, to augment the practice's own compliance efforts.

The opportunities for collaborative compliance efforts could include participating in training and education programs or using another entity's policies and procedures as a template from which the physician practice creates its own version. The OIG encourages this type of collaborative effort, where the content is appropriate to the setting involved (i.e., the training is relevant to physician practices as well as the sponsoring provider), because it provides a means to promote the desired objective without imposing excessive burdens on the practice or requiring physicians to undertake duplicative action. However, to prevent possible anti-kickback or self-referral issues, the OIG recommends that physicians consider limiting their participation in a sponsoring provider's compliance program to the areas of training and education or policies and procedures.

The key to avoiding possible conflicts is to ensure that the entity providing compliance services to a physician practice (its referral source) is not perceived as nor is it operating the practice compliance program at no charge. For example, if the sponsoring entity conducted claims review for the physician practice as part of a compliance program or provided compliance oversight without charging the practice fair market value for those services, the anti-kickback and Stark self-referral laws would be implicated. The payment of fair market value by referral sources for compliance services will generally address these concerns.

B. Steps for Implementing a Voluntary Compliance Program

As previously discussed, implementing a voluntary compliance program can be a multi-tiered process. Initial development of the compliance program can be focused on practice risk areas that have been problematic for the practice such as coding and

billing. Within this area, the practice should examine its claims denial history or claims that have resulted in repeated overpayments, and identify and correct the most frequent sources of those denials or overpayments. A review of claim denials will help the practice scrutinize a significant risk area and improve its cash flow by submitting correct claims that will be paid the first time they are submitted. As this example illustrates, a compliance program for a physician practice often makes sound business sense.

The following is a suggested order of the steps a practice could take to begin the development of a compliance program. The steps outlined below articulate all seven components of a compliance program and there are numerous suggestions for implementation within each component. Physician practices should keep in mind, as stated earlier, that it is up to the practice to determine the manner in which and the extent to which the practice chooses to implement these voluntary measures.

Step One: Auditing and Monitoring

An ongoing evaluation process is important to a successful compliance program. This ongoing evaluation includes not only whether the physician practice's standards and procedures are in fact current and accurate, but also whether the compliance program is working, *i.e.*, whether individuals are properly carrying out their responsibilities and claims are submitted appropriately. Therefore, an audit is an excellent way for a physician practice to ascertain what, if any, problem areas exist and focus on the risk areas that are associated with those problems. There are two types of reviews that can be performed as part of this evaluation: (1) a standards and procedures review; and (2) a claims submission audit.

1. Standards and Procedures

It is recommended that an individual(s) in the physician practice be charged with the responsibility of periodically reviewing the practice's standards and procedures to determine if they are current and complete. If the standards and procedures are found to be ineffective or outdated, they should be updated to reflect changes in Government regulations or compendiums generally relied upon by physicians and insurers (*i.e.*, changes in Current Procedural Terminology (CPT) and ICD-9-CM codes).

2. Claims Submission Audit

In addition to the standards and procedures themselves, it is advisable that bills and medical records be reviewed for compliance with applicable coding, billing and documentation requirements. The individuals from the physician practice involved in these self-audits would ideally include the person in charge of billing (if the practice has such a person) and a medically trained person (*e.g.*, registered nurse or preferably a physician (physicians can rotate in this position)). Each physician practice needs to decide for itself whether to review claims retrospectively or concurrently with the claims submission. In the Third-Party Medical Billing Compliance Program Guidance, the OIG recommended that a baseline, or "snapshot," be used to enable a practice to judge over time its progress in reducing or eliminating potential areas of vulnerability. This practice, known as "benchmarking," allows a practice to chart its compliance efforts by showing a reduction or increase in the number of claims paid and denied.

The practice's self-audits can be used to determine whether:

- Bills are accurately coded and accurately reflect the services provided (as documented in the medical records);
- Documentation is being completed correctly;
- Services or items provided are reasonable and necessary; and
- Any incentives for unnecessary services exist.

A baseline audit examines the claim development and submission process, from patient intake through claim submission and payment, and identifies elements within this process that may contribute to non-compliance or that may need to be the focus for improving execution. This audit will establish a consistent methodology for selecting and examining records, and this methodology will then serve as a basis for future audits.

There are many ways to conduct a baseline audit. The OIG recommends that claims/services that were submitted and paid during the initial three months after implementation of the education and training program be examined, so as to give the physician practice a benchmark against which to measure future compliance effectiveness.

Following the baseline audit, a general recommendation is that periodic audits be conducted at least once each year to ensure that the compliance program is being followed. Optimally, a randomly selected number of medical records could be reviewed to ensure that the coding was performed accurately. Although there is no set formula to how many medical records should be reviewed, a basic guide is five or more medical records per Federal payor (*i.e.*, Medicare, Medicaid), or five to ten medical records per physician. The OIG realizes that physician practices receive reimbursement from a number of different payors, and we would encourage a physician practice's auditing/monitoring process to consist of a review of claims from all Federal payors from which the practice receives reimbursement. Of course, the larger the sample size, the larger the comfort level the physician practice will have about the results. However, the OIG is aware that this may be burdensome for some physician practices, so, at a minimum, we would encourage the physician practice to conduct a review of claims that have been reimbursed by Federal health care programs.

If problems are identified, the physician practice will need to determine whether a focused review should be conducted on a more frequent basis. When audit results reveal areas needing additional information or education of employees and physicians, the physician practice will need to analyze whether these areas should be incorporated into the training and educational system.

There are many ways to identify the claims/services from which to draw the random sample of claims to be audited. One methodology is to choose a random sample of claims/services from either all of the claims/services a physician has received reimbursement for or all claims/services from a particular payor. Another method is to identify risk areas or potential billing vulnerabilities. The codes associated with these risk areas may become the universe of claims/services from which to select the sample. The OIG recommends that the physician practice evaluate claims/services selected to determine if the codes billed and reimbursed were accurately ordered, performed, and reasonable and necessary for the treatment of the patient.

One of the most important components of a successful compliance audit protocol is an appropriate response when the physician practice identifies a problem. This action should be taken as soon as possible after the date the problem is identified. The specific action a physician practice takes should depend on the circumstances of the situation. In some cases, the response can be as straightforward as generating a repayment with appropriate explanation to Medicare or the appropriate payor from which the overpayment was received. In others, the physician practice may want to consult with a coding/billing expert to determine the next best course of action. There is no boilerplate solution to how to handle problems that are identified.

It is a good business practice to create a system to address how physician practices will respond to and report potential problems. In addition, preserving information relating to identification of the problem is as important as preserving information that tracks the physician practice's reaction to, and solution for, the issue.

Step Two: Establish Practice Standards and Procedures

After the internal audit identifies the practice's risk areas, the next step is to develop a method for dealing with those risk areas through the practice's standards and procedures. Written standards and procedures are a central component of any compliance program. Those standards and procedures help to reduce the prospect of erroneous claims and fraudulent activity by identifying risk areas for the practice and establishing tighter internal controls to counter those risks, while also helping to identify any aberrant billing practices. Many physician practices already have something similar to this called "practice standards" that include practice policy statements regarding patient care, personnel matters and practice standards and procedures on complying with Federal and State law.

The OIG believes that written standards and procedures can be helpful to all physician practices, regardless of size and capability. If a lack of resources to develop such standards and procedures is genuinely an issue, the OIG recommends that a physician practice focus first on those risk areas most likely to arise in its particular practice. Additionally, if the physician practice works with a physician practice management company (PPMC), independent practice association (IPA), physician-hospital organization, management services organization (MSO) or third-party billing company, the practice can incorporate the compliance standards and procedures of those entities, if appropriate, into its own standards and procedures. Many physician practices have found that the adoption of a third party's compliance standards and procedures, as appropriate, has many benefits and the result is a consistent set of standards and procedures for a community of physicians as well as having just one entity that can then monitor and refine the process as needed. This sharing of compliance responsibilities assists physician practices in rural areas that do not have the staff to perform these functions, but do belong to a group that does have the resources. Physician practices using another entity's compliance materials will need to tailor those materials to the physician practice where they will be applied.

Physician practices that do not have standards or procedures in place can develop them by: (1) Developing a written standards and procedures manual; and (2) updating clinical forms periodically to make sure they facilitate and encourage clear and complete documentation of patient care. A practice's standards could also identify the clinical protocol(s), pathway(s), and other treatment guidelines followed by the practice.

Creating a resource manual from publicly available information may be a cost-effective approach for developing additional standards and procedures. For example, the practice can develop a "binder" that contains the practice's written standards and procedures, relevant HCFA directives and carrier bulletins, and summaries of informative OIG documents (e.g., Special Fraud Alerts, Advisory Opinions, inspection and audit reports). If the practice chooses to adopt this idea, the binder should be updated as appropriate and located in a readily accessible location.

If updates to the standards and procedures are necessary, those updates should be communicated to employees to keep them informed regarding the practice's operations. New employees can be made aware of the standards and procedures when hired and can be trained on their contents as part of their orientation to the practice. The OIG recommends that the communication of updates and training of new employees occur as soon as possible after either the issuance of a new update or the hiring of a new employee.

1. Specific Risk Areas

The OIG recognizes that many physician practices may not have in place standards and procedures to prevent erroneous or fraudulent conduct in their practices. In order to develop standards and procedures, the physician practice may consider what types

of fraud and abuse related topics need to be addressed based on its specific needs. One of the most important things in making that determination is a listing of risk areas where the practice may be vulnerable.

To assist physician practices in performing this initial assessment, the OIG has developed a list of four potential risk areas affecting physician practices. These risk areas include: (a) Coding and billing; (b) reasonable and necessary services; (c) documentation; and (d) improper inducements, kickbacks and self-referrals. This list of risk areas is not exhaustive, or all-encompassing. Rather, it should be viewed as a starting point for an internal review of potential vulnerabilities within the physician practice. The objective of such an assessment is to ensure that key personnel in the physician practice are aware of these major risk areas and that steps are taken to minimize, to the extent possible, the types of problems identified. While there are many ways to accomplish this objective, clear written standards and procedures that are communicated to all employees are important to ensure the effectiveness of a compliance program. Specifically, the following are discussions of risk areas for physician practices:

- a. *Coding and Billing.* A major part of any physician practice's compliance program is the identification of risk areas associated with coding and billing. The following risk areas associated with billing have been among the most frequent subjects of investigations and audits by the OIG:
 - Billing for items or services not rendered or not provided as claimed;
 - Submitting claims for equipment, medical supplies and services that are not reasonable and necessary;
 - Double billing resulting in duplicate payment;
 - Billing for non-covered services as if covered;
 - Knowing misuse of provider identification numbers, which results in improper billing;
 - Unbundling (billing for each component of the service instead of billing or using an all-inclusive code);
 - Failure to properly use coding modifiers;
 - Clustering; and
 - Upcoding the level of service provided.

The physician practice written standards and procedures concerning proper coding reflect the current reimbursement principles set forth in applicable statutes, regulations and Federal, State or private payor health care program requirements and should be developed in tandem with coding and billing standards used in the physician practice. Furthermore, written standards and procedures should ensure that coding and billing are based on medical record documentation. Particular attention should be paid to issues of appropriate diagnosis codes and individual Medicare Part B claims (including documentation guidelines for evaluation and management services). A physician practice can also institute a policy that the coder and/or physician review all rejected claims pertaining to diagnosis and procedure codes. This step can facilitate a reduction in similar errors.

- b. *Reasonable and Necessary Services.* A practice's compliance program may provide guidance that claims are to be submitted only for services that the physician practice finds to be reasonable and necessary in the particular case. The OIG recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, a physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary.

Medicare (and many insurance plans) may deny payment for a service that is not reasonable and necessary according to the Medicare reimbursement rules. Thus, when a physician provides services to a Medicare beneficiary, he or she should only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient. A physician practice can bill in order to receive a denial for services, but only if the denial is needed for reimbursement from the secondary payor. Upon request, the physician practice should be able to provide documentation, such as a patient's medical records and physician's orders, to support the appropriateness of a service that the physician has provided.

- c. *Documentation.* Timely, accurate and complete documentation is important to clinical patient care. This same documentation serves as a second function when a bill is submitted for payment, namely, as verification that the bill is accurate as submitted. Therefore, one of the most important physician practice compliance issues is the appropriate documentation of diagnosis and treatment. Physician documentation is necessary to determine the appropriate medical treatment for the patient and is the basis for coding and billing determinations. Thorough and accurate documentation also helps to ensure accurate recording and timely transmission of information.
 - i. *Medical Record Documentation.* In addition to facilitating high quality patient care, a properly documented medical record verifies and documents precisely what services were actually provided. The medical record may be used to validate: (a) The site of the service; (b) the appropriateness of the services provided; (c) the accuracy of the billing; and (d) the identity of the caregiver (service provider).

Examples of internal documentation guidelines a practice might use to ensure accurate medical record documentation

include the following:

- The medical record is complete and legible;
- The documentation of each patient encounter includes the reason for the encounter; any relevant history; physical examination findings; prior diagnostic test results; assessment, clinical impression, or diagnosis; plan of care; and date and legible identity of the observer;
- If not documented, the rationale for ordering diagnostic and other ancillary services can be easily inferred by an independent reviewer or third party who has appropriate medical training;
- CPT and ICD–9–CM codes used for claims submission are supported by documentation and the medical record; and
- Appropriate health risk factors are identified. The patient’s progress, his or her response to, and any changes in, treatment, and any revision in diagnosis is documented.

The CPT and ICD–9–CM codes reported on the health insurance claims form should be supported by documentation in the medical record and the medical chart should contain all necessary information. Additionally, HCFA and the local carriers should be able to determine the person who provided the services. These issues can be the root of investigations of inappropriate or erroneous conduct, and have been identified by HCFA and the OIG as a leading cause of improper payments.

One method for improving quality in documentation is for a physician practice to compare the practice’s claim denial rate to the rates of other practices in the same specialty to the extent that the practice can obtain that information from the carrier. Physician coding and diagnosis distribution can be compared for each physician within the same specialty to identify variances.

- ii. HCFA 1500 Form. Another documentation area for physician practices to monitor closely is the proper completion of the HCFA 1500 form. The following practices will help ensure that the form has been properly completed:
 - Link the diagnosis code with the reason for the visit or service;
 - Use modifiers appropriately;
 - Provide Medicare with all information about a beneficiary’s other insurance coverage under the Medicare Secondary Payor (MSP) policy, if the practice is aware of a beneficiary’s additional coverage.
- d. *Improper Inducements, Kickbacks and Self-Referrals.* A physician practice would be well advised to have standards and procedures that encourage compliance with the anti-kickback statute and the physician self-referral law. Remuneration for referrals is illegal because it can distort medical decision-making, cause overutilization of services or supplies, increase costs to Federal health care programs, and result in unfair competition by shutting out competitors who are unwilling to pay for referrals. Remuneration for referrals can also affect the quality of patient care by encouraging physicians to order services or supplies based on profit rather than the patients’ best medical interests.

In particular, arrangements with hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers, pharmaceutical manufacturers and vendors are areas of potential concern. In general the anti-kickback statute prohibits knowingly and willfully giving or receiving anything of value to induce referrals of Federal health care program business. It is generally recommended that all business arrangements wherein physician practices refer business to, or order services or items from, an outside entity should be on a fair market value basis. Whenever a physician practice intends to enter into a business arrangement that involves making referrals, the arrangement should be reviewed by legal counsel familiar with the anti-kickback statute and physician self-referral statute.

In addition to developing standards and procedures to address arrangements with other health care providers and suppliers, physician practices should also consider implementing measures to avoid offering inappropriate inducements to patients. Examples of such inducements include routinely waiving coinsurance or deductible amounts without a good faith determination that the patient is in financial need or failing to make reasonable efforts to collect the cost-sharing amount. Possible risk factors relating to this risk area that could be addressed in the practice’s standards and procedures include:

- Financial arrangements with outside entities to whom the practice may refer Federal health care program business;
- Joint ventures with entities supplying goods or services to the physician practice or its patients;
- Consulting contracts or medical directorships;
- Office and equipment leases with entities to which the physician refers; and
- Soliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician practice’s referral of Federal health care program business.

In order to keep current with this area of the law, a physician practice may obtain copies, available on the OIG web site or in hard copy from the OIG, of all relevant OIG Special Fraud Alerts and Advisory Opinions that address the application of the anti-kickback and physician self-referral laws to ensure that the standards and procedures reflect current positions and opinions. *[Editor's note: See the "Fraud Alerts" section of this book for Special Fraud Alerts aimed at physicians]*

2. Retention of Records

In light of the documentation requirements faced by physician practices, it would be to the practice's benefit if its standards and procedures contained a section on the retention of compliance, business and medical records. These records primarily include documents relating to patient care and the practice's business activities. A physician practice's designated compliance contact could keep an updated binder or record of these documents, including information relating to compliance activities. The primary compliance documents that a practice would want to retain are those that relate to educational activities, internal investigations and internal audit results. We suggest that particular attention should be paid to documenting investigations of potential violations uncovered by the compliance program and the resulting remedial action. Although there is no requirement that the practice retain its compliance records, having all the relevant documentation relating to the practice's compliance efforts or handling of a particular problem can benefit the practice should it ever be questioned regarding those activities.

Physician practices that implement a compliance program might also want to provide for the development and implementation of a records retention system. This system would establish standards and procedures regarding the creation, distribution, retention, and destruction of documents. If the practice decides to design a record system, privacy concerns and Federal or State regulatory requirements should be taken into consideration.

While conducting its compliance activities, as well as its daily operations, a physician practice would be well advised, to the extent it is possible, to document its efforts to comply with applicable Federal health care program requirements. For example, if a physician practice requests advice from a Government agency (including a Medicare carrier) charged with administering a Federal health care program, it is to the benefit of the practice to document and retain a record of the request and any written or oral response (or nonresponse). This step is extremely important if the practice intends to rely on that response to guide it in future decisions, actions, or claim reimbursement requests or appeals.

In short, it is in the best interest of all physician practices, regardless of size, to have procedures to create and retain appropriate documentation. The following record retention guidelines are suggested:

- The length of time that a practice's records are to be retained can be specified in the physician practice's standards and procedures (Federal and State statutes should be consulted for specific time frames, if applicable);
- Medical records (if in the possession of the physician practice) need to be secured against loss, destruction, unauthorized access, unauthorized reproduction, corruption, or damage; and
- Standards and procedures can stipulate the disposition of medical records in the event the practice is sold or closed.

Step Three: Designation of a Compliance Officer/Contact(s)

After the audits have been completed and the risk areas identified, ideally one member of the physician practice staff needs to accept the responsibility of developing a corrective action plan, if necessary, and oversee the practice's adherence to that plan. This person can either be in charge of all compliance activities for the practice or play a limited role merely to resolve the current issue. In a formalized institutional compliance program there is a compliance officer who is responsible for overseeing the implementation and day-to-day operations of the compliance program. However, the resource constraints of physician practices make it so that it is often impossible to designate one person to be in charge of compliance functions.

It is acceptable for a physician practice to designate more than one employee with compliance monitoring responsibility. In lieu of having a designated compliance officer, the physician practice could instead describe in its standards and procedures the compliance functions for which designated employees, known as "compliance contacts," would be responsible. For example, one employee could be responsible for preparing written standards and procedures, while another could be responsible for conducting or arranging for periodic audits and ensuring that billing questions are answered. Therefore, the compliance-related responsibilities of the designated person or persons may be only a portion of his or her duties.

Another possibility is that one individual could serve as compliance officer for more than one entity. In situations where staffing limitations mandate that the practice cannot afford to designate a person(s) to oversee compliance activities, the practice could outsource all or part of the functions of a compliance officer to a third party, such as a consultant, PPMC, MSO, IPA or third-party billing company. However, if this role is outsourced, it is beneficial for the compliance officer to have sufficient interaction with the physician practice to be able to effectively understand the inner workings of the practice. For example, consultants that are not in close geographic proximity to a practice may not be effective compliance officers for the practice.

One suggestion for how to maintain continual interaction is for the practice to designate someone to serve as a liaison with the outsourced compliance officer. This would help ensure a strong tie between the compliance officer and the practice's daily operations. Outsourced compliance officers, who spend most of their time offsite, have certain limitations that a physician practice

should consider before making such a critical decision. These limitations can include lack of understanding as to the inner workings of the practice, accessibility and possible conflicts of interest when one compliance officer is serving several practices.

If the physician practice decides to designate a particular person(s) to oversee all compliance activities, not just those in conjunction with the audit- related issue, the following is a list of suggested duties that the practice may want to assign to that person(s):

- Overseeing and monitoring the implementation of the compliance program;
- Establishing methods, such as periodic audits, to improve the practice's efficiency and quality of services, and to reduce the practice's vulnerability to fraud and abuse;
- Periodically revising the compliance program in light of changes in the needs of the practice or changes in the law and in the standards and procedures of Government and private payor health plans;
- Developing, coordinating and participating in a training program that focuses on the components of the compliance program, and seeks to ensure that training materials are appropriate;
- Ensuring that the HHS–OIG's List of Excluded Individuals and Entities, and the General Services Administration's (GSA's) List of Parties Debarred from Federal Programs have been checked with respect to all employees, medical staff and independent contractors; and
- Investigating any report or allegation concerning possible unethical or improper business practices, and monitoring subsequent corrective action and/or compliance.

Each physician practice needs to assess its own practice situation and determine what best suits that practice in terms of compliance oversight.

Step Four: Conducting Appropriate Training and Education

Education is an important part of any compliance program and is the logical next step after problems have been identified and the practice has designated a person to oversee educational training. Ideally, education programs will be tailored to the physician practice's needs, specialty and size and will include both compliance and specific training. There are three basic steps for setting up educational objectives:

- Determining who needs training (both in coding and billing and in compliance);
- Determining the type of training that best suits the practice's needs (*e.g.*, seminars, in-service training, self-study or other programs); and
- Determining when and how often education is needed and how much each person should receive.

Training may be accomplished through a variety of means, including in-person training sessions (*i.e.*, either on site or at outside seminars), distribution of newsletters, or even a readily accessible office bulletin board. Regardless of the training modality used, a physician practice should ensure that the necessary education is communicated effectively and that the practice's employees come away from the training with a better understanding of the issues covered.

1. Compliance Training

Under the direction of the designated compliance officer/contact, both initial and recurrent training in compliance is advisable, both with respect to the compliance program itself and applicable statutes and regulations. Suggestions for items to include in compliance training are: The operation and importance of the compliance program; the consequences of violating the standards and procedures set forth in the program; and the role of each employee in the operation of the compliance program.

There are two goals a practice should strive for when conducting compliance training: (1) All employees will receive training on how to perform their jobs in compliance with the standards of the practice and any applicable regulations; and (2) each employee will understand that compliance is a condition of continued employment. Compliance training focuses on explaining why the practice is developing and establishing a compliance program. The training should emphasize that following the standards and procedures will not get a practice employee in trouble, but violating the standards and procedures may subject the employee to disciplinary measures. It is advisable that new employees be trained on the compliance program as soon as possible after their start date and employees should receive refresher training on an annual basis or as appropriate.

2. Coding and Billing Training

Coding and billing training on the Federal health care program requirements may be necessary for certain members of the physician practice staff depending on their respective responsibilities. The OIG understands that most physician practices do not employ a professional coder and that the physician is often primarily responsible for all coding and billing. However, it is in the practice's best interest to ensure that individuals who are directly involved with billing, coding or other aspects of the Federal health care programs receive extensive education specific to that individual's responsibilities. Some examples of items that could

be covered in coding and billing training include:

- Coding requirements;
- Claim development and submission processes;
- Signing a form for a physician without the physician's authorization;
- Proper documentation of services rendered;
- Proper billing standards and procedures and submission of accurate bills for services or items rendered to Federal health care program beneficiaries; and
- The legal sanctions for submitting deliberately false or reckless billings.

3. Format of the Training Program

Training may be conducted either in-house or by an outside source. Training at outside seminars, instead of internal programs and in-service sessions, may be an effective way to achieve the practice's training goals. In fact, many community colleges offer certificate or associate degree programs in billing and coding, and professional associations provide various kinds of continuing education and certification programs. Many carriers also offer billing training.

The physician practice may work with its third-party billing company, if one is used, to ensure that documentation is of a level that is adequate for the billing company to submit accurate claims on behalf of the physician practice. If it is not, these problem areas should also be covered in the training. In addition to the billing training, it is advisable for physician practices to maintain updated ICD-9, HCPCS and CPT manuals (in addition to the carrier bulletins construing those sources) and make them available to all employees involved in the billing process. Physician practices can also provide a source of continuous updates on current billing standards and procedures by making publications or Government documents that describe current billing policies available to its employees.

Physician practices do not have to provide separate education and training programs for the compliance and coding and billing training. All in-service training and continuing education can integrate compliance issues, as well as other core values adopted by the practice, such as quality improvement and improved patient service, into their curriculum.

4. Continuing Education on Compliance Issues

There is no set formula for determining how often training sessions should occur. The OIG recommends that there be at least an annual training program for all individuals involved in the coding and billing aspects of the practice. Ideally, new billing and coding employees will be trained as soon as possible after assuming their duties and will work under an experienced employee until their training has been completed.

Step Five: Responding to Detected Offenses and Developing Corrective Action Initiatives

When a practice determines it has detected a possible violation, the next step is to develop a corrective action plan and determine how to respond to the problem. Violations of a physician practice's compliance program, significant failures to comply with applicable Federal or State law, and other types of misconduct threaten a practice's status as a reliable, honest, and trustworthy provider of health care. Consequently, upon receipt of reports or reasonable indications of suspected noncompliance, it is important that the compliance contact or other practice employee look into the allegations to determine whether a significant violation of applicable law or the requirements of the compliance program has indeed occurred, and, if so, take decisive steps to correct the problem. As appropriate, such steps may involve a corrective action plan, the return of any overpayments, a report to the Government, and/or a referral to law enforcement authorities.

One suggestion is that the practice, in developing its compliance program, develop its own set of monitors and warning indicators. These might include: Significant changes in the number and/or types of claim rejections and/or reductions; correspondence from the carriers and insurers challenging the medical necessity or validity of claims; illogical patterns or unusual changes in the pattern of CPT-4, HCPCS or ICD-9 code utilization; and high volumes of unusual charge or payment adjustment transactions. If any of these warning indicators become apparent, then it is recommended that the practice follow up on the issues. Subsequently, as appropriate, the compliance procedures of the practice may need to be changed to prevent the problem from recurring.

For potential criminal violations, a physician practice would be well advised in its compliance program procedures to include steps for prompt referral or disclosure to an appropriate Government authority or law enforcement agency. In regard to overpayment issues, it is advised that the physician practice take appropriate corrective action, including prompt identification and repayment of any overpayment to the affected payor.

It is also recommended that the compliance program provide for a full internal assessment of all reports of detected violations. If the physician practice ignores reports of possible fraudulent activity, it is undermining the very purpose it hoped to achieve by implementing a compliance program.

It is advised that the compliance program standards and procedures include provisions to ensure that a violation is not compounded once discovered. In instances involving individual misconduct, the standards and procedures might also advise as to whether the individuals involved in the violation either be retrained, disciplined, or, if appropriate, terminated. The physician practice may also prevent the compounding of the violation by conducting a review of all confirmed violations, and, if appropriate, self-reporting the violations to the applicable authority.

The physician practice may consider the fact that if a violation occurred and was not detected, its compliance program may require modification. Physician practices that detect violations could analyze the situation to determine whether a flaw in their compliance program failed to anticipate the detected problem, or whether the compliance program's procedures failed to prevent the violation. In any event, it is prudent, even absent the detection of any violations, for physician practices to periodically review and modify their compliance programs.

Step Six: Developing Open Lines of Communication

In order to prevent problems from occurring and to have a frank discussion of why the problem happened in the first place, physician practices need to have open lines of communication. Especially in a smaller practice, an open line of communication is an integral part of implementing a compliance program. Guidance previously issued by the OIG has encouraged the use of several forms of communication between the compliance officer/ committee and provider personnel, many of which focus on formal processes and are more costly to implement (e.g., hotlines and e-mail). However, the OIG recognizes that the nature of some physician practices is not as conducive to implementing these types of measures. The nature of a small physician practice dictates that such communication and information exchanges need to be conducted through a less formalized process than that which has been envisioned by prior OIG guidance.

In the small physician practice setting, the communication element may be met by implementing a clear "open door" policy between the physicians and compliance personnel and practice employees. This policy can be implemented in conjunction with less formal communication techniques, such as conspicuous notices posted in common areas and/or the development and placement of a compliance bulletin board where everyone in the practice can receive up-to-date compliance information.

A compliance program's system for meaningful and open communication can include the following:

- The requirement that employees report conduct that a reasonable person would, in good faith, believe to be erroneous or fraudulent;
- The creation of a user-friendly process (such as an anonymous drop box for larger practices) for effectively reporting erroneous or fraudulent conduct;
- Provisions in the standards and procedures that state that a failure to report erroneous or fraudulent conduct is a violation of the compliance program;
- The development of a simple and readily accessible procedure to process reports of erroneous or fraudulent conduct;
- If a billing company is used, communication to and from the billing company's compliance officer/contact and other responsible staff to coordinate billing and compliance activities of the practice and the billing company, respectively. Communication can include, as appropriate, lists of reported or identified concerns, initiation and the results of internal assessments, training needs, regulatory changes, and other operational and compliance matters;
- The utilization of a process that maintains the anonymity of the persons involved in the reported possible erroneous or fraudulent conduct and the person reporting the concern; and
- Provisions in the standards and procedures that there will be no retribution for reporting conduct that a reasonable person acting in good faith would have believed to be erroneous or fraudulent.

The OIG recognizes that protecting anonymity may not be feasible for small physician practices. However, the OIG believes all practice employees, when seeking answers to questions or reporting potential instances of erroneous or fraudulent conduct, should know to whom to turn for assistance in these matters and should be able to do so without fear of retribution. While the physician practice may strive to maintain the anonymity of an employee's identity, it also needs to make clear that there may be a point at which the individual's identity may become known or may have to be revealed in certain instances.

Step Seven: Enforcing Disciplinary Standards Through Well-Publicized Guidelines

Finally, the last step that a physician practice may wish to take is to incorporate measures into its practice to ensure that practice employees understand the consequences if they behave in a non-compliant manner. An effective physician practice compliance program includes procedures for enforcing and disciplining individuals who violate the practice's compliance or other practice standards. Enforcement and disciplinary provisions are necessary to add credibility and integrity to a compliance program.

The OIG recommends that a physician practice's enforcement and disciplinary mechanisms ensure that violations of the

practice's compliance policies will result in consistent and appropriate sanctions, including the possibility of termination, against the offending individual. At the same time, it is advisable that the practice's enforcement and disciplinary procedures be flexible enough to account for mitigating or aggravating circumstances. The procedures might also stipulate that individuals who fail to detect or report violations of the compliance program may also be subject to discipline. Disciplinary actions could include: Warnings (oral); reprimands (written); probation; demotion; temporary suspension; termination; restitution of damages; and referral for criminal prosecution. Inclusion of disciplinary guidelines in in-house training and procedure manuals is sufficient to meet the "well publicized" standard of this element.

It is suggested that any communication resulting in the finding of non-compliant conduct be documented in the compliance files by including the date of incident, name of the reporting party, name of the person responsible for taking action, and the follow-up action taken. Another suggestion is for physician practices to conduct checks to make sure all current and potential practice employees are not listed on the OIG or GSA lists of individuals excluded from participation in Federal health care or Government procurement programs.

C. Assessing A Voluntary Compliance Program

A practice's commitment to compliance can best be assessed by the active application of compliance principles in the day-to-day operations of the practice. Compliance programs are not just written standards and procedures that sit on a shelf in the main office of a practice, but are an everyday part of the practice operations. It is by integrating the compliance program into the practice culture that the practice can best achieve maximum benefit from its compliance program.

III. Conclusion

Just as immunizations are given to patients to prevent them from becoming ill, physician practices may view the implementation of a voluntary compliance program as comparable to a form of preventive medicine for the practice. This voluntary compliance program guidance is intended to assist physician practices in developing and implementing internal controls and procedures that promote adherence to Federal health care program requirements.

As stated earlier, physician compliance programs do not need to be time or resource intensive and can be developed in a manner that best reflects the nature of each individual practice. Many of the recommendations set forth in this document are ones that many physician practices already have in place and are simply good business practices that can be adhered to with a reasonable amount of effort. By implementing an effective compliance program, appropriate for its size and resources, and making compliance principles an active part of the practice culture, a physician practice can help prevent and reduce erroneous or fraudulent conduct in its practice. These efforts can also streamline and improve the business operations within the practice and therefore inoculate itself against future problems.

Additional Risk Areas

[This section] describes additional risk areas that a physician practice may wish to address during the development of its compliance program. If any of the following risk areas are applicable to the practice, the practice may want to consider addressing the risk areas by incorporating them into the practice's written standards and procedures manual and addressing them in its training program.

I. Reasonable and Necessary Services

A. Local Medical Review Policy

An area of concern for physicians relating to determinations of reasonable and necessary services is the variation in local medical review policies (LMRPs) among carriers. Physicians are supposed to bill the Federal health care programs only for items and services that are reasonable and necessary. However, in order to determine whether an item or service is reasonable and necessary under Medicare guidelines, the physician must apply the appropriate LMRP.

With the exception of claims that are properly coded and submitted to Medicare solely for the purpose of obtaining a written denial, physician practices are to bill the Federal health programs only for items and services that are covered. In order to determine if an item or service is covered for Medicare, a physician practice must be knowledgeable of the LMRPs applicable to its practice's jurisdiction. The practice may contact its carrier to request a copy of the pertinent LMRPs, and once the practice receives the copies, they can be incorporated into the practice's written standards and procedures manual. When the LMRP indicates that an item or service may not be covered by Medicare, the physician practice is responsible to convey this information to the patient so that the patient can make an informed decision concerning the health care services he/she may want to receive. Physician practices convey this information through Advance Beneficiary Notices (ABNs).

B. Advance Beneficiary Notices

Physicians are required to provide ABNs before they provide services that they know or believe Medicare does not consider reasonable and necessary. (The one exception to this requirement is for services that are performed pursuant to EMTALA requirements as described below). A properly executed ABN acknowledges that coverage is uncertain or yet to be determined, and stipulates that the patient promises to pay the bill if Medicare does not. Patients who are not notified before they receive such

services are not responsible for payment. The ABN must be sufficient to put the patient on notice of the reasons why the physician believes that the payment may be denied. The objective is to give the patient sufficient information to allow an informed choice as to whether to pay for the service. Accordingly, each ABN should:

- I. Be in writing;
- II. Identify the specific service that may be denied (procedure name and CPT/HCPC code is recommended);
- III. State the specific reason why the physician believes that service may be denied; and
- IV. Be signed by the patient acknowledging that the required information was provided and that the patient assumes responsibility to pay for the service.

The *Medicare Carrier's Manual* provides that an ABN will not be acceptable if: (1) the patient is asked to sign a blank ABN form; or (2) the ABN is used routinely without regard to a particularized need. The routine use of ABNs is generally prohibited because the ABN must state the specific reason the physician anticipates that the specific service will not be covered.

A common risk area associated with ABNs is in regard to diagnostic tests or services. There are three steps that a physician practice can take to help ensure it is in compliance with the regulations concerning ABNs for diagnostic tests or services:

1. Determine which tests are not covered under national coverage rules;
2. Determine which tests are not covered under local coverage rules such as LMRPs (contact the practice's carrier to see if a listing has been assembled); and
3. Determine which tests are only covered for certain diagnoses.

The OIG is aware that the use of ABNs is an area where physician practices experience numerous difficulties. Practices can help to reduce problems in this area by educating their physicians and office staff on the correct use of ABNs, obtaining guidance from the carrier regarding their interpretation of whether an ABN is necessary where the service is not covered, developing a standard form for all diagnostic tests (most carriers have a developed model), and developing a process for handling patients who refuse to sign ABNs.

C. Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services

In January 1999, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at oig.hhs.gov/fraud/docs/alertsandbulletins/dme.htm. [Editor's note: See the "Fraud Alerts" section of this book]

D. Billing for Non-covered Services as if Covered

In some instances, we are aware that physician practices submit claims for services in order to receive a denial from the carrier, thereby enabling the patient to submit the denied claim for payment to a secondary payer.

A common question relating to this risk area is: If the medical services provided are not covered under Medicare, but the secondary or supplemental insurer requires a Medicare rejection in order to cover the services, then would the original submission of the claim to Medicare be considered fraudulent? Under the applicable regulations, the OIG would not consider such submissions to be fraudulent. For example, the denial may be necessary to establish patient liability protections as stated in section 1879 of the Social Security Act (the Act) (codified at 42 U.S.C. 1395pp). As stated, Medicare denials may also be required so that the patient can seek payment from a secondary insurer. In instances where a claim is being submitted to Medicare for this purpose, the physician should indicate on the claim submission that the claim is being submitted for the purpose of receiving a denial, in order to bill a secondary insurance carrier. This step should assist carriers and prevent inadvertent payments to which the physician is not entitled.

In some instances, however, the carrier pays the claim even though the service is non-covered, and even though the physician did not intend for payment to be made. When this occurs, the physician has a responsibility to refund the amount paid and indicate that the service is not covered.

II. Physician Relationships with Hospitals

A. The Physician Role in EMTALA

The Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. 1395dd, is an area that has been receiving increasing scrutiny. The statute is intended to ensure that all patients who come to the emergency department of a hospital receive care, regardless of their insurance or ability to pay. Both hospitals and physicians need to work together to ensure compliance with the provisions of this law.

The statute imposes three fundamental requirements upon hospitals that participate in the Medicare program with regard to patients requesting emergency care. First, the hospital must conduct an appropriate medical screening examination to determine if an emergency medical condition exists. Second, if the hospital determines that an emergency medical condition exists, it must either provide the treatment necessary to stabilize the emergency medical condition or comply with the statute's requirements to effect a proper transfer of a patient whose condition has not been stabilized. A hospital is considered to have met this second

requirement if an individual refuses the hospital's offer of additional examination or treatment, or refuses to consent to a transfer, after having been informed of the risks and benefits.

If an individual's emergency medical condition has not been stabilized, the statute's third requirement is activated. A hospital may not transfer an individual with an unstable emergency medical condition unless: (1) The individual or his or her representative makes a written request for transfer to another medical facility after being informed of the risk of transfer and the transferring hospital's obligation under the statute to provide additional examination or treatment; (2) a physician has signed a certification summarizing the medical risks and benefits of a transfer and certifying that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the transfer outweigh the increased risks; or (3) if a physician is not physically present when the transfer decision is made, a qualified medical person signs the certification after the physician, in consultation with the qualified medical person, has made the determination that the benefits of transfer outweigh the increased risks. The physician must later countersign the certification.

Physician and/or hospital misconduct may result in violations of the statute. One area of particular concern is physician on-call responsibilities. Physician practices whose members serve as on-call emergency room physicians with hospitals are advised to familiarize themselves with the hospital's policies regarding on-call physicians. This can be done by reviewing the medical staff bylaws or policies and procedures of the hospital that must define the responsibility of on-call physicians to respond to, examine, and treat patients with emergency medical conditions. Physicians should also be aware of the requirement that, when medically indicated, on-call physicians must generally come to the hospital to examine the patient. The exception to this requirement is that a patient may be sent to see the on-call physician at a hospital-owned contiguous or on-campus facility to conduct or complete the medical screening examination as long as:

1. All persons with the same medical condition are moved to this location;
2. There is a bona fide medical reason to move the patient; and
3. Qualified medical personnel accompany the patient. *[Editor's note: See the "EMTALA" section of this book for additional information]*

B. Teaching Physicians

Special regulations apply to teaching physicians' billings. Regulations provide that services provided by teaching physicians in teaching settings are generally payable under the physician fee schedule only if the services are personally furnished by a physician who is not a resident or the services are furnished by a resident in the presence of a teaching physician. Unless a service falls under a specified exception, such as the Primary Care Exception, the teaching physician must be present during the key portion of any service or procedure for which payment is sought. Physicians should ensure the following with respect to services provided in the teaching physician setting:

- Only services actually provided are billed;
- Every physician who provides or supervises the provision of services to a patient is responsible for the correct documentation of the services that were rendered;
- Every physician is responsible for assuring that in cases where the physician provides evaluation and management (E&M) services, a patient's medical record includes appropriate documentation of the applicable key components of the E&M services provided or supervised by the physician (e.g., patient history, physician examination, and medical decision making), as well as documentation to adequately reflect the procedure or portion of the services provided by the physician; and
- Unless specifically excepted by regulation, every physician must document his or her presence during the key portion of any service or procedure for which payment is sought.

C. Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

In July 1999, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm. The following is a summary of the Special Fraud Alert.

The term "gainsharing" typically refers to an arrangement in which a hospital gives a physician a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physician's efforts. The civil monetary penalty (CMP) that applies to gainsharing arrangements is set forth in 42 U.S.C. 1320a-7a(b)(1). This section prohibits any hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under a physician's care.

It is the OIG's position that the Civil Monetary Penalties Law clearly prohibits any gainsharing arrangements that involve payments by, or on behalf of, a hospital to physicians with clinical care responsibilities to induce a reduction or limitation of services to Medicare or Medicaid beneficiaries. However, hospitals and physicians are not prohibited from working together to reduce

unnecessary hospital costs through other arrangements. For example, hospitals and physicians may enter into personal services contracts where hospitals pay physicians based on a fixed fee at fair market value for services rendered to reduce costs rather than a fee based on a share of cost savings.

D. Physician Incentive Arrangements

The OIG has identified potentially illegal practices involving the offering of incentives by entities in an effort to recruit and retain physicians. The OIG is concerned that the intent behind offering incentives to physicians may not be to recruit physicians, but instead the offer is intended as a kickback to obtain and increase patient referrals from physicians. These recruitment incentive arrangements are implicated by the Anti-Kickback Statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid. Some examples of questionable incentive arrangements are:

- Provision of free or significantly discounted billing, nursing, or other staff services.
- Payment of the cost of a physician's travel and expenses for conferences.
- Payment for a physician's services that require few, if any, substantive duties by the physician.
- Guarantees that if the physician's income fails to reach a predetermined level, the entity will supplement the remainder up to a certain amount.

III. Physician Billing Practices

A. Third-Party Billing Services

Physicians should remember that they remain responsible to the Medicare program for bills sent in the physician's name or containing the physician's signature, even if the physician had no actual knowledge of a billing impropriety. The attestation on the HCFA 1500 form, *i.e.*, the physician's signature line, states that the physician's services were billed properly. In other words, it is no defense for the physician if the physician's billing service improperly bills Medicare.

One of the most common risk areas involving billing services deals with physician practices contracting with billing services on a percentage basis. Although percentage based billing arrangements are not illegal *per se*, the Office of Inspector General has a longstanding concern that such arrangements may increase the risk of intentional upcoding and similar abusive billing practices.

A physician may contract with a billing service on a percentage basis. However, the billing service cannot directly receive the payment of Medicare funds into a bank account that it solely controls. Under 42 U.S.C. 1395u(b)(6), Medicare payments can only be made to either the beneficiary or a party (such as a physician) that furnished the services and accepted assignment of the beneficiary's claim. A billing service that contracts on a percentage basis does not qualify as a party that furnished services to a beneficiary, thus a billing service cannot directly receive payment of Medicare funds. According to the *Medicare Carriers Manual* Section 3060(A), a payment is considered to be made directly to the billing service if the service can convert the payment to its own use and control without the payment first passing through the control of the physician. For example, the billing service should not bill the claims under its own name or tax identification number. The billing service should bill claims under the physician's name and tax identification number. Nor should a billing service receive the payment of Medicare funds directly into a bank account over which the billing service maintains sole control. The Medicare payments should instead be deposited into a bank account over which the provider has signature control.

Physician practices should review the third-party medical billing guidance for additional information on third-party billing companies and the compliance risk areas associated with billing companies.

B. Billing Practices by Non-Participating Physicians

Even though nonparticipating physicians do not accept payment directly from the Medicare program, there are a number of laws that apply to the billing of Medicare beneficiaries by non-participating physicians.

Limiting Charges

42 U.S.C. 1395w-4(g) prohibits a nonparticipating physician from knowingly and willfully billing or collecting on a repeated basis an actual charge for a service that is in excess of the Medicare limiting charge. For example, a nonparticipating physician may not bill a Medicare beneficiary \$50 for an office visit when the Medicare limiting charge for the visit is \$25. Additionally, there are numerous provisions that prohibit nonparticipating physicians from knowingly and willfully charging patients in excess of the statutory charge limitations for certain specified procedures, such as cataract surgery, mammography screening and coronary artery bypass surgery. Failure to comply with these sections can result in a fine of up to \$10,000 per violation or exclusion from participation in Federal health care programs for up to 5 years.

Refund of Excess Charges

42 U.S.C. 1395w-4(g) mandates that if a nonparticipating physician collects an actual charge for a service that is in excess of the limiting charge, the physician must refund the amount collected above the limiting charge to the individual within 30 days notice of the violation. For example, if a physician collected \$50 from a Medicare beneficiary for an office visit, but the limiting

charge for the visit was \$25, the physician must refund \$25 to the beneficiary, which is the difference between the amount collected (\$50) and the limiting charge (\$25). Failure to comply with this requirement may result in a fine of up to \$10,000 per violation or exclusion from participation in Federal health care programs for up to 5 years. Specifically, 42 U.S.C. 1395u(l)(A)(iii) mandates that a nonparticipating physician must refund payments received from a Medicare beneficiary if it is later determined by a Peer Review Organization or a Medicare carrier that the services were not reasonable and necessary. Failure to comply with this requirement may result in a fine of up to \$10,000 per violation or exclusion from participation in Federal health care programs for up to 5 years.

C. Professional Courtesy

The term “professional courtesy” is used to describe a number of analytically different practices. The traditional definition is the practice by a physician of waiving all or a part of the fee for services provided to the physician’s office staff, other physicians, and/or their families. In recent times, “professional courtesy” has also come to mean the waiver of coinsurance obligations or other out-of-pocket expenses for physicians or their families (*i.e.*, “insurance only” billing), and similar payment arrangements by hospitals or other institutions for services provided to their medical staffs or employees. While only the first of these practices is truly “professional courtesy,” in the interests of clarity and completeness, we will address all three.

In general, whether a professional courtesy arrangement runs afoul of the fraud and abuse laws is determined by two factors: (i) How the recipients of the professional courtesy are selected; and (ii) how the professional courtesy is extended. If recipients are selected in a manner that directly or indirectly takes into account their ability to affect past or future referrals, the anti-kickback statute—which prohibits giving anything of value to generate Federal health care program business—may be implicated. If the professional courtesy is extended through a waiver of copayment obligations (*i.e.*, “insurance only” billing), other statutes may be implicated, including the prohibition of inducements to beneficiaries, section 1128A(a)(5) of the Act (codified at 42 U.S.C. 1320a–7a(a)(5)). Claims submitted as a result of either practice may also implicate the civil False Claims Act.

The following are general observations about professional courtesy arrangements for physician practices to consider:

- A physician’s regular and consistent practice of extending professional courtesy by waiving the entire fee for services rendered to a group of persons (including employees, physicians, and/or their family members) may not implicate any of the OIG’s fraud and abuse authorities so long as membership in the group receiving the courtesy is determined in a manner that does not take into account directly or indirectly any group member’s ability to refer to, or otherwise generate Federal health care program business for, the physician.
- A physician’s regular and consistent practice of extending professional courtesy by waiving otherwise applicable copayments for services rendered to a group of persons (including employees, physicians, and/or their family members), would not implicate the anti-kickback statute so long as membership in the group is determined in a manner that does not take into account directly or indirectly any group member’s ability to refer to, or otherwise generate Federal health care program business for, the physician.
- Any waiver of copayment practice, including that described in the preceding bullet, does implicate section 1128A(a)(5) of the Act if the patient for whom the copayment is waived is a Federal health care program beneficiary who is not financially needy.

The legality of particular professional courtesy arrangements will turn on the specific facts presented, and, with respect to the anti-kickback statute, on the specific intent of the parties. A physician practice may wish to consult with an attorney if it is uncertain about its professional courtesy arrangements. [*Editor’s note: See the “Professional Courtesy” section of this book for more information*]

IV. Other Risk Areas

A. Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer

In February 2000, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at oig.hhs.gov/authorities/docs/fraudalert.pdf.

B. Unlawful Advertising

42 U.S.C. 1320b–10 makes it unlawful for any person to advertise using the names, abbreviations, symbols, or emblems of the Social Security Administration, Health Care Financing Administration, Department of Health and Human Services, Medicare, Medicaid or any combination or variation of such words, abbreviations, symbols or emblems in a manner that such person knows or should know would convey the false impression that the advertised item is endorsed by the named entities. For instance, a physician may not place an ad in the newspaper that reads “Dr. X is a cardiologist approved by both the Medicare and Medicaid programs.” A violation of this section may result in a penalty of up to \$5,000 (\$25,000 in the case of a broadcast or telecast) for each violation.

[\(Back\)](#)

Corporate Donations to Political Candidates

Kentucky law prohibits corporations from contributing either directly or indirectly, any money, service, or other thing of value towards the nomination or election of any state, county, city, or district officer. [KRS 121.035] A medical practice's funds or resources are not to be used to contribute to political campaigns, or for gifts or payments to any political party or any of their affiliated organizations. A practice's resources include financial and non-financial donations such as using work time and telephones to solicit for a political cause or candidate or the loaning of the practice's property for use in the political campaign.

Employees of a practice may make personal contributions to federal, state, and local candidates in their sole discretion. These contributions should be made in compliance with the applicable federal or state campaign finance laws. Under no condition should personal campaign contributions be reimbursed by the practice. ([Back](#))

Death and Death Certificates

Death must be determined in accordance with the usual and customary standards of medical practice, although certain minimal conditions must be met. When respiration and circulation are not artificially maintained, there must be an irreversible cessation of spontaneous respiration and circulation. When respiration and circulation are artificially maintained, there must be a total and irreversible cessation of all brain function, including the brain stem and the determination of death must be made by two (2) licensed physicians [KRS 446.400].

A funeral director must present a certificate of death to the attending physician, the physician pronouncing death, advanced practice registered nurse, physician assistant, if any, or to the health officer, or coroner for the medical certificate of the cause of death and other particulars [KRS 213.076(1)]. If any certificate is incomplete or unsatisfactory, the state registrar must call attention to the defects and require the person responsible for the entry to complete or correct it. The state registrar may also require additional information about the circumstances and medical conditions surrounding a death in order to properly code and classify the underlying cause. A funeral director cannot be held responsible for the failure of a physician, advanced practice registered nurse, physician assistant, dentist, chiropractor, or coroner to complete or correct the entry for which he or she is responsible [KRS 213.076(2)]. Effective January 1, 2015, all certificates of death must be filed with the Cabinet for Health and Family Services using the Kentucky Electronic Death Registration System according to rules established by the state registrar. [KRS 213.076(1)]

A physician, advanced practice registered nurse, physician assistant, chiropractor, or dentist "in charge of the patient's care for the illness or condition which resulted in death" must complete and sign the medical certification of death, unless an inquiry into the death is required. This certification must be returned to the funeral director within five working days after presentation to the physician, advanced practice registered nurse, physician assistant, dentist, or chiropractor [KRS 213.076(3)]. If death occurs more than 36 hours after the decedent was last treated or attended by a physician, advanced practice registered nurse, physician assistant, dentist, or chiropractor, the case must be referred to the coroner for investigation to determine and certify the cause of death [KRS 213.076(4)].

If the cause of death is unknown or under investigation, it must be shown as such on the certificate. A supplemental report providing the medical information omitted from the original certificate must be filed by the certifier with the state registrar within five (5) days after receiving results of the inquiry [KRS 213.076(3)].

In the case of a death in which diabetes was known to be an underlying cause or contributing condition, diabetes must be listed in the appropriate location on the death certificate by the physician, advanced practice registered nurse, physician assistant, dentist, chiropractor or coroner who certifies to the cause of death [KRS 213.076(5)(b)].

When the determination and pronouncement of death of a patient whose circulation and respiration are not being artificially maintained occurs in a hospital or nursing facility, that declaration may be made by a registered nurse. The nurse must notify the patient's attending physician of the death in accordance with the hospital's or facility's policy [KRS 314.181(4)]. A registered nurse may also make the actual determination and pronouncement of death if the patient dies at home or is in a hospice inpatient program or unit, although the registered nurse must be employed by the attending hospice and treated the patient [KRS 314.046].

A registered nurse employed by an ambulance service shall determine whether or not a patient served by the ambulance service is dead. The registered nurse shall, when responding to a patient, first attempt resuscitation, unless the protocol indicates that the patient is not capable of being resuscitated [KRS 314.181(2)]. If it is determined that death has occurred in accordance with the procedures of KRS 446.400 with regard to patients who have not been resuscitated, the registered nurse who is employed by an

ambulance service may make the actual determination and pronouncement of death. This does not apply to patients who are in a hospital when apparent death occurs [KRS 314.181(3)].

The time of death of a donor of organs must be determined by a physician who tends the donor at his death or, if none, the physician who certifies the death. The physician who certifies the death of an organ donor must not participate in the procedures for removing or transplanting a part of the body of the donor [KRS 311.225]. ([Back](#))

Dispensing Medication

A physician may dispense legend drugs for a legitimate medical purpose, and in the course of professional practice, or distribute a legend drug to a person licensed to administer, dispense, distribute or possess a legend drug [KRS 217.182(3)]. An advanced registered nurse practitioner may dispense noncontrolled legend drug samples from pharmaceutical manufacturers to patients at no charge to the patient or any other party, as well as noncontrolled legend drugs from a local, district, and independent health department, subject to the direction of the appropriate governing board of the individual health department [KRS 314.011(8); KRS 314.011(17)].

A physician may also dispense controlled substances for a legitimate medical purpose, and in the course of professional practice, or distribute a controlled substance to a person registered pursuant to the federal controlled substance laws [KRS 218A.170(3)]. A legend drug is a drug defined by the Federal Food, Drug and Cosmetic Act, as amended, and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription" [KRS 217.015(28)]. A controlled substance is defined as methamphetamine or a drug, substance, or immediate precursor in schedules I through V and includes a controlled substance analog [KRS 218A.010(6)].

Practitioners who dispense controlled substances are required to report to the Cabinet. KRS 218A.202 requires the Cabinet to implement a computerized monitoring system for controlled substances dispensed within the Commonwealth. This system is known as the Kentucky All Schedule Prescriptions Electronic Reporting (KASPER). Practitioners authorized to prescribe or dispense controlled substances are required to register with KASPER and maintain registration throughout the practitioner's term of licensure within Kentucky. All dispensers of controlled substances (in-state pharmacies, out-of-state pharmacies and practitioners who dispense from their office) are required to report specific information for each dispensation. There are very strict deadlines for such reports. If you dispense controlled substances, you should contact the Drug Control Branch for information about how to report. (Dispensing means supplying take-home doses; it does not include single doses that the patient takes immediately nor does it include prescriptions that are written). The data submitted is stored in a high-security database and access to the information is strictly limited by statute. Drug Control uses the data to identify patients who appear to be drug seekers by obtaining prescriptions from multiple practitioners and pharmacies.

Practitioners are sometimes asked by patients to prescribe certain narcotics or other controlled substances. While most instances are legitimate, sometimes the practitioner may feel uncomfortable and wonder if the patient is a drug seeker who tries to obtain drugs from multiple practitioners. The KASPER program allows a physician to make a request to Drug Control and obtain a report. Practitioners and their employees will be able to use the report's data to confirm whether a patient is seeing other practitioners for controlled substances. Practitioners and their employees who obtain KASPER data may share the report with the patient or person authorized to act on the patient's behalf and place the report in the patient's medical record, with that individual report then being deemed a medical record subject to disclosure on the same terms and conditions as an ordinary medical record. Practitioners and/or their employees may also use KASPER data to review and assess practitioners' prescribing and dispensing patterns to ensure accuracy and completeness of the information contained within KASPER. [KRS 218A.202]

Prescribing and Dispensing Standards

In the aftermath of 2012 House Bill 1, KMA published a detailed overview of statutes and regulations adopted by the Kentucky General Assembly, Kentucky Board of Medical Licensure (KBML), and the Cabinet for Health and Family Services' Office of Inspector General (OIG) that impact physicians' ability to prescribe, dispense, and administer controlled substances. The summary is divided into sections outlining, among other items, requirements pertaining to documentation, patient education, continuing medical education, data reporting, and appropriate prescribing and dispensing. [KRS 218A.172, KRS 218A.202, KRS 218.205, 201 KAR 9:220, 201 KAR 9:260, 201 KAR 9:310, 902 KAR 55:110] These requirements went into effect on March 4, 2013. To access the summary, [click here](#).

The information prepared by KMA is merely a summary of certain portions of the controlled substance statutes and regulations. Physicians should review the actual statutes and regulations, as this summary is not comprehensive nor intended to take the place of reading those laws. A link to the revised statutes and regulations can be found on the [KBML's website](#) and the [OIG's website](#). The information provided in this summary should not be considered legal advice or a legal opinion. For specific legal advice, please consult an attorney familiar with such issues.

Naloxone

A physician may, directly or by standing order, prescribe or dispense naloxone to a person or agency who the physician believes is capable of administering the drug for an emergency opioid overdose. [KRS 217.186]

A prescription for naloxone may include authorization for administration of the drug to the person for whom it is prescribed by a third party if the prescribing instructions indicate the need for the third party upon administering the drug to immediately notify a local public safety entity. [KRS 217.186]

A person or agency, including a peace officer, jailer, firefighter, paramedic, EMT, or an authorized school employee, may receive a prescription for naloxone, possess naloxone and any equipment needed for administration, and administer naloxone to an individual suffering from an apparent opiate-related overdose. [KRS 217.186]

A pharmacist who holds a separate certification issued by the Kentucky Board of Pharmacy may, without a prescription, initiate the dispensing of naloxone but only if certain requirements are met, including the pharmacist's adherence to a physician-approved protocol established by the Kentucky Board of Pharmacy in consultation with the Kentucky Board of Medical Licensure before dispensing the drug. [KRS 217.186] ([Back](#))

Domestic Violence

KRS 209A.030 requires a physician, as well as other health care providers, to report suspected spousal abuse or neglect. Death of the suspected victim of spousal abuse does not relieve one of the responsibility for reporting the circumstances surrounding the death. An oral or written report must be made immediately to the cabinet upon knowledge of the suspected abuse or neglect and the report must provide the following information, if known:

- (a) The name and address of the victim;
- (b) The age of the victim;
- (c) The nature and extent of the abuse or neglect, including any evidence of previous abuse or neglect;
- (d) The identity of the perpetrator, if known;
- (e) The identity of the complainant, if possible; and
- (f) Any other information that the person believes might be helpful in establishing the cause of abuse or neglect.

“Abuse” is defined as the infliction of injury, unreasonable confinement, intimidation, or punishment resulting in physical harm or pain, including mental injury [KRS 209A.020(6)]. “Neglect” means a situation in which a person deprives his spouse of reasonable services to maintain health and welfare [KRS 209A.020(9)].

Any representative of the cabinet actively involved in the conduct of an abuse or neglect investigation must be allowed access to the mental and physical health records of the adult which are in the possession of any individual, hospital, or other facility if necessary to complete the investigation [KRS 209A.030(7)].

KRS 209A.050 provides immunity from civil or criminal liability for anyone who has “reasonable cause” to make a report regarding adult abuse.

Federal HIPAA privacy regulations allow physicians to make reports of suspected abuse as long as the report is mandated by state law. As discussed previously, Kentucky does mandate such reports. HIPAA also requires, however, that if a report of abuse is made to state authorities, the patient who is the subject of the report must be informed by the physician of the report. This notice may be made orally rather than in writing, although it would be wise to document such notice. ([Back](#))

Emergency Care

A managed care plan must cover emergency room screening and stabilization without prior authorization as needed for conditions that reasonably appear to constitute an emergency medical condition [KRS 304.17A-580]. An “emergency medical condition” is a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, that a prudent

layperson would reasonably have cause to believe constitutes a condition that the absence of immediate medical attention could reasonably be expected to result in: (1) placing the health of the individual in serious jeopardy; (2) serious impairment of bodily functions; or (3) serious dysfunction of any bodily organ or part; or (4) with respect to a pregnant woman who is having contractions, a situation in which there is inadequate time to affect a safe transfer to another hospital before delivery, or a situation in which transfer may pose a threat to the health or safety of the woman or the unborn child [KRS 304.17A-500(4)].

Where a covered person with an emergency medical condition has been stabilized in the emergency department of a nonparticipating hospital, and an insurer under its health benefit plan requires prior authorization for poststabilization treatment, approval or denial under the preauthorization requirement must be provided in a timely manner appropriate to conditions of the patient and delivery of the services, but in no case to exceed two (2) hours from the time the request is made and all relevant information is provided. The insurer's failure to make a determination within the two (2) hour time frame constitutes an authorization for the hospital to provide the medical service for which prior authorization was sought [KRS 304.17A-641]. ([Back](#))

Emergency Medical Treatment and Active Labor Act (EMTALA)

This material was prepared by the American Medical Association and is intended as an abbreviated summary of what is expected of on-call physicians under EMTALA. For more extensive information regarding requirements and obligations for EMTALA compliance, physicians are urged to review the EMTALA statutes, relevant EMTALA regulations, and obtain appropriate counsel from their own attorneys.

What is the Emergency Medical Treatment and Active Labor Act (EMTALA)?

EMTALA is the federal "anti-dumping law" enacted by Congress in 1986 to assure that patients who come to hospitals for treatment of an emergency medical condition are not turned away or transferred to another facility, based on their ability to pay. It applies to any patient who seeks care, whether the patient's access is through the emergency department or any other department of the hospital.

What are the responsibilities of hospitals and what treatment and services must be provided to be in compliance with EMTALA?

- ❑ Provide an appropriate medical screening examination to all individuals seeking emergency services to determine the presence or absence of an emergency medical condition either by a physician or other qualified medical personnel as specified in medical staff bylaws, rules and regulations, or policy and procedures.
- ❑ Stabilize the medical condition of the individual, within the capabilities of the staff and facilities available at the hospital, prior to discharge or transfer.
 - Obstetrical patients with contractions are considered unstable until delivery of baby and placenta.
- ❑ An unstable patient cannot be transferred unless the patient (or a person acting on his or her behalf) requests the transfer or the transferring physician certifies in writing that the medical benefits of the transfer, outweigh the risks, and is in the best medical interest of the patient.
 - Stabilize within the hospital's capabilities to minimize the risk of the transfer.
 - Obtain the acceptance of the receiving hospital.
 - Send all pertinent medical records available at the time of the transfer to the receiving hospital.
 - Effect the transfer through qualified persons and transportation equipment (including life support measures)
- ❑ A receiving hospital, with specialized capabilities, must accept a patient transfer unless that acceptance would exceed its capability and capacity for providing care.
- ❑ Hospitals are responsible for ensuring that on-call physicians respond within a reasonable period of time.
- ❑ The hospital must provide the name and address of any on-call physician who refused to respond or failed to make a timely response, along with the transfer records, of any patient transferred as a result of that refusal or lack of timely response.
- ❑ Prior to screening and stabilization, the hospital emergency department may follow normal registration processes, as long as they **do not delay care**, and prior authorization is not received before screening or commencing stabilizing treatment is allowed.
- ❑ Conspicuous signage must be posted in the emergency department stating the rights of individuals under EMTALA

and whether the hospital participates in the Medicaid program; and also maintain a 24 hour/7-day (24/7) on-call schedule of physicians taking call for the emergency department.-

What is an on-call list?

An on-call list is a roster of physicians providing the date and time when those physicians are scheduled to respond to the hospital to provide evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition. The list is to be comprised: (1) in a manner that best meets the needs of the patients who receive care under EMTALA; and (2) in accordance with the hospital's resources, which includes the availability of on-call physicians. The on-call list must include specialists and sub-specialists routinely available to the Emergency Department. Hospitals may establish a reasonable on-call schedule other than 24/7 if they are unable to secure agreement by physicians to take call round-the-clock because of the dearth of specialists in the area.

- ❑ The on-call list is maintained by the hospital and medical staff and must be immediately updated to reflect any changes in physician staffing.
- ❑ Physicians whose names appear on the on-call list are responsible for finding a suitable replacement if they cannot be available for duty and for updating the on-call list with the replacement physician's name and other appropriate information.

Which medical staff documents define the responsibilities of on-call physicians?

- ❑ The medical staff bylaws, rules and regulations, or policies and procedures should define the responsibility of on-call physicians to respond, examine and treat patients with emergency medical conditions.
- ❑ The medical staff and hospital should have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.
- ❑ Hospitals must have written policies and procedures in place: (1) to respond to situations when a particular specialty is not available; (2) to respond to situations when an on-call physician cannot respond due to circumstances out of his control; and (3) to provide that emergency services are available to meet patients' needs if it permits physicians to schedule elective surgery during on-call duties or allows physicians to have simultaneous on-call duties.

What are the responsibilities of on-call physicians to be in compliance with EMTALA?

- ❑ On-call physicians **MUST** respond to the hospital when requested to attend to patients in a timely manner and complete a medical screening examination or provide stabilizing care. *CMS has not set a specific rule for response time, but some CMS officials have mentioned 30 minutes.*
- ❑ The transferring physician **MUST** discuss the case with the receiving hospital's authorized representative and obtain agreement to accept the patient in transfer. (All hospitals with specialized capabilities, including physician specialists, have a responsibility to accept a transfer when such transfer is necessary to stabilize an emergency medical condition .)
- ❑ On-call physicians, who may be on-call at another hospital, simultaneously, **MUST NOT** request that a patient be transferred to a second hospital for the physician's convenience.
- ❑ On-call physicians who, as part of their routine responsibilities, are charged with the duty to accept patients transferred from other facilities, may not refuse any unstable transfer as long as their hospital has the capability and capacity to provide treatment.
- ❑ Hospitals may permit physicians: (1) to schedule elective surgery during the time they are on-call; and (2) to have simultaneous on-call duties among different hospitals in the community. If a physician is unable to respond to call due to performing surgery or responding to call at another facility, then he/she is not required to respond because the situation would be considered beyond the physician's control.
- ❑ Under EMTALA, physicians are not required to take call or to be on-call at all times.

Can an emergency patient be sent to the office of an on-call physician for the medical screening exam and stabilization?

No, not unless the on-call physician's office is located in a hospital-owned building which is contiguous or located in a hospital-owned building that is "on campus" and the service must be billed under the hospital's provider number. (New Outpatient Prospective Payment System regulations may change this guideline)

A patient can be transferred to a physician's office IF the physician's office has specialized equipment and capability that the transferring hospital does not have. The transferring physician must certify that the medical benefits of the transfer outweigh the risks and it is in the best medical interest of the patient. Under no circumstance should a patient be transferred for the convenience of the physician.

What are the possible penalties or sanctions for EMTALA violations?

Medicare-participating hospitals and physicians found to be in violation of EMTALA could be sanctioned as follows:

- ❑ Termination of the hospital and/or physician Medicare provider agreement.
- ❑ Imposition of civil monetary penalties against the hospital with 100 or more beds of \$50,000, per violation. The fine per violation for hospitals with less than 100 beds cannot exceed \$25,000.
- ❑ Civil monetary penalties for physicians can be up to \$50,000 per violation.
- ❑ On-call physicians responsible for examination, treatment, or transfer of an individual are subject to potential civil fines of up to \$50,000 per violation for failing to come to the hospital, and may be excluded from Medicare.
- ❑ "EMTALA provides a private right of action against a hospital for an EMTALA violation. There is no private right of action, however, against a physician for violating EMTALA. ...Private EMTALA actions are subject to a two-year statute of limitations."

What if an on-call physician refuses or fails to show up or answer when called?

The physician's name and address will be included in the medical record and he or she may be subject to sanctions. Hospitals may, however, permit physicians: (1) to schedule elective surgery during the time they are on-call; and (2) to have simultaneous on-call duties among different hospitals in the community. If a physician is unable to respond to call due to performing surgery or responding to call at another facility, then he/she is not required to respond because the situation would be considered beyond the physician's control.

Important terms under EMTALA

Emergency medical condition: The statute defines an "emergency medical condition" as:

- (A) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:
 - (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,
 - (ii) serious impairment to bodily functions, or
 - (iii) serious dysfunction of any bodily organ or part; or
- (B) with respect to a pregnant woman who is having contractions --
 - (i) there is inadequate time to effect a safe transfer to another hospital before delivery, or
 - (ii) that transfer may pose a threat to the health or safety of the woman or unborn child.

Medical Screening Exam (MSE): "The process required to reach with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist. If a hospital applies in a nondiscriminatory manner (i.e., a different level of care must not exist based on payment status, race, national origin) a screening process that is reasonably calculated to determine whether a medical emergency condition exists, it has met its obligations under [EMTALA]. Depending on the patient's presenting symptoms, the medical screening examination represents a spectrum ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans, and/or diagnostic tests and procedures."

Stabilization: Under the statute, "to stabilize" an emergency medical condition means "to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to [a pregnant woman], to deliver (including the placenta)."

Transfer: "Movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by or affiliated or associated, directly or indirectly, with the hospital, *but does not include such a movement of an individual who:* (A) has been declared dead, or (B) leaves the facility without the permission of any such person." ([Back](#))

Employee Retirement Income Security Act (ERISA)

The Employee Retirement Income Security Act of 1974 (ERISA) is a comprehensive federal statute that imposes minimum standards on employee benefit plans [29 U.S.C. § 1002(1)]. The statute broadly includes any plan, fund or program maintained for the purpose of providing employees with any number of benefits such as pension, health care, disability, death or vacation benefits.

It is primarily a remedial statute with two purposes: (1) to protect the financial solvency of employee pension and health benefits, and (2) to give employers and unions greater flexibility to provide benefits without conflicting state regulations.

To achieve these goals, ERISA sets forth a complex and detailed federal system, which “pre-empts” (overrides) the regulation or application of most state laws. This pre-emption clause expressly provides that ERISA supersedes all state laws insofar as they even “relate to any employee benefit plan” [29 U.S.C. § 1144(a)]. ERISA provides an exception for any law that specifically “regulates insurance, banking or securities,” but employee benefit plans are deemed not to be insurance companies by statutory definitions [29 U.S.C. § 1144(b)(2)(A)].

Courts interpreting ERISA, consequently, have virtually unanimously upheld its pre-emption of state benefit or insurance laws, even where the courts suspected the benefits plans had engaged in discrimination or bad faith. Although this result likely was not intended by ERISA’s authors (who believed the federal government would be more sympathetic than the states to employee rights), the preemption clause which appeared reasonable in 1974 has proved to be a significant detriment to the provision of health care and the availability of health care benefits.

This development has occurred in large part due to dramatic changes in the provision of health care benefits and related costs. When ERISA was enacted, only a minimal number of larger employers had self-insured plans. The field rapidly changed, however, as health care cost increases served as a catalyst in the growth of ERISA plans that successfully challenged any state intervention or impact. Over the years, court rulings established that ERISA plans were exempt from state laws and requirements relating to insurance premium taxes; mandated benefits; taxes and charges related to funding uninsured risk pools and uncompensated care; and in several recent decisions, even state anti-discrimination laws and tort actions for bad faith practices.

As employers have discovered the considerable cost control potential and legal protections offered by ERISA, the number of self-insured health plans have soared. In Kentucky, more than 50% of all persons with some form of health insurance are members of self-insured plans covered by ERISA. This means many of Kentucky’s insurance reforms do not apply to over half of the insured population, which has also served to ally business as a powerful force to counteract ERISA reform efforts.

In recent years, employers and unions operating self-insured plans (which typically are managed in-house or through contracts with insurers as third party administrators), have recognized ERISA’s tremendous loophole potential. These entities increasingly have tested the law’s limits by aggressively reducing or withdrawing certain types of expensive or long-term benefits in the name of cost containment.

Accordingly, ERISA carries no penalties comparable to those offered under state law to deter misconduct. Moreover, attorneys have no incentive to represent plaintiffs in complex, time consuming cases that generally involve claims of less than \$5,000 and no guarantee of fees.

ERISA also has proved to be a significant detriment to state efforts to increase access to health care for the uninsured. A number of states attempting to enact reforms to improve access have been frustrated because ERISA bars any legislation “relating to” a benefits plan. Under this rationale, self-insured plans have been able to invoke ERISA pre-emption to avoid paying taxes on insurance premiums or taxes to fund state risk pools. As a result, ERISA has substantially limited states’ ability to finance health care proposals.

On the cost containment front, ERISA pre-emption does allow self-insured plans greater flexibility to control costs and to escape numerous and often expensive state insurance requirements such as state-mandated benefits provisions.

ERISA will continue to cause access problems by allowing benefit plans to: (1) continue engaging in bad faith and discriminatory practices due to lack of state or adequate federal regulation; and (2) avoid state health reform efforts. While recent court opinions have begun to chip away at ERISA’s pre-emption of some state laws, legislative relief may be needed to close this significant loophole for self-insured plans. [\(Back\)](#)

False Claims

The most dangerous area of potential fraud and abuse for physicians is in the submission of claims. If a physician claims additional payments above what is allowed or fills out a claim improperly, several laws apply which have a variety of penalties. In some cases, the physician has to “know” the claim was submitted improperly, while in other instances the standard is whether the physician “should have known.” Such a broad standard can subject almost any physician to liability.

Of the numerous laws available to penalize physicians for improper coding, some of them are criminal in nature and subject physicians to possible prison sentences. Others, however, are civil in nature and may not result in prison sentences, but may involve substantial monetary penalties. The most common law used against physicians is the False Claims Act, which allows for *quit tam* lawsuits to be brought by competitors, employees or patients. Below is a discussion of some of the criminal and civil statutes that

may be used against physicians.

False Claims--Criminal Statutes

1. *Health Care Fraud* (18 USC § 1347): This statute was passed as part of the Health Insurance Portability and Accountability Act of 1996 and provides criminal penalties, which include up to ten years imprisonment and forfeiture of property, for violations of the law. The law prohibits defrauding health care benefit programs by the use of false pretenses or representations. This includes the submission of a "false claim." The statute does provide that the violation must be "knowing and willful," which means the government must show actual intent to violate the law. However, the real danger this law presents concerns its applicability to "any health care benefit program." Such language means the statute applies, not just to claims submitted to Medicare or Medicaid, but also claims submitted to private health insurance plans.
2. *Social Security Act* [42 USC § 1320a-7b(a)(1)-(2)]: This law provides penalties for making a false statement of a material fact in any application for any payment under a federal health care program, although it does not apply to claims submitted to private insurance companies. The language of this statute is very broad because it says a claim submitted to the government cannot contain "any false statement of a material fact." Violations of this law must be "knowing and willful" and can result in up to five years imprisonment.
3. *Mail and Wire Fraud* (18 USC § 1341 and 18 USC § 1343): These statutes make it a crime to commit fraud by use of the mail or wire services. If a physician mails, faxes, or phones in a claim that is false, one of these laws has been violated. Over the years, these statutes have been used to prosecute many different people, including members of organized crime, because almost everyone who commits a criminal act uses the phone or mail to help commit the crime. Violations of these laws can result in up to five years imprisonment.
4. *Money Laundering* (18 USC § 1956-57): This law makes it illegal to engage in a "monetary transaction in criminally derived property" if the money derives from "specified unlawful activity" including any offense involving a Federal health care offense. While this statute is criminal in nature, it also has tough forfeiture provisions that allow the government to confiscate any property that was bought with "tainted" money. Therefore, if a false claim is submitted and the money from those claims is used to buy a house, the government can take the house.
5. *Making False Statements* (18 USC § 1035): This law is similar to the provisions of the Social Security Act discussed above; however, it specifically prohibits making "material" statements in the connection of delivering or receiving payment for health care benefits or services. The law must be violated "knowingly and willfully" and provides for up to five years imprisonment. As with the Health Care Fraud law discussed above, this statute also applies to both public and private health plans.
6. *Theft or Embezzlement* (18 USC § 669): This statute makes it illegal to willfully embezzle or steal "moneys, funds, securities, premiums, credits, property or other assets of a health care benefit program." Penalties include up to ten years imprisonment.

False Claims--Civil Statutes

1. *Social Security Act* [42 USC § 1320a-7a(a)]: This law provides authority for the government to impose civil money penalties for certain actions involving federal health care programs, including the submission of false claims. To violate this law, one must have known or "should have known" the claim submitted was false. This is a broad standard and allows the government to easily argue that the physician who provided the service was in the best position to have known what information should have been put on a claim. The law defines "should know" as "acting in deliberate ignorance of the truth or falsity of the information" or "in reckless disregard of the truth or falsity of the information."

This law applies to a claim that:

- Is for a medical item or service that the person knows or should know is not provided as claimed.
- Is for a Medicare item or service and the person knows or should know the claim is false or fraudulent.
- Is presented for a physician service by a person who knows or should know that the individual who provided the service was not a licensed physician.

A specific civil money penalty for physicians executing a certification that a patient meets the requirements for home health services has also been added. Penalties include \$10,000 for each item claimed plus three times the amount of the claim.

2. *Federal False Claims Act* (31 USC § 3729): This law prohibits a person from knowingly submitting claims in order to secure payment from the Federal government for a false or fraudulent claim. The law was passed during the Civil War to ensure that government contractors could be prosecuted for submitting inflated claims for payment of goods provided to the government. In the past, this law was used against other government contractors, but

has become very popular in the health care field because of the number of health care claims submitted to the government each year. Another reason this law is so popular is because it encourages *qui tam* suits, which allow an individual to report a person or entity for submitting false claims and if liability is found by a court, the person who reported the violation shares in the amount of money recovered. If the person who reports the violation is an employee of the physician who is reported, the employee is protected from retribution under the “whistleblower” provisions of federal law. That means such an employee cannot be sanctioned or fired for reporting the offense. The penalties for violations of this law include a civil penalty of up to \$10,000 for each violation (\$10,000 for each claim submitted); triple damages (three times the amount of the claim); and, payment of the costs associated with bringing the action.

State Law

Kentucky law also has provisions regarding the submission of false claims and false statements.

1. KRS 205.8463
 - a. Section 1
 - Prohibits anyone from knowingly or wantonly devising a scheme or conspiracy to obtain payments under the Medicaid program by means of any false application, claim, report, or documents submitted to the Cabinet for Human Resources.
 - b. Section 2
 - Prohibits anyone from intentionally, knowingly, or wantonly making to any employee of the Cabinet for Human Resources any false, or fraudulent statement, or entry in any application, claim, report, or document used in determining rights to any benefit or payment.
 - Note that this section does not limit itself to Medicaid.
 - c. Section 3
 - Prohibits a person from making a false statement or false representation of a material fact to allow an institution, facility or provider to qualify for services under the Medicaid program.
 - d. Section 4
 - No person can knowingly falsify, conceal or cover-up any scheme or make any false statement or representation or use any false writing or document knowing the same to contain any false statement or entry.
 - e. Section 5
 - Penalties for Sections 1 and 2 can be a Class A Misdemeanor unless the total amount is valued at \$300 or more, in which case it shall be a Class D Felony. Violations of Section 3 shall be a Class C Felony and violations of Section 4 will be a Class D Felony. A violation of any of the subsections can also lead to a loss of a physician’s license for up to five years.
2. KRS 304.47.020: This law provides criminal penalties for intentionally submitting a false claim to an insurance company.

Examples

1. *Billing for services not rendered*. This example is fairly straightforward. If a physician submits a claim for services or supplies not provided, it is clearly a fraudulent claim.
1. *Upcoding*: This concerns the practice of submitting claims in which a billing code is used that provides a higher payment rate than the billing code that should be used.
2. *Unbundling*: This is the practice in which a physician uses two or more codes in a claim when a single, more comprehensive code exists that accurately describes the procedure. An example the General Accounting Office has used to show this practice concerns a physician who is paid for two x-ray exams of the abdominal region on the same date of service, but according to the CPT code descriptions, an x-ray of the upper gastrointestinal tract includes the x-ray of the abdomen and may only be billed once.
3. *Waiver of Coinsurance and Deductibles*: Waivers of coinsurance and deductibles may present legal problems when they are done for any reason other than the financial need of the patient. In the false claims arena, waivers of coinsurance and deductibles may be a misstatement of the actual charge for a service. For example, if a physician claims that the charge for his service is \$100, but routinely waives the co-payment, which is \$20, the actual charge is \$80. The carrier, therefore, should be paying 80% of \$80, rather than 80% of \$100.

[\(Back\)](#)

Fee Schedules

An insurer issuing a managed care plan in Kentucky must, upon request of a health care provider, provide or make available to the health care provider, when contracting or renewing an existing contract with such provider, the payment or fee schedules or other information sufficient to enable the health care provider to determine the manner and amount of payments under the contract for the health care provider's services prior to final execution or renewal of the contract. The payment or fee schedule or other information submitted to a health care provider must include a description of processes and factors that may be applicable and that may affect actual payment, including copayments, coinsurance, deductibles, risk sharing arrangements, and liability of third parties. Nothing in this requirement prohibits a plan from making any part of the information requested available electronically or via a Web site. [KRS 304.17A-577(1)(a)]

An insurer issuing a managed care plan, upon request of a health care provider, must provide or make available to the health care provider an explanation of the methodology, such as relative value unit system and conversion factor, percentage of Medicare payment system, or percentage of billed charges, used to determine actual payment for procedures frequently performed by the provider that involve combinations of services or payment codes, if the actual payment for the procedures cannot be ascertained from the fee schedule or other information submitted to a health care provider. As applicable, the methodology disclosure must include:

- The name of any relative value system;
- The version, edition, or publication date of the relative value system; and
- Any applicable conversion or geographic factor.

Nothing in this requirement prohibits a plan from making any part of the information requested available electronically or via a Web site. [KRS 304.17A-577(1)(b)] In addition, requiring the submission of a fee schedule or other information upon renewal of an existing contract is not applicable to renewal of an existing contract when the payment or fee schedule previously provided to the health care provider has not changed. [KRS 304.17A-577(1)(c)]

A health care provider receiving such fee schedule information may not share this information with an unrelated person without the prior written consent of the insurer. The remedies available to an insurer to enforce this requirement include without limitation injunctive relief. An insurer seeking extraordinary relief to enforce this requirement may not be required to establish irreparable harm with regard to the sharing of competitively sensitive information. [KRS 304.17A-577(3)]

Any change to payment or fee schedules applicable to providers under contract with an insurer issuing a managed care plan must be made available to such providers at least ninety (90) days prior to the effective date of the amendment. This does not apply to changes in standard codes and guidelines developed by the American Medical Association or similar organization. [KRS 304.17A-577(2)] ([Back](#))

Fraud Alerts

To put the health care community on notice of certain actions that may constitute fraud and abuse, the government occasionally issues what have become known as "Fraud Alerts." These bulletins give specific examples of practices that the Department for Health and Human Services, Office of Inspector General (OIG) believes constitute fraud and abuse. Over the past several years, there have been a number of such fraud alerts issued. Below are those alerts issued by the government that have involved physicians. Throughout the discussion, the word "we" refers to the Office of Inspector General (OIG). The entire fraud alert is not always reproduced word-for-word, but instead includes those portions relevant to physician practices. Copies of all OIG Special Fraud Alerts are available at oig.hhs.gov/compliance/alerts/index.asp.

FRAUD ALERT # 2-2000

RENTAL OF SPACE IN PHYSICIAN OFFICES BY PERSONS OR ENTITIES TO WHICH PHYSICIANS REFER

This Special Fraud Alert focuses on the rental of space in physicians' offices by persons or entities that provide health care items or services (suppliers) to patients that are referred either directly or indirectly by their physician-landlords. In this Special Fraud Alert, we describe some of the potentially illegal practices the OIG has identified in such rental relationships.

Questionable Rental Arrangements For Space in Physician Offices

A number of suppliers that provide health care items or services rent space in the offices of physicians or other practitioners. Typically, most of the items or services provided in the rented space are for patients, referred or sent, either directly or indirectly, to the supplier by the physician-landlord. In particular, we are aware of rental arrangements between physician-landlords and:

- comprehensive outpatient rehabilitation facilities (CORFs) that provide physical and occupational therapy and speech-language pathology services in physicians' and other practitioners' offices;
- mobile diagnostic equipment suppliers that perform diagnostic related tests in physicians' offices; and
- suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) that set up "consignment closets" for their supplies in physicians' offices.

The OIG is concerned that in such arrangements, the rental payments may be disguised kickbacks to the physician-landlords to induce referrals. We have received numerous credible reports that in many cases, suppliers, whose businesses depend on physicians' referrals, offer and pay "rents" -- either voluntarily or in response to physicians' requests -- that are either unnecessary or in excess of the fair market value for the space to access the physicians' potential referrals.

The Anti-Kickback Law Prohibits Any Payments to Induce Referrals

Kickbacks can distort medical decision-making, cause overutilization, increase costs and result in unfair competition by freezing out competitors who are unwilling to pay kickbacks. Kickbacks can also adversely affect the quality of patient care by encouraging physicians to order services or recommend supplies based on profit rather than the patients' best medical interests.

Section 1128B(b) of the Social Security Act (the Act) prohibits knowingly and willfully soliciting, receiving, offering or paying anything of value to induce referrals of items or services payable by a Federal health care program. Both parties to an impermissible kickback transaction are liable. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. The OIG may also initiate administrative proceedings to exclude persons from Federal health care programs or to impose civil money penalties for fraud, kickbacks and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

Suspect Rental Arrangements For Space in Physician Offices

The questionable features of suspect rental arrangements for space in physicians' offices may be reflected in three areas:

- the appropriateness of rental agreements;
- the rental amounts; and
- time and space considerations.

Below, we examine these suspect areas, which separately or together may result in an arrangement that violates the anti-kickback statute, in order to help identify questionable rental arrangements between physicians and the suppliers to which they refer patients. This list is not exhaustive, but rather gives examples of indicators of potentially unlawful activity.

Appropriateness of Rental Agreements. The threshold inquiry when examining rental payments is whether payment for rent is appropriate at all. Payments of "rent" for space that traditionally has been provided for free or for a nominal charge as an accommodation between the parties for the benefit of the physicians' patients, such as consignment closets for DMEPOS, may be disguised kickbacks. In general, payments for rent of consignment closets in physicians' offices are suspect.

Rental Amounts. Rental amounts should be at fair market value, be fixed in advance and not take into account, directly or indirectly, the volume or value of referrals or other business generated between the parties. Fair market value rental payments should not exceed the amount paid for comparable property. Moreover, where a physician rents space, the rate paid by the supplier should not exceed the rate paid by the physicians in the primary lease for their office space, except in rare circumstances. Examples of suspect arrangements include:

- rental amounts in excess of amounts paid for comparable property rented in arms-length transactions between persons not in a position to refer business;
- rental amounts for subleases that exceed the rental amounts per square foot in the primary lease;
- rental amounts that are subject to modification more often than annually;
- rental amounts that vary with the number of patients or referrals;
- rental arrangements that set a fixed rental fee per hour, but do not fix the number of hours or the schedule of usage in advance (i.e., "as needed" arrangements);
- rental amounts that are only paid if there are a certain number of Federal health care program beneficiaries referred each month; and
- rental amounts that are conditioned upon the supplier's receipt of payments from a Federal health care program.

Time and Space Considerations. Suppliers should only rent premises of a size and for a time that is reasonable and necessary for a commercially reasonable business purpose of the supplier. Rental of space that is in excess of suppliers' needs creates a presumption that the payments may be a pretext for giving money to physicians for their referrals. Examples of suspect arrangements include:

- rental amounts for space that is unnecessary or not used. For instance, a CORF requires one examination room and rents physician office space one afternoon a week when the physician is not in the office. The CORF calculates its rental payment on the square footage for the entire office, since it is the only occupant during that time, even though the CORF only needs one examination room;
- rental amounts for time when the rented space is not in use by the supplier. For example, an ultrasound supplier has enough business to support the use of one examination room for four hours each week, but rents the space for an amount equivalent to eight hours per week;
- non-exclusive occupancy of the rented portion of space. For example, a physical therapist does not rent space in a physician's office, but rather moves from examination room to examination room treating patients after they have been seen by the physician. Since no particular space is rented, we will closely scrutinize the proration of time and space used to calculate the therapist's "rent".

In addition, rental amount calculations should prorate rent based on the amount of space and duration of time the premises are used. The basis for any proration should be documented and updated as necessary. Depending on the circumstances, the supplier's rent can consist of three components: (1) exclusive office space; (2) interior office common space; and (3) building common space.

1. Apportionment of exclusive office space - The supplier's rent should be calculated based on the ratio of the time the space is in use by the supplier to the total amount of time the physician's office is in use. In addition, the rent should be calculated based on the ratio of the amount of space that is used exclusively by the supplier to the total amount of space in the physician's office. For example, where a supplier rents an examination room for four hours one afternoon per week in a physician's office that has four examination rooms of equal size and is open eight hours a day, five days per week, the supplier's prorated annual rent would be calculated as follows:

Physician Office Rent Per Day	% of Physician Office Space Rented by Supplier	% of Each Day Rented by Supplier	No. of Days Rented by Supplier Per Year	= Supplier's annual rent for exclusive space
<u>Annual rent of primary lease</u> no. of work days per year	X $\frac{\text{sq. ft. exclusively occupied by supplier}}{\text{total office sq. ft.}}$ X	$\frac{4 \text{ hours}}{8 \text{ hours}}$ X	52 days (i.e., 1 day per week)	

2. Apportionment of interior office common space - When permitted by applicable regulations, rental payments may also cover the interior office common space in physicians' offices that are shared by the physicians and any subtenants, such as waiting rooms. If suppliers use such common areas for their patients, it may be appropriate for the suppliers to pay a prorated portion of the charge for such space. The charge for the common space must be apportioned among all physicians and subtenants that use the interior office common space based on the amount of non-common space they occupy and the duration of such occupation. Payment for the use of office common space should not exceed the supplier's pro rata share of the charge for such space based upon the ratio of the space used exclusively by the supplier to the total amount of space (other than common space) occupied by all persons using such common space.
3. Apportionment of building common space - Where the physician pays a separate charge for areas of a building that are shared by all tenants, such as building lobbies, it may be appropriate for the supplier to pay a prorated portion of such charge. As with interior office common space, the cost of the building common space must be apportioned among all physicians and subtenants based on the amount of non-common space they occupy and the duration of such occupation. For instance, in the example in number one above, the supplier's share of the additional levy for building common space could not be split 50/50.

The Space Rental Safe Harbor Can Protect Legitimate Arrangements

We strongly recommend that parties to rental agreements between physicians and suppliers to whom the physicians refer or for which physicians otherwise generate business make every effort to comply with the space rental safe harbor to the anti-kickback statute. [See 42 CFR 1001.952(b), as amended by 64 FR 63518 (November 19, 1999)]. When an arrangement meets all of the criteria of a safe harbor, the arrangement is immune from prosecution under the anti-kickback statute. The following are the safe harbor criteria, all of which must be met:

- The agreement is set out in writing and signed by the parties.
- The agreement covers all of the premises rented by the parties for the term of the agreement and specifies the premises covered by the agreement.

- If the agreement is intended to provide the lessee with access to the premises for periodic intervals of time rather than on a full-time basis for the term of the rental agreement, the rental agreement specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- The term of the rental agreement is for not less than one year.
- The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.
- The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

Arrangements for office equipment or personal services of physicians' office staff can also be structured to comply with the equipment rental safe harbor and personal services and management contracts safe harbor. (See 42 CFR 1001.952(c) and (d), as amended by 64 FR 63518 (November 19, 1999)). Specific equipment used should be identified and documented and payment limited to the prorated portion of its use. Similarly, any services provided should be documented and payment should be limited to the time actually spent performing such services.

FRAUD ALERT # 1-99

PHYSICIAN LIABILITY FOR CERTIFICATIONS IN THE PROVISION OF MEDICAL EQUIPMENT AND SUPPLIES AND HOME HEALTH SERVICES

We are issuing this Fraud Alert because physicians may not appreciate the legal and programmatic significance of certifications they make in connection with the ordering of certain items and services for their Medicare patients. While the OIG believes that the actual incidence of physicians' intentionally submitting false or misleading certifications of medical necessity for durable medical equipment or home health care is relatively infrequent, physician laxity in reviewing and completing these certifications contributes to fraudulent and abusive practices by unscrupulous suppliers and home health providers. We urge physicians and their staff to report any suspicious activity in connection with the solicitation or completion of certifications to the OIG.

Physicians should also be aware that they are subject to substantial criminal, civil, and administrative penalties if they sign a certification knowing that the information relating to medical necessity is false, or with reckless disregard as to the truth of the information being submitted. While a physician's signature on a false or misleading certification made through mistake, simple negligence, or inadvertence will not result in personal liability, the physician may unwittingly be facilitating the perpetration of fraud on Medicare by suppliers or providers. Accordingly, we urge all physicians to review and familiarize themselves with the information in this Fraud Alert. If a physician has any questions as to the application of these requirements to specific facts, the physician should contact the appropriate Medicare Fiscal Intermediary or Carrier.

The Importance of Physician Certification for Medicare

The Medicare program only pays for health care services that are medically necessary. In determining what services are medically necessary, Medicare primarily relies on the professional judgment of the beneficiary's treating physician, since he or she knows the patient's history and makes critical decisions, such as admitting the patient to the hospital; ordering tests, drugs, and treatments; and determining the length of treatment. In other words, the physician has a key role in determining both the medical need for, and utilization of, many health care services, including those furnished and billed by other providers and suppliers.

Congress has conditioned payment for many Medicare items and services on a certification signed by a physician attesting that the item or service is medically necessary. For example, physicians are routinely required to certify to the medical necessity for any service for which they submit bills to the Medicare program.

Physicians also are involved in attesting to medical necessity when ordering services or supplies that must be billed and provided by an independent supplier or provider. Medicare requires physicians to certify to the medical necessity for many of these items and services through prescriptions, orders, or, in certain specific circumstances, Certificates of Medical Necessity (CMNs). These documentation requirements substantiate that the physician has reviewed the patient's condition and has determined that services or supplies are medically necessary.

Two areas where the documentation of medical necessity by physician certification plays a key role are (i) home health services and (ii) durable medical equipment (DME). Through various OIG audits, we have discovered that physicians sometimes fail to discharge their responsibility to assess their patients' conditions and need for home health care. Similarly, the OIG has found numerous examples of physicians who have ordered DME or signed CMNs for DME without reviewing the medical necessity for the item or even knowing the patient.

Physician Certification for Home Health Services

Medicare will pay a Medicare-certified home health agency for home health care provided under a physician's plan of care to a patient confined to the home. Covered services may include skilled nursing services, home health aide services, physical and occupational therapy and speech language pathology, medical social services, medical supplies (other than drugs and biologicals), and DME.

As a condition for payment, Medicare requires a patient's treating physician to certify initially and recertify at least every 62 days (2 months) that:

- the patient is confined to the home;
- the individual needs or needed (i) intermittent skilled nursing care; (ii) speech or physical therapy or speech-language pathology services; or (iii) occupational therapy or a continued need for occupational therapy (payment for occupational therapy will be made only upon an initial certification that includes care under (i) or (ii) or a recertification where the initial certification included care under (i) or (ii));
- a plan of care has been established and periodically reviewed by the physician; and
- the services are (were) furnished while the patient is (was) under the care of a physician.

The physician must order the home health services, either orally or in writing, prior to the services being furnished. The physician certification must be obtained at the time the plan of treatment is established or as soon thereafter as possible. The physician certification must be signed and dated prior to the submission of the claim to Medicare. If a physician has any questions as to the application of these requirements to specific facts, the physician should contact the appropriate Medicare Fiscal Intermediary or Carrier.

Physician Orders and Certificates of Medical Necessity for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Home Use

DME is equipment that can withstand repeated use, is primarily used for a medical purpose, and is not generally used in the absence of illness or injury. Examples include hospital beds, wheelchairs, and oxygen delivery systems. Medicare will cover medical supplies that are necessary for the effective use of DME, as well as surgical dressings, catheters, and ostomy bags. However, Medicare will only cover DME and supplies that have been ordered or prescribed by a physician. The order or prescription must be personally signed and dated by the patient's treating physician.

DME suppliers that submit bills to Medicare are required to maintain the physician's original written order or prescription in their files. The order or prescription must include:

- the beneficiary's name and full address;
- the physician's signature;
- the date the physician signed the prescription or order;
- a description of the items needed;
- the start date of the order (if appropriate); and
- the diagnosis (if required by Medicare program policies) and a realistic estimate of the total length of time the equipment will be needed (in months or years).

For certain items or supplies, including supplies provided on a periodic basis and drugs, additional information may be required. For supplies provided on a periodic basis, appropriate information on the quantity used, the frequency of change, and the duration of need should be included. If drugs are included in the order, the dosage, frequency of administration, and, if applicable, the duration of infusion and concentration should be included.

Medicare further requires claims for payment for certain kinds of DME to be accompanied by a CMN signed by a treating physician (unless the DME is prescribed as part of a plan of care for home health services). When a CMN is required, the provider or supplier must keep the CMN containing the treating physician's original signature and date on file.

Generally, a CMN has four sections:

- Section A contains general information on the patient, supplier, and physician. Section A may be completed by the supplier.
- Section B contains the medical necessity justification for DME. This cannot be filled out by the supplier. Section B must be completed by the physician, a non-physician clinician involved in the care of the patient, or a physician employee. If the physician did not personally complete section B, the name of the person who did complete section B and his or her title and employer must be specified.
- Section C contains a description of the equipment and its cost. Section C is completed by the supplier.

- Section D is the treating physician's attestation and signature, which certifies that the physician has reviewed sections A, B, and C of the CMN and that the information in section B is true, accurate, and complete. Section D must be signed by the treating physician. Signature stamps and date stamps are not acceptable.

By signing the CMN, the physician represents that:

- he or she is the patient's treating physician and the information regarding the physician's address and unique physician identification number (UPIN) is correct;
- the entire CMN, including the sections filled out by the supplier, was completed prior to the physician's signature; and
- the information in section B relating to medical necessity is true, accurate, and complete to the best of the physician's knowledge.

Improper Physician Certifications Foster Fraud

Unscrupulous suppliers and providers may steer physicians into signing or authorizing improper certifications of medical necessity. In some instances, the certification forms or statements are completed by DME suppliers or home health agencies and presented to the physician, who then signs the forms without verifying the actual need for the items or services. In many cases, the physician may obtain no personal benefit when signing these unverified orders and is only accommodating the supplier or provider. While a physician's signature on a false or misleading certification made through mistake, simple negligence, or inadvertence will not result in personal liability, the physician may unwittingly be facilitating the perpetration of fraud on Medicare by suppliers or providers. When the physician knows the information is false or acts with reckless disregard as to the truth of the statement, such physician risks criminal, civil, and administrative penalties.

Sometimes, a physician may receive compensation in exchange for his or her signature. Compensation can take the form of cash payments, free goods, or any other thing of value. Such cases may trigger additional criminal and civil penalties under the anti-kickback statute.

The following are examples of inappropriate certifications uncovered by the OIG in the course of its investigations of fraud in the provision of home health services and medical equipment and supplies:

- A physician knowingly signs a number of forms provided by a home health agency that falsely represent that skilled nursing services are medically necessary in order to qualify the patient for home health services.
- A physician certifies that a patient is confined to the home and qualifies for home health services, even though the patient tells the physician that her only restrictions are due to arthritis in her hands, and she has no restrictions on her routine activities, such as grocery shopping.
- At the prompting of a DME supplier, a physician signs a stack of blank CMNs for transcutaneous electrical nerve stimulators (TENS) units. The CMNs are later completed with false information in support of fraudulent claims for the equipment. The false information purports to show that the physician ordered and certified to the medical necessity for the TENS units for which the supplier has submitted claims.
- A physician signs CMNs for respiratory medical equipment falsely representing that the equipment was medically necessary.
- A physician signs CMNs for wheelchairs and hospital beds without seeing the patients, then falsifies his medical charts to indicate that he treated them.
- A physician accepts anywhere from \$50 to \$400 from a DME supplier for each prescription he signs for oxygen concentrators and nebulizers.

Potential Consequences for Unlawful Acts

A physician is not personally liable for erroneous claims due to mistakes, inadvertence, or simple negligence. However, knowingly signing a false or misleading certification or signing with reckless disregard for the truth can lead to serious criminal, civil, and administrative penalties including:

- criminal prosecution;
- fines as high as \$10,000 per false claim plus treble damages; or
- administrative sanctions including: exclusion from participation in Federal health care programs, withholding or recovery of payments, and loss of license or disciplinary actions by state regulatory agencies.

Physicians may violate these laws when, for example:

- they sign a certification as a "courtesy" to a patient, service provider, or DME supplier when they have not first made

a determination of medical necessity;

- they knowingly or recklessly sign a false or misleading certification that causes a false claim to be submitted to a Federal health care program; or
- they receive any financial benefit for signing the certification (including free or reduced rent, patient referrals, supplies, equipment, or free labor).

Even if they do not receive any financial or other benefit from providers or suppliers, physicians may be liable for making false or misleading certifications.

FRAUD ALERT # 6-96

FRAUD AND ABUSE IN THE PROVISION OF SERVICES IN NURSING FACILITIES

This Special Fraud Alert focuses on the provision of medical and other health care services to residents of nursing facilities and identifies some of the illegal practices that the OIG has uncovered.

How Nursing Facility Benefits Are Reimbursed

There were 17,000 nursing facilities in the United States, as of June 1995. An OIG study reported that in 1992, Medicare payments to nursing facilities included Part B payments of \$2.7 billion and Part A payments of \$3.1 billion for covered stays in nursing facilities. When the Federal share of the \$24 billion spent by Medicaid is factored in, the Federal cost of nursing care reached a total of approximately \$20 billion.

Many nursing facilities receive reimbursement from both Medicare and Medicaid for care and services provided to eligible residents. Under Medicare Part A, skilled nursing facility services are paid on the basis of cost for covered stays of a limited length. Nursing facility residents may be concurrently eligible for benefits under Medicare Part B. For Medicaid-eligible residents, extended nursing facility stays may be reimbursed by state-administered programs financed in part by Medicaid.

Nursing facilities and their residents have become common targets for fraudulent schemes. Nursing facilities represent convenient resident “pools” and make it lucrative for unscrupulous persons to carry out fraudulent schemes. The OIG has become aware of a number of fraudulent arrangements by which health care providers, including medical professionals, inappropriately bill Medicare and Medicaid for the provision of unnecessary services and services which were not provided at all. Sometimes, nursing facility management and staff also are involved in these schemes.

False or Fraudulent Claims Relating to the Provision of Health Care Services

The government may prosecute persons who submit or cause the submission of false or fraudulent claims to the Medicare or Medicaid program. Examples of false or fraudulent claims include claims for items that were never provided or were not provided as claimed, and claims for services which a person knows are not medically necessary. Submitting or causing false claims to be submitted to Medicare or Medicaid may subject the individual or entity to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. The OIG has uncovered the following types of fraudulent transactions related to the provision of health care services to residents of nursing facilities reimbursed by Medicare and Medicaid:

Claims for Services Not Rendered or Not Provided as Claimed

Common schemes entail falsifying bills and medical records to misrepresent the services, or extent of services, provided at nursing facilities. Some examples follow:

- One physician improperly billed \$350,000 over a 2-year period for comprehensive physical examinations of residents without ever seeing a single resident. The physician went so far as to falsify medical records to indicate that nonexistent services were rendered.
- A psychotherapist working in nursing facilities manipulated Medicare billing codes to charge for 3 hours of therapy for each resident when, in fact, he spent only a few minutes with each resident. In a nursing facility, 3 hours of psychotherapy is highly unusual and often clinically inappropriate.
- An investigation of a speech specialist uncovered documentation showing that he overstated the time spent on each session claimed. Claims analysis showed that the speech specialist actually claimed to spend 20 hours with residents every day, far more time than possible. Further investigation revealed that some residents had never met the specialist, and some were dead at the time when the specialist claimed to have provided speech services to them.
- A company providing mobile X-ray services made visits to nursing facilities, and billed for taking two X-rays when only one was actually taken. The case also presented serious concerns about quality of care when the investigation revealed that company personnel were not certified to take X-rays.

Claims Falsified To Circumvent Coverage Limitations on Medical Specialties

Practitioners of medical specialties have been found to misrepresent the nature of services provided to Medicare and Medicaid beneficiaries because the Federally funded programs have stringent coverage limitations for some specialties, including podiatry, audiology, and optometry. For instance:

- The OIG has learned about podiatrists whose entire practices consisted of visits to nursing facilities. Non-covered routine care is provided, e.g., toenail clipping, but Medicare is billed for covered services which were not provided or needed. In one case, an investigator discovered suspicious billing for foot care when it was reported that a podiatrist was performing an excessive number of toenail removals, a service that is covered but not frequently or routinely needed. This podiatrist billed Medicare as much as \$100,000 in 1 year for toenail removals. Investigators discovered one resident for whom bills were submitted claiming a total of 11 toenail removals.
- An optometrist claimed reimbursement for covered eye care consultations when he, in fact, performed routine exams and other non-covered services. His billing history indicated that he claimed to have performed as many as 25 consultations in one day at a nursing home. This is an unreasonably high number, given the nature of a Medicare-covered consultation.
- An audiologist made arrangements with a nursing facility and affiliated physicians to get orders for hearing exams that were not medically necessary. The audiologist used this access to residents exclusively to market hearing aids. In this case, the facility and physicians, in addition to the audiologist, could be held liable for false or fraudulent claims if they acted with knowledge of the claims for unnecessary service.

What to Look For in the Provision of Services to Nursing Facilities

The following situations may suggest fraudulent or abusive activities:

- “Gang visits” by one or more medical professionals where large numbers of residents are seen in a single day. The practitioner may be providing medically unnecessary services, or the level of service provided may not be of a sufficient duration or scope consistent with the service billed to Medicare or Medicaid.
- Frequent and recurring “routine visits” by the same medical professional. Seeing residents too often may indicate that the provider is billing for services that are not medically necessary.
- Unusually active presence in nursing facilities by health care practitioners who are given or request unlimited access to resident medical records. These individuals may be collecting information used in the submission of false claims.
- Questionable documentation for medical necessity of professional services. Practitioners who are billing inappropriately may also enter, or fail to enter, important information on medical charts.

FRAUD ALERT # 8-95

HOME HEALTH FRAUD

What is Home Health Care And Who Is Eligible To Receive It?

Medicare’s home health benefit allows people with restricted mobility to remain non-institutionalized and receive needed care at home. Home health services and supplies are typically provided by nurses and aides under a physician-certified plan of care.

Medicare will pay for home health services if a beneficiary’s physician certifies that he or she is homebound—i.e., confined to the home except for infrequent or short absences or trips for medical care, and requires one or more of the following qualifying services: physical therapy, speech-language pathology, or intermittent skilled nursing.

If a homebound patient requires a qualifying service, Medicare also covers services of medical social workers and certain personal care such as bathing, feeding, and assistance with medications. However, a beneficiary who needs only this type of personal or custodial care does not qualify for the home health benefit.

Fraud and Abuse in the Home Health Industry.

Home care is consuming a rapidly increasing portion of the federal health budget. This year, Medicare payments for home health will reach close to \$16 billion, up from \$3.3 billion in 1990—nearly a five-fold increase. Home health care is particularly vulnerable to fraud and abuse because:

- Medicare covers an unlimited number of visits per patient;
- Beneficiaries pay no co-payments except on medical equipment;
- Patients don’t receive explanations of benefits (EOBs) for bills submitted for home health services; and
- There is limited direct medical supervision of home health services provided by non-medical personnel.

The OIG has learned of several types of fraudulent conduct, outlined below, which have or could result in improper Medicare

reimbursement for home health services.

- False or Fraudulent Claims Relating to the Provision of Home Health Services

The government may prosecute persons who submit or cause false or fraudulent claims for payment to be submitted to the Medicare or Medicaid programs. Examples of false or fraudulent claims include claims for services that were never provided, duplicate claims submitted for the same service, and claims for services to ineligible patients. A claim for a service that a health care provider knows was not medically necessary may also be a fraudulent claim.

Submitting or causing false claims to be submitted to Medicare or Medicaid may subject a person to criminal prosecution, civil penalties including treble damages, and exclusion from participation in the Medicare and Medicaid programs. OIG has uncovered the following types of fraudulent claims related to the provision of home health services.

- Claims For Home Health Visits That Were Never Made And For Visits to Ineligible Beneficiaries

OIG has uncovered instances where home health agencies are submitting false claims for home health visits. These include:

- Claims for visits not made.
- Claims for visits to beneficiaries not homebound.
- Claims for visits to beneficiaries not requiring a qualifying service.
- Claims for visits not authorized by a physician.

One home health agency billed Medicare for 123 home health visits to a patient who never received a single visit, and submitted claims for beneficiaries who were in an acute care hospital during the period the agency claimed to have provided home visits. Another agency provided a home health aide to a beneficiary so mobile that he volunteered at a local hospital several times a week.

A third agency claimed nearly \$26 million during one year in visits that were not made, visits to patients that were not homebound, and visits not authorized by a physician. OIG interviews indicated that beneficiary signatures were forged on visit logs and physician signatures were forged on plans of care. This agency had subcontracted with other entities to provide home health care to its patients, and claimed that the subcontractors falsely documented that visits were made and services were provided.

Medicare permits a home health agency to contract with other organizations, including agencies not certified by Medicare, to provide care to its patients. However, the agency remains liable for all billed services provided by its subcontractors. The use of subcontracted care imposes a duty on home health agencies to monitor the care provided by the subcontractor. Home health agencies, as well as the physicians who order home health services, are responsible for ensuring the medical necessity of claims submitted to Medicare. A physician who orders unnecessary home health care services may be liable for causing false claims to be submitted by the home health agency, even though the physician does not submit the claim. Furthermore, if agency personnel believe that services ordered by a physician are excessive or otherwise inappropriate, the agency cannot avoid liability for filing improper claims simply because a physician has ordered the services.

- Fraud in Annual Cost Report Claims

In addition to submitting claims for specific services, home health agencies submit annual cost reports to Medicare for reimbursement of administrative, overhead and other general costs. For these costs to be allowable, Medicare regulations require that they be (1) reasonable, (2) necessary for the maintenance of the health care entity, and (3) related to patient care. However, the OIG has audited cost reports which include costs for entertainment, travel, lobbying, gifts, and other expenses unrelated to patient care such as luxury automobiles and cruises. One home health agency claimed several million dollars in unallowable costs during one cost reporting year. These included utility and maid service payments for the owner's condominium, golf pro shop expenses, lease payments on a luxury car for the owner's son at college, and payment of cable television fees for the owner's mother.

Medicare also requires home health agencies to disclose in their cost reports the identity of related parties with whom they conduct business, in order to adjust costs that are likely to be inflated by health care providers who self-deal (i.e., purchase goods or services from related companies). A related party issue exists when there is common control or common interest between the provider and the organization with whom it is doing business. OIG has investigated home health agencies which failed to disclose ownership or other relationships with entities with whom they contracted for accounting services, management/consulting services, and medical supplies. These agencies billed Medicare unallowable amounts for marked-up supplies and services.

- Paying or Receiving Kickbacks In Exchange For Medicare or Medicaid Referrals

Kickbacks in exchange for the referral of reimbursable home health services is another type of fraud that OIG has observed. The Medicare program guarantees freedom of choice to its beneficiaries in the selection of health care providers. Because kickbacks violate that principle and also increase the cost of care, they are prohibited under the Medicare and Medicaid programs. Under the anti-kickback statute, it is illegal to knowingly and willfully solicit, receive, offer or pay anything of value to induce, or in return for, referring, recommending or arranging for the furnishing of any item or service payable by Medicare or Medicaid.

OIG is aware of home health providers offering kickbacks to physicians, beneficiaries, hospitals, and rest homes in return for referrals. Kickbacks have taken the following forms:

- Payment of a fee to a physician for each plan of care certified by the physician on behalf of the home health agency.
- Disguising referral fees as salaries by paying referring physicians for services not rendered, or in excess of fair market value for services rendered.
- Offering free services to beneficiaries, including transportation and meals, if they agree to switch home health providers.
- Providing hospitals with discharge planners, home care coordinators, or home care liaisons in order to induce referrals.
- Providing free services, such as 24 hour nursing coverage, to retirement homes or adult congregate living facilities in return for home health referrals.
- Subcontracting with retirement homes or adult congregate living facilities for the provision of home health services, to induce the facility to make referrals to the agency.

Parties that violate the anti-kickback statute may be criminally prosecuted, and also may be subject to exclusion from the Medicare and Medicaid programs.

FRAUD ALERT # 12-94

VIOLATIONS OF THE ANTI-KICKBACK STATUTE

To help reduce fraud in the Medicare and Medicaid programs, the OIG is actively investigating violations of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. Section 1320a-7b(b).

What is the Medicare and Medicaid Anti-Kickback Law?

Among its provisions, the anti-kickback statute penalizes anyone who knowingly and willfully solicits, receives, offers or pays remuneration in cash or in kind to induce, or in return for:

- A. Referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service payable under the Medicare or Medicaid program; or
- B. Purchasing, leasing or ordering , or arranging for or recommending purchasing, leasing or ordering, any goods, facility, service or item payable under the Medicare or Medicaid program.

Violators are subject to criminal penalties, or exclusion from participation in the Medicare and Medicaid programs, or both. In 1987, section 14 of the Medicare and Medicaid Patient and Program Protection Act, PL 100-93, directed this Department to promulgate “safe harbor” regulations, in order to provide health care providers a mechanism to assure them that they will not be prosecuted under the anti-kickback statute for engaging in particular practices. The Department published 11 final “safe harbor” regulations on July 29, 1991 (42 CFR 1001.952, 56 FR 35952), and two more on November 5, 1992 (42 CFR 1001.952, 57 FR 52723). The scope of the anti-kickback statute is not expanded by the “safe harbor” regulations; these regulations give those in good faith compliance with a “safe harbor” the assurance that they will not be prosecuted under the anti-kickback statute.

Joint Venture Arrangements

The Office of Inspector General has become aware of a proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays. Some examples of the items or services provided in these arrangements include clinical diagnostic laboratory services, durable medical equipment (DME), and other diagnostic services. Sometimes these deals are called “joint ventures.” A joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services, or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services. Of course, there may be legitimate reasons to form a joint venture, such as raising necessary investment capital. However, the Office of Inspector General believes that some of these joint ventures may violate the Medicare and Medicaid anti-kickback statute.

Under these suspect joint ventures, physicians may become investors in a newly formed joint venture entity. The investors refer their patients to this new entity, and are paid by the entity in the form of “profit distributions.” These subject joint ventures may be intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals. Because physician investors can benefit financially from their referrals, unnecessary procedures and tests may be ordered or performed, resulting in unnecessary program expenditures.

The questionable features of these suspect joint ventures may be reflected in three areas:

- (1) The manner in which investors are selected and retained;

- (2) The nature of the business structure of the joint venture; and
- (3) The financing and profit distributions.

Suspect Joint Ventures: What To Look For

To help you identify these suspect joint ventures, the following are examples of questionable features, which separately or taken together may result in a business arrangement that violates the anti-kickback statute. Please note that this is not intended as an exhaustive list, but rather gives examples of indicators of potentially unlawful activity.

Investor

- Investors are chosen because they are in a position to make referrals.
- Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals.
- Physician investors may be actively encouraged to make referrals to the joint venture, and may be encouraged to divest their ownership interest if they fail to sustain an “acceptable” level of referrals.
- The joint venture tracks its sources of referrals, and distributes this information to the investors.
- Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled or retire.
- Investment interests may be nontransferable.

Business Structure

- The structure of some joint ventures may be suspect. For example, one of the parties may be an ongoing entity already engaged in a particular line of business. That party may act as the reference laboratory or DME supplier for the joint venture. In some of these cases, the joint venture can be best characterized as a “shell.”
- In the case of a shell laboratory joint venture, for example:
 - It conducts very little testing on the premises, even though it is Medicare certified.
 - The reference laboratory may do the vast bulk of the testing at its central processing laboratory, even though it also serves as the “manager” of the shell laboratory.
 - Despite the location of the actual testing, the local “shell” laboratory bills Medicare directly for these tests.
- In the case of a shell DME joint venture, for example:
 - It owns very little of the DME or other capital equipment; rather the ongoing entity owns them.
 - The ongoing entity is responsible for all day-to-day operations of the joint venture, such as delivery of the DME and billing.

Financing and Profit Distribution

- The amount of capital invested by the physician may be disproportionately small and the returns on investment may be disproportionately large when compared to a typical investment in a new business enterprise.
- Physician investors may invest only a nominal amount, such as \$500 to \$1500.
- Physician investors may be permitted to “borrow” the amount of the “investment” from the entity, and pay it back through deductions from profit distributions, thus eliminating even the need to contribute cash to the partnership.
- Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50 to 100 percent per year.

Routine Waiver of Copayments or Deductibles Under Medicare Part B

To help reduce fraud in the Medicare program, the Office of Inspector General is actively investigating health care providers, practitioners and suppliers of health care items and services who (1) are paid on the basis of charges and (2) routinely waive (do not bill) Medicare deductible and copayment charges to beneficiaries for items and services covered by the Medicare program.

What Are Medicare Deductible and Copayment Charges?

The Medicare “deductible” is the amount that must be paid by a Medicare beneficiary before Medicare will pay for any items or services for that individual. Currently, the Medicare Part B deductible is \$100 per year.

“Copayment” (“coinsurance”) is the portion of the cost of an item or service which the Medicare beneficiary must pay. Currently, the Medicare Part B coinsurance is generally 20 percent of the reasonable charge for the item or service. Typically, if the Medicare reasonable charge for a Part B item or service is \$100, the Medicare beneficiary (who has met his [or her] deductible) must pay \$20 of the physician’s bill, and Medicare will pay \$80.

Why Is it Illegal for “Charged-Based” Providers, Practitioners and Suppliers to Routinely Waive Medicare Copayment and Deductibles?

Routine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare.

A “charge-based” provider, practitioner or supplier is one who is paid by Medicare on the basis of the “reasonable charge” for the item or service provided. 42 U.S.C. 1395u(b)(3); 42 CFR 405.501. Medicare typically pays 80 percent of the reasonable charge. 42 U.S.C. 1395l(a)(1). The criteria for determining what charges are reasonable are contained in regulations, and include an examination of (1) the actual charge for the item or service, (2) the customary charge for the item or service, (3) the prevailing charge in the same locality for similar items or services. The Medicare reasonable charge cannot exceed the actual charge for the item or service, and may generally not exceed the customary charge or the highest prevailing charge for the item or service. In some cases, the provider, practitioner or supplier will be paid the lesser of his [or her] actual charge or an amount established by a fee schedule.

A provider, practitioner or supplier who routinely waives Medicare copayments or deductibles is misstating its actual charge. For example, if a supplier claims that its charge for a piece of equipment is \$100, but routinely waives the copayment, the actual charge is \$80. Medicare should be paying 80 percent of \$80 (or \$64), rather than 80 percent of \$100 (or \$80). As a result of the supplier’s misrepresentation, the Medicare program is paying \$16 more than it should for this item.

In certain cases, a provider, practitioner or supplier who routinely waives Medicare copayments or deductibles also could be held liable under the Medicare and Medicaid anti-kickback statute. 42 U.S.C. 1320a-7b(b). The statute makes it illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid. When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them.

At first glance, it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries. By waiving Medicare copayments and deductibles, the provider of services may claim that the beneficiary incurs no costs. In fact, this is not true. Studies have shown that if patients are required to pay even a small portion of their care, they will be better health care consumers, and select items or services because they are medically needed, rather than simply because they are free. Ultimately, if Medicare pays more for an item or service than it should, or if it pays for unnecessary items or services, there are less Medicare funds available to pay for truly needed services.

One important exception to the prohibition against waiving copayments and deductibles is that providers, practitioners or suppliers may forgive the copayment in consideration of a particular patient’s financial hardship. This hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made. Otherwise, claims submitted to Medicare may violate the statutes discussed above and other provisions of the law.

What Penalties Can Someone Be Subject to for Routinely Waiving Medicare Copayments or Deductibles?

Whoever submits a false claim to the Medicare program (for example, a claim misrepresents an actual charge) may be subject to criminal, civil or administrative liability for making false statements and/or submitting false claims to the Government. 18 U.S.C. 287 and 1001; 31 U.S.C. 3729; 42 CFR 1320a-7a). Penalties can include imprisonment, criminal fines, civil damages and forfeitures, civil monetary penalties and exclusion from Medicare and the State health care programs.

In addition, anyone who routinely waives copayments or deductibles can be criminally prosecuted under 42 U.S.C. 1320a-7b(b), and excluded from participating in Medicare and the State health care programs under the anti-kickback statute. 42 U.S.C. 1320a-7(b)(7).

Finally, anyone who furnishes items or services to patient substantially in excess of the needs of such patients can be excluded from Medicare and the State health care programs. 42 U.S.C. 1320a-7(b)(6)(B).

Indications of Improper Waiver of Deductibles and Copayments

To help you identify charge-based providers, practitioners or suppliers who routinely waive Medicare deductibles and copayments, listed below are some suspect marketing practices. Please note that this list is not intended to be exhaustive but, rather, to highlight some indicators of potentially unlawful activity.

- Advertisements which state: “Medicare Accepted As Payment in Full,” “Insurance Accepted As Payment in Full,” or “No Out-Of-Pocket Expense.”

- Advertisements which promise that “discounts” will be given to Medicare beneficiaries.
- Routine use of “Financial hardship” forms which state that the beneficiary is unable to pay the coinsurance/deductible (i.e., there is no good faith attempt to determine the beneficiary’s actual financial condition).
- Collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance (“Medigap”) coverage (i.e., the items or services are “free” to the beneficiary).
- Charges to Medicare beneficiaries which are higher than those made to other persons for similar services and items (the higher charges offset the waiver of coinsurance.)
- Failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance or deductible for all patients from a particular hospital, in order to get referrals).
- “Insurance programs” which cover copayments or deductibles only for items or services provided by the entity offering the insurance. The “insurance premium” paid by the beneficiary is insignificant and can be as low as \$1 a month or even \$1 a year. These premiums are not based upon actuarial risks, but instead are a sham used to disguise the routine waiver of copayments and deductibles.

Hospital Incentives to Physicians

Why Do Hospitals Provide Economic Incentives to Physicians?

As many hospitals have become more aggressive in their attempts to recruit and retain physicians and increase patient referrals, physician incentives (sometimes referred to as “practice enhancements”) are becoming increasingly common. Some physicians actively solicit such incentives. These incentives may result in reductions in the physician’s professional expenses or an increase in his or her revenues. In exchange, the physician is aware that he or she is often expected to refer the majority, if not all, of his or her patients to the hospital providing the incentives.

Why is it Illegal for Hospitals to Provide Financial Incentives to Physicians for Their Referrals?

The Office of Inspector General has become aware of a variety of hospital incentive programs used to compensate physicians (directly or indirectly) for referring patients to the hospital. These arrangements are implicated by the anti-kickback statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid. In addition, they are not protected under the existing “safe harbor” regulations.

These incentive programs can interfere with the physician’s judgment of what is the most appropriate care for a patient. They can inflate costs to the Medicare program by causing physicians to overuse inappropriately the services of a particular hospital. The incentives may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute care facility) offering the best or most appropriate care for that patient.

Suspect Hospital Incentive Arrangements--What To Look For

To help identify suspect incentive arrangements, examples of practices which are often questionable are listed [below]. Please note that this list is not intended to be exhaustive but, rather, to suggest some indicators of potentially unlawful activity.

- Payment of any sort of incentive by the hospital each time a physician refers a patient to the hospital.
- The use of free or significantly discounted office space or equipment (in facilities usually located close to the hospital).
- Provision of free or significantly discounted billing, nursing or other staff services.
- Free training for a physician’s office staff in such areas as management techniques, CPT coding and laboratory techniques.
- Guarantees which provide that, if the physician’s income fails to reach a predetermined level, the hospital will supplement the remainder up to a certain amount.
- Low-interest or interest-free loans, or loans which may be “forgiven” if a physician refers patients (or some number of patients) to the hospital.
- Payment of the cost of a physician’s travel and expenses for conferences.
- Payment for a physician’s continuing education courses.
- Coverage on hospitals’ group health insurance plans at an inappropriately low cost to the physician.
- Payment for services (which may include consultations at the hospital) which require few, if any, substantive duties

by the physician, or payment for services in excess of the fair market value of services rendered.

Financial incentive packages which incorporate these or similar features may be subject to prosecution under the Medicare and Medicaid anti-kickback statute, if one of the purposes of the incentive is to influence the physician's medical decision as to where to refer his or her patients for treatment.

Prescription Drug Marketing Schemes

How Does the Anti-Kickback Law Relate to Prescription Drug Marketing Schemes?

In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. Prescription drugs supplied under one of these programs are often reimbursed under Medicaid. Among the specific activities, which the OIG has identified, are the following actual cases:

- A "product conversion" program which resulted in 96,000 brand-name conversions. In this scenario, for instance, Drug Company A offered a cash award to pharmacies for each time a drug prescription was changed from Drug Company B's product to Drug Company A's product. The pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescription.
- A "frequent flier" campaign in which physicians were given credit toward airline frequent flier mileage each time the physician completed a questionnaire for a new patient placed on the drug company's product.
- A "research grant" program in which physicians were given substantial payments for de minimis recordkeeping tasks. The physician administered the drug manufacturer's product to the patient and made brief notes, sometimes a single word, about the treatment outcome. Upon completion of a limited number of such "studies," the physician received payment from the manufacturer.

If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated. There is no statutory exception or "safe harbor" to protect such activities. Thus a physician, pharmacy or other practitioner or supplier receiving payment under these activities may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products. The OIG is investigating various drug marketing schemes, and enforcing the anti-kickback laws where these practices affect the Federal health care programs.

What to Look For

Generally, a payment or gift may be considered improper under 42 U.S.C. 1320a-7b(b) if it is:

- Made to a person in a position to generate business for the paying party;
- Related to the volume of business generated; and
- More than nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.

OIG investigation may be warranted where one or more of the following features is present in prescription drug marketing activities:

- Any prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers (including pharmacies, mail order prescription drug companies and managed care organizations) in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.
- Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented "educational" or "counseling" contacts, or physician and/or patient outreach, etc.
- Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based

on, or related to, use of the product.

- Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is made fully consistent with a “safe harbor” regulation, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices.

Arrangements for the Provision of Clinical Lab Services

How Does the Anti-Kickback Statute Relate to Arrangements for the Provision of Clinical Lab Services?

Many physicians and other health care providers rely on the services of outside clinical laboratories to which they may refer high volumes of patient specimens every day. The quality, timeliness and cost of these services are of obvious concern to Medicare and Medicaid patients and to the programs that finance their health care services. Since the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician’s decision regarding where to refer specimens is based only on the best interests of the patient.

Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business. The same is true whenever a referral source solicits or receives anything of value from the laboratory. By “fair market value” we mean value for general commercial purposes. However, “fair market value” must reflect an arms length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.

The office of Inspector General has become aware of a number of practices engaged in by clinical laboratories and health care providers that implicate the anti-kickback statute in this manner. Below are some examples of lab services arrangements that may violate the anti-kickback statute.

Provision of Phlebotomy Services to Physicians

When permitted by State law, a laboratory may make available to a physician’s office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician’s office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician’s office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician’s office laboratory, or performing clerical services.

Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician’s referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals.

Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG’s concern, where the phlebotomist is not closely monitored by his [of her] employer or where the contractual prohibition is not rigorously enforced.

Lab Pricing at Renal Dialysis Centers

The Medicare program pays for laboratory tests provided to patients with end stage renal disease (ESRD) in two different ways. Some laboratory testing is considered routine and payment is included in the composite rate paid by Medicare to the ESRD facility which in turn pays the laboratory. Some laboratory testing required by the patient is not included in the composite rate, and these additional tests are billed by the laboratory directly to Medicare and paid at the usual laboratory fee schedule price.

The OIG is aware of cases where a laboratory offers to perform the tests encompassed by the composite rate at a price below fair market value of the tests performed. In order to offset the low charges on the composite rate tests, the ESRD facility agrees to refer all or most of its non-composite rate tests to the laboratory. This arrangement appears to be an offer of something of value (composite rate tests below fair market value) in return for the ordering of additional tests which are billed directly to the Medicare program.

If offered or accepted in return for referral of additional business, the lab’s pricing scheme is illegal remuneration under the anti-kickback statute. The statutory exception and “safe harbor” for “discounts” does not apply to immunize parties to this type of transaction, since discounts on the composite rate tests are offered to induce referral of other tests. See 42 CFR 1001.952(h)(3)(ii).

Waiver of Charges to Managed Care Patients

Managed care plans may require a physician or other health care provider to use only the laboratory with which the plan has negotiated a fee schedule. In such situations, the plan usually will refuse to pay claims submitted by other laboratories. The provider, however, may use a different laboratory and may wish to continue to use that laboratory for non-managed care patients. In order to retain the provider as a client, the laboratory that does not have the managed care contract may agree to perform the

managed care work free of charge.

The status of such agreements under the anti-kickback statute depends in part on the nature of the contractual relationship between the managed care plan and its providers. Under the terms of many managed care contracts, a provider receives a bonus or other payment if utilization of ancillary services, such as laboratory testing, is kept below a particular level. Other managed care plans impose financial penalties if the provider's utilization of services exceeds pre-established levels. When the laboratory agrees to write off charges for the physician's managed care work, the physician may realize a financial benefit from the managed care plan created by the appearance that utilization of tests has been reduced.

In cases where the provision of free services results in a benefit to the provider, the anti-kickback statute is implicated. If offered or accepted in return for the referral of Medicare or State health care plan business, both the laboratory and the physician may be violating the anti-kickback statute. There is no statutory exception or "safe harbor" to immunize any party to such a practice because the Federal programs do not realize the benefit of these "free" services. See 42 CFR 1001.952(h)(3)(iii).

Other Inducements

The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute:

- Free pick-up and disposal of bio-hazardous waste products (such as sharps) unrelated to the collection of specimens for the outside laboratory.
- Provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.
- Provision of free laboratory testing for health care providers, their families and their employees.

When one purpose of these arrangements is to induce the referral of program-reimbursed laboratory testing, both the clinical laboratory and the health care provider may be liable under the statute and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs. ([Back](#))

Health Insurance Portability and Accountability Act (HIPAA)

The federal government has issued regulations concerning the privacy of health information. The regulations mandate what physician practices and other health care providers and entities must do to protect patient information, as well as what must be done prior to releasing patient information. The KMA has developed a separate book on this subject that includes sample forms, checklists and other materials. To obtain this information, visit the KMA website at www.kyma.org or contact KMA to order a copy of the book. ([Back](#))

Hearing Aids

Physicians who engage in the sale of hearing instruments must hold a license issued by the Kentucky Licensing Board for Specialists in Hearing Instruments [KRS 334.020]. A health benefit plan must provide coverage for the full cost of one hearing aid per hearing impaired ear up to one thousand four hundred dollars (\$1400) every thirty six months for hearing aids for insured individuals under age eighteen. [KRS 304.17A-132]. ([Back](#))

Hospitalists

A hospitalist is a physician who works in a hospital setting and serves as the physician-of-record after accepting hospitalized patients from primary care physicians, returning the patients to the primary care physician at the time of hospital discharge. The use of hospitalists has grown around the country and in some states, managed care companies have required primary care physicians to use hospitalists. Kentucky law prohibits a contract between an insurer and a physician from requiring the mandatory use of a hospitalist [KRS 304.17A-532]. ([Back](#))

Insurance-Patient Information/Protections

Insurers must provide their enrollees and insureds, in writing, with the terms and conditions of their health insurance plans, and must provide the enrollee with written notification of any change in the terms and conditions prior to the effective date of the change. Information that must be disclosed by a health plan includes a description of covered services and benefits including restrictions; financial responsibility of the enrollee, including co-payments and deductibles; prior authorization and any other review requirements with respect to covered services; where and in what manner covered services may be obtained; changes in covered services or benefits; appeal procedures with respect to the denial, reduction, or termination of a service including internal and external appeals; measures in place to ensure confidentiality of the physician/patient relationship; a summary of the drug formulary including a listing of the most commonly used drugs, drugs requiring preauthorization, and restrictions on obtaining drugs on the formulary or the complete drug formulary if requested; a statement that if the provider meets the insurer's enrollment criteria and is willing to meet the terms and conditions for participation, the provider has the right to become a provider for the insurer; and, other information as required by the Department of Insurance [KRS 304.17A-505].

Managed care plans must also provide to enrollees a current participating provider directory, as well as information regarding financial incentives between the participating providers and the insurer, the insurer's managed care plan's standard for customary waiting times for appointments for urgent and routine care, and any hold harmless agreements with providers and their effect on enrollees [KRS 304.17A-510(1)]. The insurer must also provide, upon the request of an enrollee, information pertaining to a particular provider's board certification and whether the provider is currently accepting new patients [KRS 304.17A-510 (2)].

A managed care plan must arrange for a sufficient number and type of primary care providers and specialists throughout the plan's service area to meet the needs of enrollees. Each managed care plan must demonstrate that it offers an adequate number of accessible acute care hospital services, where available; an adequate number of accessible primary care providers, including family practice and general practice physicians, internists, obstetricians/gynecologists, and pediatricians, where available; an adequate number of accessible specialists and subspecialists, and when the specialist needed for a specific condition is not represented on the plan's list of participating specialists, enrollees have access to nonparticipating health care providers with prior plan approval; the availability of specialty services; and a provider network that meets the following accessibility requirements:

1. For urban areas, a provider network that is available to all persons enrolled in the plan within thirty (30) miles or thirty (30) minutes of each person's place of residence or work, to the extent that services are available; or
2. For areas other than urban areas, a provider network that makes available primary care physician services, hospital services, and pharmacy services within thirty (30) minutes or thirty (30) miles of each enrollee's place of residence or work, to the extent those services are available. All other providers shall be available to all persons enrolled in the plan within fifty (50) minutes or fifty (50) miles of each enrollee's place of residence or work, to the extent those services are available [KRS 304.17A-515].

A managed care plan must provide telephone access to the plan during business hours to ensure plan approval of non-emergency care and establish reasonable standards for waiting times to obtain appointments, except as provided for emergency care [KRS 304.17A-515]. An insurer must also provide a covered person with access to a consultation with a participating health care provider for a second opinion and the second opinion may not cost the covered person more than the covered person's normal copay or coinsurance amounts [KRS 304.17A-520(4)]. A managed care plan must allow a covered person to choose or change primary care providers from among participating providers in the network and, when appropriate, choose a specialist from among participating providers subject to the availability of the specialist to accept new patients [KRS 304.17A-545(2)(e)]. Managed care plans must permit enrollees to choose their primary care providers from a list of health care providers within the plan. The list must include a sufficient number of primary care providers who are accepting new enrollees and women must be able to choose a qualified health care provider for the provision of covered care necessary to provide routine and preventive women's health care services [KRS 304.17A-520]. When prior approval has been obtained, coverage cannot be retrospectively denied unless the approval was based upon fraudulent, materially inaccurate, or misrepresented information by either the patient or the provider [KRS 304.17A-545(2)(b)].

An insurer may not prohibit a primary care physician from authorizing a covered person's referral to a participating nonprimary care physician specialist. A primary care physician treating a covered person who has a chronic, disabling, congenital, or life-threatening condition may authorize a referral to a participating nonprimary care physician specialist, up to twelve (12) months or for the contract period, whichever is shorter. Under this referral arrangement the covered person will have direct access to the nonprimary care physician specialist, without the need of further contact or referral by the primary care physician [KRS 304.17A-645].

An insurer may not prohibit a primary care physician from authorizing a covered person's referral to a participating obstetrician or gynecologist. A primary care physician treating a covered person who is pregnant or has a chronic gynecological condition may authorize a referral to a participating obstetrician or gynecologist, up to twelve (12) months or for the contract period, whichever is shorter. Under this referral arrangement the covered person will have direct access to the obstetrician or gynecologist, without the need of further contact or referral by the primary care physician [KRS 304.17A-647]. [\(Back\)](#)

Insurance-Physician Selection

A managed care plan must have a process for the selection of health care providers for its list of participating providers, with policies and procedures for review and approval. The plan must establish minimum professional requirements and may not discriminate against a provider solely on the basis of the provider's license by the state. The plan must also demonstrate that it has consulted with appropriately qualified health care providers in establishing the minimum professional requirements and the selection process must include verification of each provider's license, history of license suspension or revocation, and liability claims history. Each managed care plan must establish a formal written, ongoing process for the reevaluation of each provider within a specified number of years after the provider's initial acceptance into the plan. The reevaluation must include an update of the previous review criteria and an assessment of the provider's performance based on criteria such as enrollee clinical outcomes, number of complaints, and malpractice actions [KRS 304.17A-545(4)].

Insurers must establish relevant, objective standards for initial consideration of providers and for providers to continue as a participating provider in the plan. Standards must be reasonably related to the services provided. Selection or participation standards based on the economics or capacity of a provider's practice must be adjusted to account for case mix, severity of illness, patient age and other features that may account for higher-than-or lower-than-expected costs. All data profiling or other data analysis pertaining to participating providers must be done in a manner that is valid and reasonable. Plans may not use criteria that would allow an insurer to avoid high-risk populations by excluding providers because they are located in geographic areas that contain populations or providers presenting a risk of higher-than-average claims, losses, or health services utilization or that would exclude providers because they treat or specialize in treating populations presenting a risk of high-than-average claims, losses, or health services utilization [KRS 304.17A-525(1)].

Insurers must establish mechanisms for soliciting and acting upon applications for provider participation in the plan in a fair and systematic manner. These mechanisms must, at a minimum, include:

- ❑ Allowing all providers who desire to apply for participation in the plan an opportunity to apply at any time during the year or, where an insurer does not conduct open continuous provider enrollment, conducting a provider enrollment period at least annually with the date publicized to providers located in the geographic service area of the plan at least thirty (30) days in advance of the enrollment periods; and
- ❑ Making criteria for provider participation in the plan available to all applicants [KRS 304.17A-525(2)].

An insurer issuing a managed care plan must notify an applicant of its determination regarding a properly submitted application for credentialing within ninety (90) days of receipt of an application containing all information required by the most recent version of the Council for Affordable Healthcare (CAQH) credentialing form. Nothing in this law shall prevent an insurer from requiring information beyond that contained in the credentialing form to make a determination regarding the application. The ninety (90) day requirement shall not apply if the failure to notify is due to or results from, in whole or in part, acts or events beyond the control of the insurer issuing a managed care plan, including but not limited to acts of God, natural disasters, epidemics, strikes or other labor disruptions, war, civil disturbances, riots, or complete or partial disruptions of facilities. Following credentialing, the applicant and, upon the applicant's signing of a contract with the managed care plan, the insurer shall make payments to the applicant for services rendered during the credentialing process in accordance with procedures for reimbursement for participating providers. An applicant for which an application for credentialing is denied shall be reimbursed, if the enrollee is enrolled in a plan, which provides for out-of-network benefits, by the insurer issuing a managed care plan in accordance with procedures for reimbursement to nonparticipating providers [KRS 304.17A-576].

A managed care plan must establish a policy governing the removal of and withdrawal of health care providers from its provider network. The plan must inform a provider of the plan's removal and withdrawal policy at the time the plan contracts with the provider, and when changed thereafter. If a provider's participation will be terminated or withdrawn prior to the date of the termination of the contract as a result of a professional review action, the plan and provider must comply with the standards set out in federal law. If the plan finds that a provider represents an imminent danger to a patient or the public health, safety, or welfare, the plan's medical director must promptly notify the appropriate state licensing board [KRS 304.17A-525(4)].

Managed care organizations must accept providers that are willing to meet "terms and conditions" established by the managed care organization [KRS 304.17A-110 and KRS 304.17A-270]. [\(Back\)](#)

Itinerant Physicians

Itinerant (traveling) physicians may not practice medicine in Kentucky without first obtaining a license (KRS 311.260). [\(Back\)](#)

Living Wills

KRS 311.623 allows an individual to indicate health care choices in advance and designate a trusted individual familiar with one's values to interpret those choices in the actual situation and make choices for unforeseen circumstances. Specifically, this law allows an adult with decisional capacity to make a written living will directive that:

- (1.) directs the withholding or withdrawal of life-prolonging treatment; or
- (2.) directs the withholding or withdrawal of artificially provided nutrition or hydration; or
- (3.) designates one (1) or more adults as a surrogate or successor surrogate to make health care decisions on behalf of the grantor; or
- (4.) directs the giving of all or any part of the adult's body upon death for any purpose specified in KRS 311.1929 (Kentucky's anatomical gift law).

Living will directives made pursuant to this legislation must be honored by the grantor's family, regular family physician or attending physician, and any health care facility. Additionally, notification to any emergency medical responder of a person's wish not to be resuscitated shall be recognized if on a standard form or identification approved by the Kentucky Board of Medical Licensure and the Cabinet for Health Services.

Living will directives must substantially follow a standard form contained in KRS 311.625. That form is set out at the conclusion of this discussion. All advance directives must be in writing, dated, and signed by the grantor, or at the grantor's direction, and either witnessed by two (2) or more adults in the presence of the grantor, or acknowledged before a notary public. The following individuals may not serve as witnesses:

- (1) a blood relative of the grantor;
- (2) a beneficiary of the grantor;
- (3) an employee of a health care facility in which the grantor is a patient, unless the employee serves as a notary public;
- (4) an attending physician of the grantor; or
- (5) any person directly financially responsible for the grantor's health care.

An advance directive may be revoked in writing by the grantor, by an oral statement made in the presence of two (2) adults, or by destruction of the document by the grantor. The revocation is effective immediately. Upon receiving notice of the revocation, the attending physician or health care facility must record the time, date, and place of notice receipt in the grantor's medical record [KRS 311.627].

A surrogate may make health care decisions provided all the decisions are made in accordance with the desires of the grantor as indicated in the advance directive. A surrogate may authorize the withdrawal or withholding of artificially provided nutrition and hydration in the following circumstances:

- (1) When inevitable death is imminent, which for the purpose of this provision means when death is expected, by reasonable medical judgment, within a few days; or
- (2) When a patient is in a permanently unconscious state if the grantor has executed an advance directive authorizing the withholding or withdrawal of artificially provided nutrition and hydration; or
- (3) When the provision of artificial nutrition cannot be physically assimilated by the person; or
- (4) When the burden of the provision of artificial nutrition and hydration itself shall outweigh its benefit. Even in the exceptions listed in paragraphs (1), (2), and (3) above, artificially provided nutrition and hydration shall not be withheld or withdrawn if it is needed for comfort or the relief of pain [KRS 311.629(3)].

Notwithstanding the execution of an advance directive, life sustaining treatment and artificially provided nutrition and hydration shall be provided to a pregnant woman unless, to a reasonable degree of medical certainty, as certified on the woman's medical chart by the attending physician and one (1) other physician who has examined the woman, the procedures will not maintain the woman in a way to permit the continuing development and live birth of the unborn child; will be physically harmful to the woman; or will prolong severe pain which cannot be alleviated by medication [KRS 311.629].

A health care facility, physician, or other person acting under the direction of a physician shall not be subject to criminal prosecution or civil liability or be deemed to have engaged in unprofessional conduct as a result of the withholding or the withdrawal of life-prolonging treatment or artificially provided nutrition and hydration from a patient in a terminal condition in accordance with an advance directive. A person who authorizes the withholding or withdrawal of life-prolonging treatment or artificially provided nutrition and hydration from a patient in a terminal condition in accordance with an advance directive shall not be subject to criminal prosecution or civil liability for the action [KRS 311.635].

If an adult patient whose physician has determined that he or she does not have decisional capacity has not executed an advance directive, or to the extent the advance directive does not address a decision that must be made, any one (1) of the following

responsible parties, in the following order of priority if no individual in a prior class is reasonably available, willing, and competent to act, is authorized to make health care decisions on behalf of the patient:

- (1) The judicially - appointed guardian of the patient, if the guardian has been appointed and if medical decisions are within the scope of the guardianship;
- (2) The attorney-in-fact named in a durable power of attorney, if the durable power of attorney specifically includes authority for health care decisions;
- (3) The spouse of the patient;
- (4) An adult child of the patient, or if the patient has more than one (1) child, the majority of the adult children who are reasonably available for consultation;
- (5) The parents of the patient;
- (6) The nearest living relative of the patient, or if more than one (1) relative of the same relation is reasonably available for consultation, a majority of the nearest living relatives.

If a healthcare decision is made by a surrogate and there is no living will, the decision must be noted in the patient's medical record. In any case in which a health care decision is made by a surrogate, hospitalization for psychiatric treatment must not exceed fourteen [14] consecutive days without a court order. If there is no living will, the surrogate may make the decision to withhold artificially provided nutrition and hydration, but such a decision must be under the same circumstances for withholding nutrition and hydration as if there were a living will [KRS 311.631].

An attending physician or health care facility that refuses to comply with the advance directive of a patient or decision made by a surrogate or responsible party must immediately inform the patient or the patient's responsible party and the family or guardian of the patient of the refusal. No physician or health care facility which refuses to comply with the advance directive of a qualified patient or decision made by a responsible party shall impede the transfer of the patient to another physician or health care facility which will comply with the advance directive. If the patient, the family, or the guardian of the patient has requested and authorized a transfer, the transferring attending physician and health care facility shall supply the patient's medical records and other information or assistance medically necessary for the continued care of the patient, to the receiving physician and health care facility [KRS 311.633 (2)].

Nothing in the law condones, authorizes, or otherwise approves euthanasia, mercy killing, or any other affirmative or deliberate act to end life other than to permit the natural process of dying.

LIVING WILL DIRECTIVE

My wishes regarding life-prolonging treatment and artificially provided nutrition and hydration to be provided to me if I no longer have decisional capacity, have a terminal condition, or become permanently unconscious, have been indicated by checking and initialing the appropriate lines below. By checking and initialing the appropriate lines, I specifically:

_____ Designate _____ as my health care surrogate(s) to make health care decisions for me in accordance with this directive when I no longer have decisional capacity. If _____ refuses or is not able to act for me, I designate _____ as my health care surrogate(s).

Any prior designation is revoked.

If I do not designate a surrogate, the following are my directions to my attending physician. If I have designated a surrogate, my surrogate shall comply with my wishes as indicated below:

_____ Direct that treatment be withheld or withdrawn, and that I be permitted to die naturally with only the administration of medication or the performance of any medical treatment deemed necessary to alleviate pain.

_____ DO NOT authorize that life-prolonging treatment be withheld or withdrawn.

_____ Authorize the withholding or withdrawal of artificially provided food, water, or other artificially provided nourishment or fluids.

_____ DO NOT authorize the withholding or withdrawal of artificially provided food, water, or other artificially provided nourishment or fluids.

_____ Authorize my surrogate, designated above, to withhold or withdraw artificially provided nourishment or fluids, or other treatment if the surrogate determines that withholding or withdrawing is in my best interest; but I do

not mandate that withholding or withdrawing.

_____ Authorize the giving of all or any part of my body upon death for any purpose specified in KRS 311.1929.

_____ DO NOT authorize the giving of all or any part of my body upon death.

In the absence of my ability to give directions regarding the use of life-prolonging treatment and artificially provided nutrition and hydration, it is my intention that this directive shall be honored by my attending physician, my family, and any surrogate designated pursuant to this directive as the final expression of my legal right to refuse medical or surgical treatment, and I accept the consequences of the refusal.

If I have been diagnosed as pregnant and that diagnosis is known to my attending physician, this directive shall have no force or effect during the course of my pregnancy.

I understand the full import of this directive, and I am emotionally and mentally competent to make this directive.

Signed this _____ day of _____, 20_____.

(grantor) (address)

In our joint presence, the grantor, who is of sound mind and eighteen (18) years of age, or older, voluntarily dated and signed this writing or directed it to be dated and signed for the grantor

(witness) (address)

(witness) (address)

OR

STATE OF KENTUCKY

_____ County

Before me, the undersigned authority, came the grantor who is of sound mind and eighteen (18) years of age, or older, and acknowledged that he voluntarily dated and signed this writing or directed it to be signed and dated as above.

Done this _____ day of _____, 20_____.

Notary Public: _____

Date commission expires: _____

Execution of this document restricts withholding and withdrawing of some medical procedures. Consult Kentucky Revised Statutes or your attorney.

[\(Back\)](#)

Maintenance of Certification/Maintenance of Licensure

The Kentucky Board of Medical Licensure cannot require any form of maintenance of licensure as a condition of physician licensure, including requiring any form of maintenance of licensure tied to maintenance of certification. Additionally, the Kentucky Board of Medical Licensure cannot require any form of specialty medical board certification or any maintenance of certification to practice medicine in Kentucky. [KRS 311.566]

“Maintenance of certification” means any process requiring periodic recertification examinations to maintain specialty medical board certification. “Maintenance of licensure” means the proprietary framework for physician license renewal established through the Federation of State Medical Boards or its successor organization, which includes additional periodic testing other than continuing medical education. “Specialty medical board certification” means certification by a board that specializes in one (1) particular area of medicine and typically requires additional and more strenuous examinations than the Kentucky Board of Medical Licensure’s requirements to practice medicine. [KRS 311.566] ([Back](#))

Malpractice

Portions of this material were written by Douglass Farnsley of the law firm of Stites & Harbison. The portion dealing with Constitutional Reform was taken from the KMA Legislative Handbook.

The Law

In 1970, the Kentucky Court of Appeals set forth the legal standard by which physicians are judged in medical malpractice cases. The court said physicians have a duty to use that degree of care and skill that is expected of a reasonably competent internist/cardiologist/anesthesiologist/etc., acting in the same or similar circumstances. If a physician does not comply with that duty, and such failure on his or her part was a substantial factor in causing injury to the plaintiff, the physician may be held liable and forced to pay damages. Such damages may include medical expenses, lost wages, impairment of future earning potential, and physical and mental pain and suffering.

Therefore, in order for a plaintiff to prevail in a medical malpractice action, the plaintiff has the burden of proving the following:

- That the physician fell below accepted standards;
- That the plaintiff sustained some injury; and
- That the failure on the part of the physician was a substantial factor in causing the patient’s injuries.

Some cases might turn on whether the patient consented to the procedure performed by the physician. To obtain “informed consent” from a patient, a physician must explain the risks and alternatives of the treatment or procedure in such a way that a patient would normally be expected to have understood those risks and alternatives.

The patient has the burden of proving his or her case by a preponderance of the evidence in a malpractice case. The patient must usually prove that a physician fell below the accepted standard of care by using expert testimony at trial. Expert testimony is not needed if it would be obvious to a person without medical training that the alleged conduct constituted negligence. Patients’ attorneys find expert witnesses in several ways, including from witness referral services and from referrals by physicians who regularly review cases for a patients’ attorney on an informal basis.

As with proof concerning the standard of care, the patient will usually need the services of a physician or expert to prove a causal connection between a physician’s conduct and the patient’s injuries. In some cases, the courts permit a plaintiff’s case to go forward without expert testimony on the issue of causation. As with the standard of care, the courts will permit this when the issue of causation is considered to be obvious to a person who has no medical training.

There are two common affirmative defenses available to physicians in medical malpractice claims: comparative negligence and statute of limitations. A patient has the duty to exercise ordinary care for his own health and safety. “Ordinary care” means such care as an ordinarily prudent person would exercise under like or similar circumstances. Even though a physician might have breached a legal duty owed to the patient, if a patient failed to comply with his duty and such failure on his part was a substantial factor in causing his injuries, it can be taken into consideration by a jury. If injuries were caused by a combination of failures on the part of the physician and the patient, then in assessing a patient’s damages, a jury must determine the total amount of the patient’s damages resulting from the failures by the physician and the patient and which were not caused at some other time or by reason of some other occurrence. The jury must then decide what percentage of the total combined fault of both parties causing the patient’s

injuries is allocable to each party. In determining the percentages of fault, the jury must consider both the nature of the conduct of each party at fault and the extent of the causal relation between the conduct and the damages claimed. This means that the jury assigns percentages to the fault of the physician and to the fault of the patient. If the damages total \$100,000 and the patient is found to be 25% at fault, the patient will be awarded \$75,000. The physician has the burden of proving the patient's fault.

A patient/plaintiff must also abide by the statute of limitations, which outlines how long a person has to bring a claim before a court. It is the duty of the plaintiff to file a lawsuit within one year from the date he discovered or, in the exercise of ordinary care, should have discovered that the services rendered to him by a physician were poor or inadequate. If more than one year elapsed between the time the plaintiff discovered or should have discovered that he had been injured, and discovered or should have discovered that his injuries were caused by alleged failures on the part of the physician, then the case must be dismissed. The physician has the burden of proof with regard to the statute of limitations.

Procedure

Normally, a malpractice action starts with some type of "triggering event," which is something that surprises or disappoints the patient. If the physician has any concern about an incident, he or she should err on the side of reporting it to his or her malpractice carrier. But physicians should note that reporting an incident to the malpractice carrier does not trigger coverage.

Once a triggering event occurs, the patient will talk to a lawyer. The lawyer then gathers records and other material in order to have the case reviewed by another physician. This review is often undertaken by a physician-friend of the attorney on an informal basis. Should the attorney bring suit, he or she may or may not rely upon the reviewing physician to serve as a witness at trial. The patient's lawyer may or may not write or call the defendant physician before filing suit; however, the physician should not talk with any patient's attorney regarding a possible claim without first notifying his or her malpractice carrier.

If the patient decides to sue the physician, the patient's lawyer files a written "complaint" with the clerk of the court. In most courts, at the time of filing the complaint, the clerk of the court randomly assigns the case to a judge. When the complaint is filed, it is a matter of public record, which means the press may report the fact that a suit has been filed before the physician knows about it.

The physician then usually receives the summons and complaint by certified mail. It is essential that the physician immediately contact his insurance carrier or attorney as soon as he or she receives the summons and complaint. The complaint filed by the plaintiff will usually not state the dollar amount being sought. This is information that the physician's attorney will undertake to obtain through "discovery," which is the process of both parties gathering information about the case. Once the physician knows the amount being sought by the plaintiff, he or she will know whether the potential exists for a verdict in excess of the available insurance coverage.

If it has not already done so, the insurance company, usually in consultation with the physician, employs a lawyer to represent the physician. While the attorney has obligations to both the physician and to the insurance carrier, his or her obligations to the physician take precedence over the obligations to the insurance carrier. Shortly after defense counsel is selected, he or she should contact the physician to arrange a first meeting. The physician should bring to the meeting the complete original records concerning the patient in question, including billing records, appointment books, telephone logs, and other office records that may have significance in defending the claim. At the initial meeting, the physician will help the lawyer understand his or her involvement in the care of the patient.

The formal discovery process then takes place, which includes interrogatories, document requests, and depositions. The sequence, timing and extent of discovery are determined largely by the lawyers. The physician should receive copies of all interrogatories, depositions, correspondence and other papers. The physician should also read everything and ask his or her lawyer for an explanation of anything which he or she does not understand. The physician may be asked to attend the depositions of the plaintiff and of plaintiff's expert witnesses, as well as other depositions. Often, these can be scheduled to accommodate the physician's schedule. Once the physician's own deposition is scheduled, his or her attorney will probably want to schedule one or more meetings to prepare for the deposition.

Up to this point, the involvement of the judge is usually minimal. The court usually will not act with regard to a particular case until asked to do so by one of the lawyers. The court acts through orders that are prepared in response to motions made by the lawyers. Usually the plaintiff's lawyer files a motion for a trial date early in the case, but a trial may not occur for several years. The trial may take as few as two days or may last several weeks. As with preparation for the deposition, the physician will need to meet with his or her attorney in advance of trial. The physician will also need to be present at trial.

How do juries treat physicians in such cases? In a study cited in the May 1993 issue of the Journal of the American Bar Association, researchers at Duke Law School studied malpractice cases in North Carolina from 1984 to 1987. The researchers found that juries ruled in favor of defendants in 18 out of 19 cases that the insurers expected to win and 13 out of 17 cases the insurers rated as a toss-up. Jurors even ruled for defendants in most of the cases--6 out of 11--that the insurers had rated as likely losers.

Settlements

A settlement is not an admission of fault. Many times cases are settled to avoid the nuisance and cost of a lawsuit. Many malpractice insurance policies provide that the physician's consent is a prerequisite to any settlement, although it is not true with all insurers. Even though the physician feels he or she did nothing wrong, settlement may be to his or her advantage. This is particularly true where the potential damages exceed the available coverage and the patient has substantial catastrophic injuries.

A great concern for many physicians is the potential for a verdict in excess of their available insurance coverage. The days may be past that medical malpractice coverage in the hundreds of thousands of dollars is adequate. Today, coverage for any physician should probably be one million dollars, at a minimum. Physicians should discuss the amount of coverage with someone knowledgeable in the area.

Counsel employed by the insurance carrier will discuss with the physician his or her assessment of the likelihood of a verdict in favor of the plaintiff and the likely range of a verdict should the plaintiff prevail. He or she will not be able to represent the physician's interests or the interests of the insurance carrier should there be a possible conflict between the physician and the insurance carrier. However, the attorney will advise the physician as to whether it would be prudent for him or her to retain the services of another attorney to represent their interests to the extent that they conflict with those of the insurance carrier. This is an issue physicians should not hesitate to bring up with counsel employed by the insurance carrier.

Constitutional Change Required for Meaningful Medical Liability Reform

In September of 2002, the KMA House of Delegates adopted the recommendations of the Ad Hoc Committee on Professional Liability Insurance. The recommendations represent a broad-based, long-term, flexible approach to stabilizing the medical liability insurance market in Kentucky. Categorized into five groups the recommendations address:

- legislative action;
- increased electoral involvement;
- insurance market analysis;
- patient safety initiatives; and
- public relations

The legislative recommendations explored various liability reforms that have been successfully implemented in other states. California's liability reforms, known as MICRA (Medical Injury Compensation Reform Act), which passed in the mid-70s, were established in KMA's recommendations as the "gold standard." Those reforms included a \$250,000 limit on pain and suffering awards.

Since the liability insurance crisis in the mid-70s, KMA has advocated legislation similar to what California and other state have passed. In the mid-80s, many of these reforms were passed by Kentucky's legislature but later were ruled unconstitutional by Kentucky's Supreme Court.

In every legislative session since then, KMA has advocated a constitutional amendment that would permit the legislature to place a cap on non-economic awards, which includes awards for pain and suffering, loss of consortium, etc. Non-economic awards do not include loss of wages, medical bills or other related economic damages. ([Back](#))

Malpractice - Countersuit

The material in this section was provided by Peggy Appenfelder of the law firm of Stites & Harbison.

Physicians sued for medical malpractice often consider the possibility of a "countersuit" against the patient or the patient's attorney. There are two potential bases for such suits: (1) malicious prosecution; and (2) abuse of process. Each has different elements that a physician must satisfy to succeed with the claim.

Malicious Prosecution

The following elements must be shown to establish a claim of malicious prosecution:

- (1.) The institution or continuation of a lawsuit, administrative or disciplinary proceeding against the physician;
- (2.) by, or at the instance, of the plaintiff patient;
- (3.) the termination of such proceedings in the physician's favor;
- (4.) malice (or improper purpose) in the patient's institution of such proceeding;
- (5.) lack of probable cause for the proceeding; and

(6.) evidence that the physician suffered some damage as a result.

The malpractice suit filed by the patient satisfies the first two elements. Because the action requires termination in the physician's favor, however, the physician must prevail in the malpractice case before being entitled to file a malicious prosecution suit. The next elements, lack of probable cause and improper purpose, are distinctly different. The physician would have the burden of proving that the patient's attorney did not have probable cause to file the medical malpractice suit. The attorney establishes probable cause if he reasonably believed in the existence of the facts upon which the claim was based and reasonably believed that under such facts, the claim may be valid under applicable law. Thus, the attorney must have made a diligent effort to determine the facts and applicable law and reasonably determine that under such facts, the claim may be valid. Improper purpose, on the other hand, addresses the issue of whether the bringing of the medical malpractice claim was primarily for a purpose other than that of securing the proper adjudication of the malpractice claim, which is a question for the jury once the court finds lack of probable cause.

Finally, when the essential elements of a cause of action for malicious prosecution or wrongful civil proceedings have been established, the physician would be entitled to recover for the following damages, if proven: (a) the harm to his reputation by any defamatory matter alleged as the basis of the proceedings, (b) the expense that he has reasonably incurred in defending himself against the proceedings, (c) any specific pecuniary loss that has resulted from the proceedings, (d) any emotional distress that is caused by the proceedings, (e) humiliation, mortification and loss of reputation, and (f) punitive damages, if the evidence demonstrates malice, willfulness or wanton disregard of the physician's rights.

Abuse of Process

The essential elements of an action for abuse of process are:

- (1.) an ulterior purpose for filing a suit against the physician;
- (2.) a willful act in the use of the judicial process of filing the suit that is not proper in the regular conduct of that proceeding; and
- (3.) injury to the physician or property rights.

Here, the physician must prove that the malpractice action was instituted for some improper purpose, which usually takes the form of coercion to obtain a collateral advantage, not properly involved in the action itself. There is, in other words, a form of extortion, and it is what is done in the course of negotiation, rather than the issuance or any formal use of the judicial system itself, which constitutes the tort. Additionally, some definite act or threat not authorized by the judicial system, or aimed at an objective not legitimate in the use of the judicial process is required. There is no liability where the defendant has done nothing more than carry out the legal process of the malpractice action to its authorized conclusion even though with bad intentions. Finally, to succeed with an abuse of action process, the physician must prove that he incurred a personal injury or property damage as a result of the malpractice claim. Injury to name or reputation is not sufficient.

Differences between the two causes of action

Abuse of process differs from malicious prosecution in that malicious prosecution consists of commencing an action maliciously or without justification. Abuse of process, however, consists of the employment of the legal process for some purpose other than that which it was intended by the law to effect. Thus, the focus of a malicious prosecution claim is whether the malpractice action was commenced without justification or probable cause. The focus of an abuse of process claim is whether the purpose for which the action was initiated is a proper one or instead, a form of coercion.

An abuse of process claim does not require that the medical malpractice claim be terminated in the physician's favor. Thus, a physician may assert the claim as a counterclaim in the initial malpractice action. Additionally, if the suit was filed to illegally compel the physician to do a collateral thing, the physician need not prove that the medical malpractice claim was brought without probable cause.

Another important difference between the two claims is the type of damages the physician must prove. In an abuse of process claim, there must be evidence that the physician suffered some personal injury or property damage; whereas, injury to the physician's name or reputation is sufficient damage for a malicious prosecution claim. ([Back](#))

Medicaid Disclosures

Each Medicaid provider, other than an individual practitioner or group of practitioners, fiscal agent that processes or pays vendor claims on behalf of the Medicaid agency, and managed care entity must file a disclosure with the Cabinet for Health and Family Services in accordance with 42 C.F.R. 455.104 relating to information on ownership and control.

Each provider shall, as a condition of participation in Medicaid, file a disclosure with the Cabinet for Health and Family Services in accordance with 42 C.F.R. 455.105 relating to business transactions and in accordance with 42 C.F.R. 455.106 relating to information on persons convicted of crimes.

Disclosures shall be provided at any of the following times or as otherwise provided by law:

- Upon submitting a provider application;
- Upon executing a provider agreement;
- Upon request of the Cabinet for Health and Family Services during a provider's revalidation of enrollment;
- Within thirty-five (35) days after any change in ownership of a health facility or health service, fiscal agent, or managed care entity;
- Upon the submission of a proposal in accordance with the state's procurement process by a fiscal agent or by a managed care entity;
- Upon execution, renewal, or extension of a contract by the state with a fiscal agent or a managed care entity; or
- Upon written request within thirty-five (35) days by the Cabinet for Health and Family Services. [KRS 205.8477]

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Medical Director

A managed care plan operating in the state of Kentucky must appoint a medical director who is a physician licensed to practice in the state of Kentucky. The medical director is responsible for the treatment policies, protocols, quality assurance activities, and utilization management decisions of the managed care plan. The medical director must also sign any decision to deny any health care benefit [KRS 304.17A-545(1)].

The medical director must ensure that any utilization management decision to deny, reduce, or terminate health care benefits, or to deny payment for a health care service, because the service is not medically necessary, is made by a physician, except in the case of a service rendered by a chiropractor or optometrist, which must be made by a chiropractor or optometrist, respectively. The medical director must also ensure that a utilization management decision does not retrospectively deny coverage for a service when prior approval has been obtained from the insurer unless the approval was based on fraudulent, materially inaccurate, or misrepresented information submitted by the covered person or the participating provider. In the case of a managed care plan, the medical director must ensure a procedure is implemented whereby participating physicians have an opportunity to review and comment on all medical and surgical and emergency room protocols of the insurer, as well as protocols within the provider's legally authorized scope of practice; the utilization management program is made available to respond to authorization requests for urgent services during normal working hours for inquiries and authorization requests for nonurgent services; and, a covered person is permitted to choose or change primary care providers from among those participating in the network, including, when appropriate, a specialist, following an authorized referral [KRS 304.17A-545(2)]. [\(Back\)](#)

Medical Order for Scope of Treatment (MOST)

An adult with decisional capacity, an adult's legal surrogate, or a responsible party may complete a medical order for scope of treatment, which is an actionable medical order, directing medical interventions. [KRS 311.6225]

The patient, the surrogate, or a responsible party shall sign the medical order for scope of treatment form; however, if it is not practicable for the patient's surrogate or a responsible party to sign the original form, the surrogate or a responsible party shall sign a copy of the completed form and return it to the health care provider completing the form. The copy of the form with the signature of the surrogate or a responsible party, whether in electronic or paper form, shall be signed by the physician and shall be placed in the patient's medical record. When the signature of the surrogate or a responsible party is on a separate copy of the form, the original form shall indicate in the appropriate signature field that the signature is attached. [KRS 311.6225]

A physician shall document the medical basis for completing a medical order for scope of treatment in the patient's medical

record. [KRS 311.6225]

A medical order for scope of treatment, if completed, shall implement or apply a health power of attorney or a living will directive if one exists. [KRS 311.621]

A medical order for scope of treatment made pursuant to KRS 311.6225 shall be honored by a patient's family, regular family physician or attending physician, and any health care facility of or in which the patient is located. [KRS 311.623] It shall be the responsibility of the patient or the responsible party of the patient to provide for notification to the patient's attending physician and health care facility where the patient is located that a medical order for scope of treatment has been made. If the patient is comatose, incompetent, or otherwise mentally or physically incapable, any other person may notify the attending physician of the existence of a medical order for scope of treatment. An attending physician who is notified shall promptly make the medical order for scope of treatment a part of the patient's medical records. [KRS 311.633]

An attending physician or health care facility which refuses to comply with a medical order for scope of treatment of a patient or decision made by a surrogate or responsible party shall immediately inform the patient or the patient's responsible party and the family or guardian of the patient of the refusal. No physician or health care facility which refuses to comply with the medical order for scope of treatment of a qualified patient or decision made by a responsible party shall impede the transfer of the patient to another physician or health care facility which will comply with the medical order for scope of treatment. [KRS 311.633] No physician, who shall state in writing to the hospital or health care facility his objection to complying with a medical order for scope of treatment, on moral, religious, or professional grounds, shall be required to, or held liable for refusal to, comply with the medical order for scope of treatment as long as the physician complies with the requirements regarding patient notification and patient transfer outlined above. [KRS 311.633] It shall be unlawful discriminatory practice for any person to impose penalties or take disciplinary action against or deny or limit licenses, certifications, degrees, or other approvals or documents of qualification to any physician who refuses to comply with the a medical order for scope of treatment, as long as the physician complies with the requirements regarding notification and transfer as outlined above. [KRS 311.633]

Notification to any emergency medical responder or any paramedic of a person's authentic wish not to be resuscitated shall be recognized only if on a standard form or identification approved by the Kentucky Board of Medical Licensure, in consultation with the Cabinet for Health and Family Services, or a standard medical order for scope of treatment form approved by the Kentucky Board of Medical Licensure. [KRS 311.623 and KRS 311.6225]

The standard medical order for scope of treatment form and a Board opinion relating to the use of medical orders for scope of treatment can be found on the [KBML's website. \(Back\)](#)

Medical Records

- I. **Ownership of medical records:** Original medical records are the physical property of the physician or the health care facility that provides care to the patient. However, the physician or facility is not considered to "own" the information contained in the records. It is the position of the American Medical Record Association, the AMA's Council of Ethical and Judicial Affairs, and most courts that patients have a right to access to the information in their medical records, except in limited circumstances. The original record and originals of any reports in the record need not and should not be surrendered.
- II. **Content of medical records:** The physician has discretion as to what information and documents are included in the patient's medical record file. Generally, it is a good idea to include only such things as the medical history, updated medical chart, reports of consultants, laboratory reports, and the like in the medical file. Billing records and other "business" aspects of the patient's care should be separately maintained. However, if separate files are maintained, in responding to a subpoena or request for records, care should be taken to include all the items specifically requested. Care should also be taken to avoid uncomplimentary comments in the chart. Physician notes may be read by the patient or may become part of a public record if the documents must be produced.
- III. **Patient's right of access to records:** Under Kentucky law, individuals are entitled to one free copy of their medical record. Physician practices may then charge for copies of information that have already been provided to the patient free of charge. This law has also been interpreted to mean that physician practices do not have to provide free copies of information that were not generated by the practice, but may be in the practice's possession. It has also been interpreted that billing records do not

fall under this mandate.

In many respects, HIPAA changes patients' rights to access of medical information and goes beyond the rights provided under Kentucky law. Under HIPAA, individuals now have a right to inspect or obtain a copy of medical information about the individual that is maintained in a designated record set. Thus, individuals have a right of access to any protected health information that is used, in whole or in part, to make decisions about individuals. Such information includes billing records. Physician practices must provide access to individuals for as long as the protected health information is maintained by the practice.

The practice must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained by the practice. Practices may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement, usually by placing such a requirement in a practice's Notice of Privacy Practices. The practice must act on a request within 30 days after receipt of the request, unless the information is not maintained on-site. If the practice is unable to act on a request within 30 days, it may extend the deadline by no more than 30 days by providing the individual with a written statement of the reasons for the delay and the date by which the practice will complete its action on the request. This written statement describing the extension must be provided within the standard deadline. A practice may only extend the deadline once per request for access. In such situations, the practice has 60 days from the date of the request. If the practice denies the request, in whole or in part, it must provide the individual with a written denial pursuant to the guidelines discussed below.

Denial of Access – Nonreviewable

A physician practice may deny a patient access to his or her medical information in certain situations. Certain denials, however, may be appealed by the patient and physician practices must review and act on the appeals.

A physician practice may deny access for the following information or under the following circumstances, *and the individual may not appeal denials made for these reasons:*

- The information constitutes psychotherapy notes.
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. A practice may therefore deny access to any information that relates specifically to legal preparations *but may not deny access to the individual's underlying health information*. This exception normally covers material that may be protected under attorney/client privilege.
- Information subject to the Clinical Laboratory Improvements Amendments [CLIA]. CLIA states that clinical laboratories may provide clinical laboratory test records and reports only to "authorized persons."
- Information regarding an inmate at a correctional institution if providing such information would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates or the safety of any institutional employee.
- Information obtained during research that includes other subjects.
- Information protected under the Federal Privacy Act.
- Information obtained from someone other than a health care provider under a request for confidentiality.

Denials of Access – Reviewable

There are situations where physician practices may deny access to a patient's protected health information, but the denial must be reviewed if requested by the patient. Denials are not mandatory; physician practices may provide the requested health information to the individual. The reasons for denial are specific and the government has said that applying these exceptions to the rule of access should be used "rarely."

- A licensed health care professional [i.e. - physician, nurse, physician assistant] has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. The most common example is when a patient exhibits suicidal tendencies.
- The protected health information makes reference to another person and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person.
- The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that access by the personal representative is reasonably likely to cause substantial harm to the individual patient or another person. There need not be a reasonable belief that the personal representative has abused or neglected the individuals and the harm that is likely to result need not be limited to the individual who is the subject of the requested protected health information.

If a physician practice denies access to protected health information, the practice must provide a written denial to the

individual within 30 days and must state the following:

- ❑ The basis for the denial;
- ❑ If applicable, a statement of the individual's review rights including a description of how the individual may exercise such review rights; and
- ❑ A description of how the individual may complain to the practice including the name, title and telephone number of the person responsible for receiving complaints, and that the individual may complain to the Secretary of Health and Human Services.

If a physician practice does not maintain the protected health information that is the subject of the individual's request for access, and the practice knows where the requested information is maintained, the practice must inform the individual where to direct the request for access.

Review of a Denial of Access

If access is denied on a ground that allows an individual to seek review of the denial, the review must be conducted by a licensed health care professional who is designated by the practice to act as a reviewing official and who did not participate in the original decision to deny access to the information. The review must be completed within a reasonable period of time, and once it is completed, the practice must provide written notice to the individual of the determination and provide or deny access based on the determination of the reviewer.

Requirements for Providing Access to Protected Health Information

If a physician practice provides an individual with access, the practice must comply with the following requirements. The following requirements attempt to combine both HIPAA and Kentucky state law regarding access to medical records.

- ❑ The practice must provide the access requested, whether it be inspection of information or obtaining a copy of information. As discussed earlier, Kentucky law mandates that individuals may obtain copies of medical records. Thus, combining both HIPAA and Kentucky law, individuals may obtain one free copy of medical records and any additional copies for a fee. Since Kentucky law does not cover billing records, practices may charge for copies of billing records, even for the first copy requested.
- ❑ The practice must provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the practice and the individual.
- ❑ The practice may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:
 - a. The individual agrees in advance to such a summary or explanation; and
 - b. The individual agrees in advance to the fees imposed, if any, by the practice for such summary or explanation.
- ❑ The practice must provide the access as requested by the individual within 30 days of the date the request was received, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request.
- ❑ If the practice denies access, in whole or in part, to protected health information, the practice must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the practice has a ground to deny access.

Fees

Under Kentucky law, if an individual requests a copy of medical records, a physician practice must provide one free copy of the medical records, but may charge for billing records, even if it is the first request. If the individual requests another copy of protected health information, including billing records, the practice may impose a reasonable, cost-based fee. This fee, pursuant to Kentucky law, may not exceed \$1.00 per page [.50 per page for workers compensation cases]. While Kentucky law does not require that copies be mailed, HIPAA does. According to HIPAA, mailing costs may be charged to the individual, as long as the charge does not exceed cost. Practices may also charge a cost-based fee for preparing an explanation or summary of the protected health information, if agreed to by the individual.

IV. **Refusal in view of unpaid bill:** The AMA's Council on Ethical and Judicial Affairs has stated that it is unethical conduct for a physician to withhold the release of a patient's medical record because the patient has an outstanding balance with the provider.

V. **Parties who may request access:** A competent adult patient may request his or her own records. In the case of minor or incompetent patients, the parent or legal guardian of the patient may request records on the patient's behalf. If the minor

is a child of divorced parents, the custodial parent is responsible for health care. If necessary to determine which parent has custodial authority, a copy of the final court ordered settlement decree explaining custody rights can be requested for the file. If the patient is deceased, the personal representative of the estate may request the records.

VI. **Requests made by attorneys:** The Kentucky Board of Medical Licensure has issued an opinion as to whether free copies of medical records must be given to attorneys who request them. The Board said:

While statute requires a patient's written request, attorneys have presented written requests on behalf of the patient as the patient's agent. It is the opinion of the Board that an attorney may transmit the written request of a patient to obtain a free copy of their medical records under KRS 422.317(1). However, an attorney may not simply request a copy of the patient's records "on behalf of..." their client. When a physician receives a patient's written request, either directly from the patient or through their agent, for a free copy of the patient's medical record, the physician is not required to mail the medical record to the patient or their agent; instead, the physician may require the patient or their agent to personally appear at the physician's office to take possession of the medical record.

VII. **Release of x-rays:** X-rays are treated like other medical records. A copy should be provided to the patient or to third parties upon proper request when the patient's identity has been verified, but the original need not and should not be surrendered. The patient may be assessed the reasonable actual cost of the reproduction. Although a report summarizing may be part of the medical records included in a free copy under KRS 422.317, it is probably permissible to charge for copies of the x-rays themselves although, again, there are no regulations concerning these matters.

VIII. **Records of patients seen by departed physician:** The AMA Code of Ethics says that patients should be given accurate and timely information and access to their records when their physicians depart from medical groups. Specifically, patients of a physician who leaves a group practice should be notified that the physician is leaving the group. Patients of the physician should also be notified of the physician's new address and offered the opportunity to have their medical records forwarded to the departing physician at his or her new practice. It is unethical to withhold such information upon request of a patient. If the responsibility for notifying patients falls to the departing physician rather than to the group, the group should not interfere with the discharge of these duties by withholding patient lists or other necessary information [*Code of Medical Ethics*, Opinion 7.03].

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Medical Records – Retention

The following material was prepared by Charles J. Cronan IV, an attorney with the law firm of Stites & Harbison.

In some instances, statutes or regulations specifically prescribe the length of time records must be kept. For example, Kentucky Medicaid regulations require the retention of patient records for a minimum of five years. Medicare conditions of participation require the retention of records pertaining to a minor for three years after the patient is deemed by state law to be an adult, or five years after the date of discharge, whichever is longer.

In other instances, the determination of a prudent time for retention of records must be derived from statutes of limitations. These are statutes which prescribe the period of time after which a claim will be time-barred if it has not been asserted. For example, civil money penalty claims under the federal False Claims Act must be brought within six years after a claim has been submitted. Yet another source of guidance on the subject is derived from court opinions pertaining to the time within which medical malpractice claims must be asserted. Kentucky statute requires that malpractice claims be brought within one year after a "cause accrues"; that is, when the injury is first discovered or should have been discovered. Until the claim is discovered, the one-year period does not begin to run. This statute also contains what is referred to as a "statute of repose" which would bar claims asserted more than five years after the date on which the alleged negligent act or omission occurred. However, in 1990, the Kentucky Supreme Court declared this section unconstitutional. Thus, most malpractice insurance carriers urge the indefinite retention of records. Under Kentucky law, the statute of limitation for personal injury to a minor does not begin to run until the patient reaches age eighteen. The statute never begins to run as to patients who are mentally incompetent. Finally, there also are ethical guidelines under which physicians are called upon to retain patient records and to make reasonable efforts to advise a patient or the patient's family of any intent to destroy those records.

Specific examples of laws and ethical opinions applicable to records retention are listed below.

Federal Anti-Fraud & Abuse Statutes: Statute of limitations for federal false claims range from six to ten years.

Civil False Claims Act (31 U.S.C. §§ 3729-3731) -- Civil actions may not be brought:

More than six years after the date of the false claim violation, or

More than three years after the date when facts material to the right of action were known or should have been known to the United States, but in no event more than ten years after the date of the violation.

Civil Monetary Penalties (42 U.S.C. § 1320a-7a) -- Civil monetary penalties for improperly filed claims may not be imposed more than six years after the claim was submitted

Program Fraud and Civil Remedies Act (31 U.S.C. §§ 3802-3803) -- Hearings regarding false claims must be commenced within six years after the date on which such claim or statement is made, presented, or submitted. Civil actions to recover penalties must be commenced within three years after the date on which the determination of liability for such penalty or assessment becomes final.

Kentucky's Medicaid Conditions of Participation for Physicians: Kentucky's Medicaid Program Physician Manual (907 KAR 3:005) requires that physicians maintain medical records of Kentucky Medicaid Program recipients for a minimum of five years. The medical records (and any other information regarding Medicaid Program paid claims) must be maintained in an organized central file, provided to the Medicaid Department upon request, and made available for inspection and photocopy by Department personnel.

Medicare Conditions of Participation for Clinics (i.e. three or more physicians practicing together) (42 C.F.R. § 485.721): Physician practices with three or more members who participate in Medicare must retain patient clinical records for at least:

Five years after the date of discharge, or

In the case of a minor, three years after the patient becomes of age under state law (18) or five years after the date of discharge, whichever is longer.

Kentucky's Statute of Limitations for Medical Malpractice Cases (KRS § 413.140): Medical malpractice cases must be brought within one year after the "cause of action accrues." A cause of action shall be deemed to accrue:

When the injury is first discovered or should have been discovered,

But in no event later than five years after the date on which the alleged negligent act or omission is said to have occurred. [Note: This subsection was declared unconstitutional in 1990 by the Kentucky Supreme Court in *McCollum v. Sisters of Charity of Nazareth*, 799 S.W.2d 15, Ky. S. Ct. (1990).]

A minor must bring a cause of action for medical malpractice within one year of reaching the age of majority.

AMA Ethical Opinion E-7.05 regarding Retention of Medical Records

The AMA Council on Ethical and Judicial Affairs issued an ethical opinion regarding retention of medical records in June 1994. Physicians have an ethical obligation to "retain patient records which may reasonably be of value to a patient." AMA guidelines for retention of medical records are listed below:

- Medical considerations are the primary basis for deciding how long to retain medical records. For example, operative notes and chemotherapy records should always be part of the patient's chart. In deciding whether to keep certain parts of the record, an appropriate criterion is whether a physician would want the information if he or she were seeing the patient for the first time.
- Medical records should be kept for at least as long as the length of time of the statute of limitations for medical malpractice claims.
- Immunization records always must be kept.
- In order to preserve confidentiality when discarding old records, all documents should be destroyed.
- Before discarding old records, patients should be given an opportunity to claim the records or have them sent to another physician, if it is feasible to give them the opportunity.

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Medical Staff

Federal regulations, accreditation standards, and state regulations require a hospital to have an organized medical staff section. The medical staff is the body responsible to the hospital's governing body for the quality of professional care rendered to patients.

Kentucky regulations require hospitals to have an organized medical staff section [902 KAR 20:016E §3(8)(a)]. "Medical staff" is defined as an organized body of physicians, and dentists when applicable, appointed to the hospital staff by the governing authority [902 KAR 20:016E §1(6)]. The medical staff must be organized under bylaws approved by the governing authority of the hospital that is responsible for the quality of medical care provided to the patients and for the ethical and professional practice of its members. The medical staff must develop and adopt policies or bylaws, subject to the approval of the governing authority, which must:

1. State necessary qualifications for medical staff membership;

2. Define and describe the responsibilities and duties of each category of medical staff, delineate the clinical privileges of staff members and allied health professionals, and establish a procedure for granting and withdrawing staff privileges to include credentials review;
3. Provide a mechanism for appeal of decisions regarding staff membership and privileges;
4. Provide a method for the selection of officers of the medical staff;
5. Establish requirements regarding the frequency of, and attendance at, general staff and department or service meetings of the medical staff;
6. Provide for the appointment of standing in special committees of the medical staff which may include: executive committee, credentials committee, medical audit committee, medical records committee, infections control committee, tissue committee, pharmacy and therapeutics committee, utilization review committee, and quality assurance committee; and
7. Establish a policy requiring a member of the medical staff to sign a verbal order for diagnostic testing or treatment as soon as possible after the order was given or within 30 days of the patient's discharge if the discharge occurred prior to the order being authenticated[902 KAR 20:016E §3(8)(b)].

This regulation also requires that medical care provided in the hospital must be under the direction of a medical staff member in accordance with staff privileges granted by the governing authority. The medical staff member must assume full responsibility for diagnosis and care of his patient. Other qualified personnel may complete medical histories, perform physical examinations, record findings, and compile discharge summaries, in accordance with their scope of practice. The medical staff member must also state his final diagnosis, assure that the discharge summary is completed and sign the records within thirty days following the patient's discharge. Physician services must be available 24 hours a day on at least an on call basis and there must be sufficient medical staff coverage for all clinical services of the hospital in keeping with its size and scope of activity [902 KAR 20:016E §4].

The national trend has been for hospitals to seek greater control over medical staffs through amendments to the medical staff bylaws, greater use of exclusive contracts, employed physicians, and other measures. Medical staffs have reacted with measures designed to protect their autonomy and the ability to exercise independent medical judgment. Medical staffs have also expressed a greater concern for the quality of patient care than for economic efficiency where the two issues may be in conflict. Medical staffs should carefully evaluate changes in medical staff bylaws proposed by hospital counsel or consultants to ensure proper balance between medical staff concerns about delivery of quality patient care and hospital concerns regarding the efficient operation as a business.

A medical staff, when drafting bylaws and handling other legal issues, should employ its own legal counsel as opposed to using the legal counsel furnished by the hospital. This will allow the medical staff to have medical staff bylaws, and changes thereto, reviewed by an outside counsel who is not employed by the hospital. Medical staffs must understand that they are not bound to adopt bylaws or to make revisions in bylaws simply because they have been prepared and submitted by the hospital. Medical staffs have clear responsibility and considerable leeway to develop and adopt bylaws that create a framework within which staff members can act with reasonable freedom and which best suit the delivery of quality patient care in their particular hospital setting. [\(Back\)](#)

Mental Health

While Kentucky law does not mandate insurance coverage for mental health conditions, a health benefit plan that provides coverage for treatment of a mental health condition must provide coverage of any treatment for a mental health condition under the same terms or conditions as provided for treatment of a physical health condition [KRS 304.17A-661(1)]. "Mental health condition" is any condition or disorder that involves mental illness or alcohol and other drug abuse [KRS 304.17A-660(1)]. "Treatment of a mental health condition" includes, but is not limited to, any necessary outpatient, inpatient, residential, partial hospitalization, day treatment, emergency detoxification, or crisis stabilization services [KRS 304.17A-660(3)]. Any mental health condition that is excluded from the standard health benefit plan authorized by law and in effect on January 1, 2000, may continue as an exclusion [KRS 304.17A-661(4)]. [\(Back\)](#)

Mental Health – Advance Directive

An “advance directive for mental health treatment” is a written document, or a document in a form consistent with the provisions of the federal Americans with Disabilities Act (ADA), made voluntarily by a grantor that provides instructions for mental health treatment. Anyone eighteen (18) years of age or older whose right to make health care decisions or to execute legal documents has not been limited may execute an advance directive for mental health treatment. A person who legally executes such a directive is known as a “grantor.” [KRS 202A.420] An adult may execute an advance directive for mental health treatment that includes one or more of the following:

- (a) Refusal of specific psychotropic medications, but not an entire class of psychotropic medications. This refusal may be due to factors that include but are not limited to their lack of efficacy, known drug sensitivity, or previous experience of adverse reactions;
- (b) Refusal of electric shock therapy (ECT);
- (c) Stated preferences for psychotropic medications;
- (d) Stated preferences for procedures for emergency interventions; and
- (e) Provision of information in any area specified by the grantor. [KRS 202A.422]

An advance directive may not override the grantor’s right under federal and state law to refuse treatment. A “surrogate” designated by a grantor in an advance directive for mental health treatment must act on behalf of the grantor in accordance with the desires of the grantor as indicated in the advance directive and may override the advance directive only if there is substantial medical evidence that failing to do so would result in harm to the grantor [KRS 202A.424]. A “surrogate” may be an adult who has not provided health care services to the grantor, who has been designated by the grantor to act, and who agrees to act on behalf of the grantor [KRS 202A.420].

When acting on behalf of the grantor, the surrogate must consider the recommendations of the health care provider and honor the decisions made by the grantor as expressed in the advance directive. If the grantor’s instructions or preferences are not stated in the advance directive, the surrogate may act in good faith on behalf of the grantor in the manner that the surrogate believes the grantor would act. A surrogate may resign at any time by giving written notice to the grantor, to the immediate successor surrogate, if any, to the attending health care provider, or to the health care facility [KRS 202A.424].

The grantor or the surrogate of the grantor is responsible for providing a copy of the advance directive to the grantor’s health care provider and health care facility where the grantor is a patient [KRS 202A.422]. An advance directive for mental health treatment must be honored in any setting, except a hospital emergency room or a hospital emergency department, that is required to honor advance directives under Title XVIII or Title XIX of the federal Social Security Act [KRS 202A.422]. A health care provider or health care facility must provide mental health treatment that complies with the instructions in an advance directive to the fullest extent possible when the instructions are within standards for mental and physical health care and permitted by state and federal law [KRS 202A.426]. A health care provider or health care facility may override expressed refusals of treatment only if:

- a) A court order contradicts the advance directive; or
- b) There is an emergency endangering a person’s life or posing a serious risk to physical health [KRS 202A.426].

A health care provider or health care facility that refuses to comply with an advance directive of a grantor or a decision made by a surrogate must immediately inform the grantor or surrogate, if one is designated, of the refusal, and not impede the transfer of the grantor to another health care provider or health care facility [KRS 202A.426]. Deviations from expressed preferences in an advance directive must be documented by the health care provider or health care facility in the grantor’s medical record [KRS 202A.426]. A health care provider, health care facility, surrogate, or other responsible party may not be subject to criminal prosecution or civil liability if acting in agreement with a properly executed advance directive for mental health treatment or if acting in good faith without knowledge of the existence or revocation of an advance directive [KRS 202A.422].

The execution of an advance directive is complete when signed by the grantor and two (2) adult witnesses who attest that the grantor is known to them; signed the advance directive in their presence; and did not appear to be under duress, fraud, or undue influence. Execution is also complete when it is signed by the grantor and acknowledged before a notary public or other person authorized to administer oaths. The following persons may not serve as a witness, a notary public, or other person authorized to administer oaths to the signing of an advance directive:

- (a) The grantor’s current health care provider or a relative of the current health care provider; and
- (b) An owner, operator, employee, or relative of an owner or operator of a health facility in which the grantor is a client or resident [KRS 202A.422].

An advance directive may be revoked in any of the following manner:

- a) A document that is signed and dated by the grantor and declares an intention to revoke;
- b) An oral statement of intent to revoke made by a grantor to a health care provider in the presence of some other person; or
- c) Destruction of the document by the grantor or by some person in the grantor's presence at the grantor's direction [KRS 202A.428].

An advance directive must be in substantially the following form:

Sample Advance Mental Health Directive

I, _____, willfully and voluntarily execute this advance directive for mental health treatment. I want the instructions in this advance directive to be followed as described below:

Designated Surrogate

____ I am naming a surrogate to see that my instructions for mental health treatment are carried out.

____ I am not naming a surrogate to see that my instructions for mental health treatment are carried out.

I designate _____ to act as my surrogate. If this person withdraws or is unwilling to act on my behalf, or if I revoke that person's authority to act as my surrogate, I designate _____ to act as my alternate surrogate.

If I do not designate a surrogate, if my surrogate and alternate surrogate withdraw or are unwilling to act on my behalf, or if I revoke their authority to act, then the health care provider and health care facility may proceed to render treatment in accordance with my instructions as described here and in accordance with standards for mental and physical health care.

The person acting as my surrogate is authorized to act in accordance with the content of this advance directive and may override the advance directive if, and only if, there is substantial medical evidence that failing to do so would result in harm to me. If my instructions and preferences are not stated in the advance directive, the surrogate may act in good faith in making treatment decisions in the manner in which the surrogate believes I would act.

Psychotropic Medication Provisions

I may indicate below any refusals of treatment with specific psychotropic medications, not to include an entire class of medications, due to factors that may include but are not limited to lack of efficacy, known drug sensitivity, or experience of adverse reaction:

I specifically do not consent and do not authorize my surrogate to consent to the administration of the following medications or their respective brand-name or generic equivalents for the reasons given:

Specific psychotropic medication:

Reason for refusal:

I may list below any specific psychotropic medications that I would be willing to have administered to me if additional medications become necessary:

Specific psychotropic medications:

Electroconvulsive Therapy Provisions

Below are my instructions regarding electroconvulsive therapy (ECT):

___ *I consent to electroconvulsive therapy (ECT) if it is deemed clinically appropriate to treat my condition.*

___ *I do not consent to electroconvulsive therapy (ECT).*

Preferred Procedures for Emergency Interventions

I may state preferences for procedures for emergency interventions to be used when necessary for my protection or the protection of others. I understand that I am requesting consideration of my preferences for procedures for emergency interventions but that my surrogate, my health care provider, and the health care facility where I am a patient are not subject to civil liability for not abiding by these preferences. I understand that in the case of possible harm to myself or others, my health care provider or the health care facility may need to use procedures that override my stated preferences. If during an admission or while a patient in a health care facility, it is determined that I am engaging in behavior that requires emergency intervention and the order that I prefer the interventions to be used are as follows:

Intervention

Order of preference

Reason for this preference

Seclusion: _____

Physical restraints: _____

Seclusion and Physical

Restraints Combined: _____

Medication by injection: _____

Medication in pill form: _____

Liquid medication: _____

Other: _____

Signed this _____ day of _____, 20__

Signature of grantor: _____

Address of grantor: _____

In my presence, the grantor voluntarily dated and signed this writing or directed it to be dated and signed. I am not the grantor's current health care provider, a relative of the current health care provider, or an owner, operator, employee or relative of an owner or operator of a health facility in which the grantor is a client or resident.

Signatures of witnesses: _____

Surrogate contact information (if designated):

Name: _____

Address: _____

Telephone: _____

Signed this _____ day of _____, 20__

Signature of surrogate: _____

Alternate surrogate contact information (if designated):

Name: _____

Address: _____

Telephone _____

Signed this _____ day of _____, 20__

Signature of alternate surrogate: _____

Mental Health – Duty to Warn

Mental health professionals, including physicians licensed in Kentucky or medical officers engaged by the federal government to perform mental health services, cannot face monetary liability or a legal cause of action for failing to predict, warn of or take precautions to provide protection against a patient’s violent behavior unless the patient communicates to the mental health professional an actual threat of physical violence against a clearly identified or reasonable identifiable victim, or the patient has communicated to the mental health professional an actual threat of some specific act.

The duty to warn can be met in the following ways:

- For “a clearly or reasonable identifiable victim”
 - Communicate the threat to the victim; and
 - Notify the police department closest to the patient’s and the victim’s residence of the threat of violence.
- For “an actual threat of some specific violent act and no particular victim is identifiable”
 - Communicate the threat to law enforcement

The duty to take reasonable precaution to provide protection from violent behavior can be met in the following way:

- Make reasonable efforts to seek civil commitment of the patient under KRS 202A.

Patient is defined as a person under observation, care, or treatment in a hospital pursuant to the provisions of KRS 202A as well as a person currently under the outpatient care or treatment of a mental health professional. [KRS 202A.400] [\(Back\)](#)

Minors, Treatment of

KRS 214.185 discusses the diagnosis and treatment of minors. This law gives a physician the authority, upon consultation by a minor as a patient, with the consent of such minor, to make a diagnostic examination for venereal disease, pregnancy, alcohol or other drug abuse or addiction. A physician may advise, prescribe for and treat such minor regarding venereal disease, alcohol and other drug abuse or addiction, contraception, pregnancy or childbirth, all without the consent of or notification to the parent or guardian of such minor patient, or to any other person having custody of such minor patient. Such treatment does not include inducing an abortion or performing a sterilization operation. A physician may also provide outpatient mental health counseling to any child age 16 or older upon request of such child without the consent of the parent.

Any emancipated minor or any minor who has contracted a lawful marriage or born a child may give consent to the furnishing of hospital, medical, dental or surgical care to his or her child or himself or herself and such consent shall not be subject to disavermments because of minority. The consent of the parent of such married or emancipated minors is not necessary in order to authorize such care. The provider of care may look only to the minor or spouse for payment for services under this section unless other persons specifically agree to assume the cost.

Medical care may be rendered to minors of any age without the consent of a parent when, in the professional’s judgment, the risk to the minor’s life or health is of such a nature that treatment should be given without delay and the requirement of consent would result in delay or denial of treatment.

The professional may inform the parent or legal guardian of the minor of any treatment given or needed when in the judgment of the professional informing the parent would benefit the health of the minor.

Parents or guardians of a minor are not financially responsible for services rendered under this law unless they are essential for the preservation of the health of the minor.

A minor, his parent or guardian, may give consent to the furnishing of medical care or counseling related to the assessment or treatment of the minor’s alcohol abuse, drug abuse, or emotional problems caused by a family member or legal guardian’s drug or alcohol problems [KRS 222.441]. [\(Back\)](#)

Newborn Screening

The Cabinet for Health and Family Services operates a newborn screening program for heritable and congenital disorders

that includes procedures for conducting initial newborn screening tests on infants twenty-eight (28) days or less of age [KRS 214.155(1)]. The person in charge of a hospital or institution caring for a newborn infant, and the attending physician or midwife must administer or verify administration in every infant in its care a blood test to detect inborn errors of metabolism or other inherited disorders including the following:

1. 3-methylcrotonyl-CoA carboxylase deficiency (3MCC);
2. 3-OH 3-CH3 glutaric aciduria (HMG);
3. argininosuccinic acidemia (ASA);
4. beta-ketothiolase deficiency (BKT);
5. biotinidase disorder;
6. carnitine uptake defect (CUD);
7. citrullinemia (CIT);
8. congenital adrenal hyperplasia (CAH);
9. congenital hypothyroidism;
10. cystic fibrosis (CF);
11. galactosemia;
12. glutaric acidemia type I (GA I);
13. Hb S/beta-thalassemia (Hb S/Th);
14. Hb S/C disease (Hb S/C);
15. homocystinuria (HCY);
16. isovaleric acidemia (IVA);
17. krabbe disease;
18. long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHAD);
19. maple syrup urine disease (MSUD);
20. medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
21. methylmalonic acidemia (Cbl A,B);
22. methylmalonic acidemia mutase deficiency (MUT);
23. multiple carboxylase deficiency (MCD);
24. phenylketonuria (PKU);
25. propionic acidemia (PA);
26. short-chain acyl-CoA dehydrogenase deficiency (SCAD);
27. sickle cell disease;
28. trifunctional protein deficiency (TFP);
29. tyrosinemia type I (TYR I); and
30. very long-chain acyl-CoA deficiency (VLCAD). [KRS 214.155(2) and 902 KAR 4:030(2)]

The person in charge of a hospital or institution caring for a newborn infant, and the attending physician or midwife must administer or verify administration in every infant in its care a screening for critical congenital heart disease (CCHD) prior to discharge unless CCHD has been ruled out or diagnosed with prior echocardiogram or prenatal diagnosis of CCHD. [KRS 214.155(3) and 902 KAR 4:030(3)]

If a baby is not born in a hospital or institution, the attending physician or midwife is responsible for ensuring such tests are administered between twenty-four (24) and forty-eight (48) hours of age [902 KAR 4:030(3)]. Additional requirements for hospitals to collect the specimens; report the screening tests; educate the parents; report the test results; and deal with abnormal results are set out in 902 KAR 4:030.

Each health care provider of newborn care must provide an infant's parent or guardian with information about the newborn screening tests [KRS 214.155(4)]. In addition each parent or guardian must be provided information by the institution or health care provider of newborn care about the availability and costs of screening tests not specified above. The parent or guardian shall be responsible for costs relating to such additional screening tests. All positive results of additional screening of these tests must be reported to the cabinet by the institution or health care provider [KRS 214.155(7)]. The institution or health care provider must also arrange for appropriate and timely follow-ups to the newborn screening tests, including but not limited to additional diagnoses, evaluation, and treatment when indicated [KRS 214.155(4)].

Such tests are not required of any child whose parents are members of a nationally recognized and established church or religious denomination, the teachings of which are opposed to medical tests, and who object in writing to the testing of his or her child on that ground [KRS 214.155(5)]. ([Back](#))

Nursing

The practice of nursing is regulated by Kentucky law and regulations. The Kentucky Board of Nursing governs the nursing profession by establishing licensure requirements and handling disciplinary actions for the profession (KRS 314.131).

Registered Nurse

To become a registered nurse, one must complete the basic curriculum for preparing registered nurses in an approved school of nursing and complete the requirements for graduation. One must also be able to speak, understand and write the English language; and pass a jurisprudence test [KRS 314.041(1)]. An applicant must also pass an examination held by the Board of Nursing [KRS 314.041(2)]. Any person who holds a license as a registered nurse is authorized to use the abbreviation "R.N." No other person can use such abbreviation, or, practice as a registered nurse unless licensed to do so [KRS 314.041(9)].

A registered nurse may perform acts relating to:

- (a) The care, counsel, and health teaching of the ill, injured, or infirm.
- (b) The maintenance of health or prevention of illness of others.
- (c) The administration of medication and treatment as prescribed by a physician, dentist, or advanced practice registered nurse and as further authorized or limited by the board, and which are consistent either with American Nurses' Association Standards of Practice or with Standards of Practice established by nationally-accepted organizations of registered nurses. Components of medication administration include, but are not limited to:
 1. Preparing and giving medications in the prescribed dosage, route, and frequency;
 2. Observing, recording, and reporting desired effects, untoward reactions, and side effects of drug therapy;
 3. Intervening when emergency care is required as a result of drug therapy;
 4. Recognizing accepted prescribing limits and reporting deviations to the prescribing individual;
 5. Recognizing drug incompatibilities and reporting interactions or potential interactions to the prescribing individual; and
 6. Instructing an individual regarding medications.
- (d) The supervision, teaching of, and delegation to other personnel in the performance of activities relating to nursing care.
- (e) The performance of other nursing acts which are authorized or limited by the Board of Nursing, and which are consistent either with American Nurses' Association Scope and Standards of Practice or with standards of practice established by nationally-accepted organizations of registered nurses [KRS 314.011(6)].

A registered nurse who is employed by an ambulance service must complete training in determination of death and preservation of evidence as required by the Board of Nursing through the promulgation of administrative regulations [KRS 314.181(1)].

Licensed Practical Nurse

To become a licensed practical nurse, one must complete the required educational program in practical nursing at an approved school of nursing and must have completed requirements for graduation. One must also be able to speak, understand and write the English language; and pass a jurisprudence test [KRS 314.051(1)]. An applicant must also pass an examination held by the Board of Nursing [KRS 314.051(3)]. Any person who holds a license as a licensed practical nurse is authorized to use the abbreviation "L.P.N." No other person can use such abbreviation, or, practice as a licensed practical nurse unless licensed to do so [KRS 314.051(9)].

Licensed practical nurses may perform acts requiring knowledge and skill such as are taught or acquired in approved schools for practical nursing in:

- (a) The observing and caring for the ill, injured, or infirm under the direction of a registered nurse, advanced practice registered nurse, physician assistant, licensed physician, or dentist.
- (b) The giving of counsel and applying procedures to safeguard life and health, as defined and authorized by the board.
- (c) The administration of medication or treatment as authorized by a physician, dentist, or advanced practice registered nurse and as further authorized or limited by the board which is consistent with the National Federation of Licensed Practical Nurses or with Standards of Practice established by nationally-accepted organizations of licensed practical nurses.
- (d) Teaching, supervising, and delegating except as limited by the board.
- (e) The performance of other nursing acts which are authorized or limited by the Board of Nursing and which

are consistent with the National Federation of Practical Nurses' Standards of Practice or with Standards of Practice established by nationally-accepted organizations of licensed practical nurses [KRS 314.011(10)].

Registered Nurse First Assistant

A "registered nurse first assistant" is one who holds a current active registered nurse license and is certified in perioperative nursing, in which the nurse provides preoperative, intraoperative, and postoperative nursing care to surgical patients. A registered nurse first assistant must have successfully completed and hold a degree or certificate from a recognized program consisting of The Association of Operating Room Nurses, Inc., Core Curriculum for the registered nurse first assistant and one (1) year of postbasic nursing study, which shall include at least forty-five (45) hours of didactic instruction and one hundred twenty (120) hours of clinical internship or its equivalent of two (2) college semesters [KRS 216B.015(21)].

Delegation of Nursing Tasks

An RN or LPN may delegate nursing tasks to unlicensed persons. Prior to such delegation, the nurse must determine the nursing care needs of a patient and retain responsibility and accountability for the nursing care of the patient. The nurse must also either instruct the unlicensed person in the delegated tasks or verify the unlicensed person's competency to perform such tasks. The assigned task must be one that a reasonable and prudent nurse would find is within the scope of sound nursing judgment and practice to delegate. The task must be one that can be safely performed by the unlicensed person involved without compromising the client's welfare. The task may not require the unlicensed person to exercise independent nursing judgment or intervention. The nurse must provide supervision of the delegated task determined after an evaluation of appropriate factors including the stability and acuity of the client's condition; the training and competency of the delegatee; the complexity of the nursing task being delegated; and the proximity and availability of the nurse delegating the task [201 KAR 20:400].

Advanced practice registered nurses

An advanced practice registered nurse (APRN) is a certified nurse practitioner, certified registered nurse anesthetist, certified nurse midwife or clinical nurse specialist who is licensed to engage in advance practice registered nursing and certified in at least one (1) population focus [KRS 314.011(7)]. A population focus means the section of the population within which the APRN has targeted to practice including family or individual across the life span; adult gerontology; neonatal; pediatrics; women's health and gender-related health; and psychiatric mental health. [KRS 314.011(20)] APRNs perform additional acts and have gained advanced clinical knowledge and skills through an accredited education program that prepares the registered nurse for one (1) of the four (4) APRN roles. They are certified by nationally-established organizations or agencies recognized by the Board of Nursing to certify registered nurses for advanced nursing practice [KRS 314.011(8)]. The additional acts in which they may engage in, subject to the Board of Nursing, include prescribing treatment, drugs, devices, and ordering diagnostic tests. Prior to prescribing or dispensing drugs, however, a nurse practitioner must have a written collaborative agreement with a physician (see discussion below); however, APRNs designated as certified registered nurse anesthetists do not have to enter into such a collaborative agreement in order to deliver anesthesia care [KRS 314.042]. APRNs may dispense noncontrolled legend drug samples from pharmaceutical manufacturers to patients at no charge to the patient or any other party if such is set out in the collaborative agreement between the APRN and the physician [KRS 314.011(17)]. An APRN may also dispense noncontrolled legend drugs from a local, district, and independent health department, subject to the direction of the appropriate governing board of the individual health department [KRS 314.011(8); KRS 314.011(17)].

An APRN may issue prescriptions for but not dispense Schedule II through V controlled substances as classified under Kentucky law as long as the APRN has a collaborative agreement as outlined below. Prescriptions issued by an APRN for Schedule II controlled substances, except for hydrocodone combination products, must be limited to a seventy-two (72) hour supply without any refill. Prescriptions issued for psychostimulants may be written for a thirty (30) day supply only by an APRN certified in psychiatric-mental health nursing who is providing services in a "health facility" or in a regional services program for mental health or individuals with an intellectual disability. [KRS 314.011(8)(a)]

Prescriptions issued by an APRN for Schedule III controlled substances and hydrocodone combination products must be limited to a thirty (30) day supply without any refill and prescriptions for Schedules IV and V controlled substances must be limited to the original prescription and refills not to exceed a six (6) month supply. [KRS 314.011(8)(a)(b)]

Limitations for specific controlled substances which are identified as having the greatest potential for abuse or diversion, based on the best available scientific and law enforcement evidence, shall be established in an administrative regulation promulgated

by the Kentucky Board of Nursing. [KRS 314.011(8)(c)]

APRNs must maintain a current active registered nurse license and maintain certification by the appropriate national organization [KRS 314.042(4)]. Any person designated as an APRN may use the titled abbreviation “APRN” [KRS 314.042(5)].

An advanced practice registered nurse may also perform a history and physical examination for a patient admitted to an acute care or psychiatric hospital, as well as order and review continuation of restraints and seclusion as a health care practitioner in accordance with federal regulations [KRS 216B.175].

Collaborative Agreements

Except as provided below, before an APRN engages in the prescribing or dispensing of nonscheduled legend drugs the APRN must enter into a written “Collaborative Agreement for the Advanced practice registered nurse’s Prescriptive Authority for Nonscheduled Legend Drugs” (CAPA-NS) with a physician licensed in Kentucky that defines the scope of the prescriptive authority for nonscheduled legend drugs. The CAPA-NS must be in writing and reviewed and signed by both the APRN and the collaborating physician. The CAPA-NS may be rescinded by either party upon written notice via registered mail to the other party, the Kentucky Board of Nursing (KBN), and the Kentucky Board of Medical Licensure (KBML). A copy of the completed collaborative agreement must be available at each site where the APRN is providing patient care. The CAPA-NS must describe the arrangement for collaboration and communication between the APRN and the collaborating physician regarding the prescribing of nonscheduled legend drugs by the APRN. The APRN who is prescribing nonscheduled legend drugs and the collaborating physician must be qualified in the same or a similar specialty. The CAPA-NS is not intended to be a substitute for the exercise of professional judgment by the APRN or by the collaborating physician [KRS 314.042(8)].

The APRN must notify KBN of the existence of the CAPA-NS and the name of the collaborating physician. The APRN must also furnish to KBN or its staff a copy of the completed CAPA-NS if requested. KBN must notify KBML that a CAPA-NS exists and furnish the collaborating physician’s name [KRS 314.042(8)].

An APRN may discontinue a CAPA-NS if the APRN has completed four (4) years of prescribing as a nurse practitioner, clinical nurse specialist, nurse midwife, or as a certified registered nurse anesthetist. For nurse practitioners and clinical nurse specialists, the four (4) years of prescribing shall be in a population focus of adult-gerontology, pediatrics, neonatal, family, women’s health, acute care, or psychiatric-mental health. To discontinue a CAPA-NS, an APRN must also have a license that is in good standing with KBN. Finally, the APRN must notify KBN that the four (4) year requirement has been met and that he or she will be prescribing nonscheduled legend drugs without a CAPA-NS. An APRN can choose to maintain a CAPA-NS with a collaborating physician after the four (4) years have expired if he or she so chooses [KRS 314.042(9)].

An APRN wishing to practice in Kentucky through licensure by endorsement is exempt from the CAPA-NS requirement if the APRN has met the prescribing requirements in a state that grants independent prescribing to APRNs and the APRN has been prescribing for at least four (4) years. An APRN wishing to practice in Kentucky through licensure by endorsement who had a collaborative prescribing agreement with a physician in another state for at least four (4) years is exempt from the CAPA-NS requirement [KRS 314.042(9)]. Pursuant to KRS 314.196, there are other instances when APRNs may receive limited exemption from the CAPA-NS requirement as well.

After July 15, 2014, an APRN who has already satisfied the four (4) year requirement, has a license in good standing, and otherwise complies with the notification requirements may begin prescribing nonscheduled legend drugs without a CAPA-NS. After July 15, 2014, an APRN who has maintained a CAPA-NS for less than four (4) years must continue to maintain a CAPA-NS until the four (4) year period is completed, after which the CAPA-NS will no longer be required. However, an APRN can choose to maintain a CAPA-NS with a collaborating physician after the four (4) years have expired if he or she so chooses [KRS 314.042(9)].

Before an APRN engages in the prescribing of Schedules II through V controlled substances, the APRN must enter into a written “Collaborative Agreement for the Advanced Practice Registered Nurse’s Prescriptive Authority for Controlled Substances” (CAPA-CS) with a physician licensed in Kentucky that defines the scope of the prescriptive authority for controlled substances. [KRS 314.042(9)] In addition the following criteria must be met:

- The APRN must notify the Kentucky Board of Nursing of the existence of the CAPA-CS and the name of the collaborating physician and shall, upon request, furnish to the board or its staff a copy of the completed CAPA-CS;
- The CAPA-CS must be in writing and signed by both the APRN and the collaborating physician. A copy of the completed collaborative agreement must be available at each site where the APRN is providing patient care;
- The CAPA-CS must describe the arrangement for collaboration and communication between the APRN and the

- collaborating physician regarding the prescribing of controlled substances by the APRN;
- The APRN who is prescribing controlled substances and the collaborating physician must be qualified in the same or a similar specialty;
- Before engaging in the prescribing of controlled substances, the APRN must:
 1. Have been licensed to practice as an APRN for one (1) year with the Kentucky Board of Nursing; or
 2. Be nationally certified as an APRN and be registered, certified, or licensed in good standing as an APRN in another state for one (1) year prior to applying for licensure by endorsement in Kentucky.
- Prior to prescribing controlled substances, the APRN must obtain a Controlled Substance Registration Certificate through the U.S. Drug Enforcement Agency;
- The CAPA-CS must be reviewed and signed by both the APRN and the collaborating physician and may be rescinded by either party upon written notice via registered mail to the other party, the Kentucky Board of Nursing, and the Kentucky Board of Medical Licensure;
- The CAPA-CS must state the limits on controlled substances, which may be prescribed by the APRN, as agreed to by the APRN and the collaborating physician. The limits so imposed may be more stringent than either the schedule limits on controlled substances established in the law or the limits imposed in regulations. [KRS 314.042(10)]

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Office Address

KRS 311.586 requires every physician to file with the Kentucky Board of Medical Licensure his or her address at which the physician maintains an office. This report must be made within 90 days after commencing the practice of medicine. The law also requires a physician who moves his office to a new address to notify the Board of the change. [\(Back\)](#)

Opening a Medical Practice

The checklist contained in this section is taken from material prepared by the American Medical Association and is intended only as a general guide. Physicians should consider discussing issues of opening a new practice with a lawyer, accountant and/or other professional.

The American Medical Association has a complete book on this subject entitled Starting a Medical Practice for sale and is available by calling (800) 621-8335. Mention product number OP315202.

As discussed in the checklist contained in this section, physicians should contact third party payers to begin the credentialing process as soon as possible when considering opening a new practice. It can take up to six months in many cases to get credentialled by health plans, hospitals and other organizations. Some of the larger payers in Kentucky are listed below along with contact information to help physicians obtain credentialing information:

CGS Administrators (Medicare):	www.cgsmedicare.com
Aetna:	www.aetna.com/index.html
Anthem:	www.anthem.com
Baptist Health:	www.baptisthealthplan.com
Humana:	www.humana.com
United HealthCare:	www.uhc.com
Kentucky Medicaid Cabinet	www.chfs.ky.gov/dms

Medicaid Managed Care Organizations

Anthem:	mss.anthem.com/ky/pages/aboutus.aspx
Humana CareSource:	www.caresource.com/members
Passport:	www.passporthealthplan.com

Other Important Contact Information

Coding Manuals	American Medical Association www.ama-assn.org/ama
Demographics	Greater Louisville, Inc. (Louisville Chamber of Commerce) www.greaterlouisville.com KY Chamber of Commerce www.kychamber.com Urban Research Institute State Data Center ksdc.louisville.edu/ US Chamber of Commerce www.uschamber.com US Department of Commerce Bureau of Census www.census.gov/#
CMS-1500 (Formerly HCFA-1500 Insurance) Claim Form	CMS www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500805.pdf
ICD-10 Book	AMA commerce.ama-assn.org/store/catalog/subCategoryDetail.jsp?category_id=cat1150010&navAction=push
Licensure/ KY Medical Directories	Kentucky Board of Medical Licensure kbml.ky.gov/Pages/default.aspx

PREPARING FOR PRIVATE PRACTICE CHECKLIST

3	THINGS TO DO EARLY (1-2 years before starting practice)
	Decide on your life's goals and your family plans.
	Think about your philosophy of practicing medicine and your desired lifestyle.
	With the above in mind, decide on the type of practice you want to be in - partnership, solo, group, multi-specialty, etc.
	Select the area of the country/city in which you want to live and practice.
	Gather demographic data from Physician Placement Offices, brokers, local hospitals, newspapers, chambers of commerce, real estate services, etc., to help in your decision.
	Begin negotiating with local hospitals, group practices you may want to join.
	Decide on a date you wish to open your office so you can set up a timetable and begin working backward.

3	THINGS TO DO ONE YEAR BEFORE STARTING PRACTICE
	If appropriate, pick your partners and establish a close working relationship with them by setting up meetings, dividing responsibilities, assigning tasks and working on specifics of your plan.
	Find an office - location, layout, number and size of rooms, rent/lease, construct.
	Develop office chart system.
	Develop patient forms - registration, patient information booklets, etc.
	Develop a projected budget.
	Contact the local phone company for listing in next phone book - white/yellow pages.
	Start researching and writing job descriptions, personnel policies.
	Start talking with community members and other physicians to establish a referral system for employees and patients.

	Start looking for medical, office and business equipment. Compare lease vs. purchase.
	Secure an attorney and other advisors, as appropriate: accountant, banker, management consultant, insurance broker, investment counselor, etc.
	Contact insurance companies, other third-party payers and hospitals regarding credentialing. The credentialing process for some payers can take as long as nine months!

3	THINGS TO DO NO LATER THAN SIX MONTHS BEFORE STARTING PRACTICE
	Determine and have a partnership agreement drawn up and signed by each partner, if appropriate.
	Make a list of all equipment needed for office (medical, business, lab, furnishings, pictures, etc.)
	Obtain bids on major office equipment and place orders as soon as possible. A good rule of thumb is to get everything ordered four to six months before opening date. Be sure to get guarantee of delivery date and in-transit insurance.
	Decide on phone system, dictation, intercom, paging, answering service, etc.
	Decide on record-keeping system, billing system, collection agency, insurance processing.
	Obtain medical, narcotics, and business licenses; federal and state tax and employee information, equipment registration, etc.
	Negotiate lease or contract for office location.

3	THINGS TO DO ABOUT FOUR MONTHS BEFORE STARTING PRACTICE
	Contact State Department of Labor for wage and hour regulations.
	Arrange for insurance: professional liability, office overhead, office liability, employee fidelity bond, office contents, umbrella, workers' compensation, health, disability, personal life, automobile.
	Open accounts at bank or credit union: also credit card payments, establish credit line.
	Order HCFA 1500 Claim Forms, CPT-4 and ICD-9 Coding Books.
	Obtain membership in organized medicine - AMA, state and county medical societies, if you have not done so by now.

3	THINGS TO DO ABOUT TWO TO THREE MONTHS BEFORE STARTING PRACTICE
	Work on patient flow & scheduling procedures.
	Work out financial controls in the office - accounts receivable/accounts payable.
	Determine a fee schedule.
	Finalize office policy manual.
	Arrange for phone installation date.
	Check on patient referral system through local medical society and/or hospitals.
	Retain a payroll company, if needed.
	Arrange for lab and x-ray services for patients.
	Order office magazines, professional journals.
	Order practice stationery, practice information booklets, prescription pads, business cards.
	Notify area pharmacists and pharmaceutical detail persons of your practice.
	Become proficient at CPT/ICD-9 Coding.
	Hire and train new employees.

3	THINGS TO DO ABOUT ONE MONTH BEFORE STARTING PRACTICE
	Have phone in operation with someone to start making appointments/screening patients at least two weeks before office opens.
	Receive equipment and supplies.

	Set up office.
	Start service contracts on selected equipment.
	Mail out announcements to other physicians/hospitals.
	Publish announcement in local newspapers and county society publications.
	See first patient.
	Congratulate yourself.

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Osteopaths

During the 2000 General Assembly, a law was passed prohibiting discrimination against doctors of osteopathy. No health benefit plan or health facility may discriminate with respect to employment, staff, privileges, or the provision of professional services against a physician licensed to practice medicine on the basis of whether the physician holds a medical doctor (M.D.) or doctor of osteopathy (D.O.) degree [KRS 216B.017 & KRS 304.17A.275].

Any reference in a Kentucky statute, an executive order or an administrative regulation to “medical doctor,” “M.D.,” or “physician” is to be deemed to include a doctor of osteopathy or D.O., unless either of those terms is specifically excluded. Any reference in Kentucky law to the American Board of Medical Specialties is to include the Bureau of Osteopathic Specialties, unless either of those terms is specifically excluded [KRS 446.012]. [\(Back\)](#)

Pain Management Facilities

Only a physician having a full and active license to practice medicine must have an ownership or investment interest in a pain management facility. A pain management facility is a facility where the majority of patients of the practitioners at the facility are provided treatment for pain that includes the use of controlled substances and:

1. the facility’s primary practice component is the treatment of pain; or
2. the facility advertises for any type of pain management services.

A pain management facility does not include the following:

1. a hospital, a facility owned by the hospital, or the office of a hospital-employed physician;
2. a school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians;
3. a hospice program or residential hospice facility;
4. an ambulatory surgical center; or
5. a long-term-care facility.

This ownership or investment requirement must not be enforced against any pain management facility existing and operating on April 24, 2012, unless there is an administrative sanction or criminal conviction relating to controlled substances imposed on the facility, any person employed by the facility, or any person working at the facility as an independent contractor for an act or omission done within the scope of the facility’s licensure or the person’s employment.

A facility meeting this exemption whose ownership has been continuously held jointly and exclusively by practitioners having full and active licenses to practice in Kentucky since April 24, 2012, may open and operate no more than two (2) additional facilities in locations other than those locations existing and operating on April 24, 2012; transfer whole or partial ownership between existing practitioner owners; transfer whole or partial ownership interests to new owners if the new owners are physicians having full and active licenses to practice in Kentucky and the facility notifies the Cabinet for Health and Family Services of the transfer thirty (30) days before the it occurs; and pass the ownership interest of a deceased former owner through that person’s estate to a physician having a full and active license to practice in Kentucky without disqualifying the facility’s grandfathered status if the facility notifies the Cabinet for Health and Family Services of the transfer thirty (30) days before it occurs in cases where the interest is being transferred to a physician who is not an existing owner in the facility.

Beginning on July 20, 2012, at least one (1) of the facility’s owners, or an owner’s designee who is a physician employed by

and under the supervision of the owner, must be physically present practicing medicine in the facility for at least fifty percent (50%) of the time that patients are present in the facility. The physician owner or designee must:

1. hold a current subspecialty certification in pain management by a member board of the American Board of Medical Specialties, or hold a current certificate of added qualification in pain management by the American Osteopathic Association Bureau of Osteopathic Specialists;
2. hold a current subspecialty certification in hospice and palliative medicine by a member board of the American Board of Medical Specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American Osteopathic Association Bureau of Osteopathic Specialists;
3. hold a current board certification by the American Board of Pain Medicine;
4. hold a current board certification by the American Board of Interventional Pain Physicians;
5. have completed a fellowship in pain management or an accredited residency program that included a rotation of at least five (5) months in pain management; or
6. if the facility is registered by the Kentucky Board of Medical Licensure, have completed or hold, or be making reasonable progress toward completing or holding, a certification or training substantially equivalent to the certifications or training specified above, as authorized by the Kentucky Board of Medical Licensure through administrative regulation.

A pain management facility must accept private health insurance as one (1) of the facility's allowable forms of payment for goods or services provided and must accept payment for services rendered or goods provided to a patient only from the patient or the patient's insurer, guarantor, spouse, parent, guardian, or legal custodian. If the pain management facility is operating under a license issued by the Cabinet for Health and Family Services (Cabinet), the Cabinet will enforce the requirements related to pain management facilities. If the pain management facility is operating as the private office or clinic of a physician under KRS 216B.020(2), the Kentucky Board of Medical Licensure will enforce the requirements related to pain management facilities. Any person who violates the provisions of this section can be criminally prosecuted. [KRS 218A.175] ([Back](#))

Peer Review

This section is taken from material prepared by Charles J. Cronan, IV, of Stites & Harbison. Portions are also taken from the Ohio State Medical Association's Physician's Guide to Ohio Law.

The term "peer review" has been interpreted as the process in which medical practitioners review professional performance, ethical behavior, quality of care, utilization patterns, or selected aspects of the performance of other healthcare professionals. A hospital medical staff is charged with responsibility to the hospital for the quality of care to patients and for the ethical and professional practice of staff members. The medical staff must, therefore, develop and adopt policies or bylaws, subject to the approval of the governing authority, on the criteria and mechanisms for conducting peer review.

A professional review action of a professional review body, its members and anyone participating with or assisting the body shall not be liable in damages under any federal or state law (except for civil rights actions) with respect to the action [42 USC §11111(a)], provided the action is taken:

"1) in the reasonable belief that the action was in the furtherance of quality health care; 2) after a reasonable effort to obtain the facts of the matter; 3) after adequate notice and hearing procedures are afforded to the physicians involved or after such other procedures as are fair to the physician under the circumstances; and 4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3)." [42 U.S.C. §11112(a)].

The protection applies to actions based upon the recommendation of a professional review body "that is based upon the competence or professional conduct of an individual physician," and that affects (or may affect) adversely the clinical privileges or membership in a professional society of the physician. It does not apply to actions based primarily upon:

"A) the physician's association, or lack of association, with a professional society or association; B) the physician's fees or the physician's advertising or engaging in other competitive acts intended to solicit or retain business; C) the physician's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis; D) a physician's association with, supervision of, delegation of authority to, support for, training of or participation in a private group practice with, a member or member of particular class of health-care practitioner or professional; or E) any other matter that does not relate to the competence or professional conduct of a physician." [42 U.S.C. §11151(9)].

If a health-care entity fails substantially to report required information to the National Practitioner Data Bank, following notice and a hearing, the health-care entity shall not be entitled to this protection [42 U.S.C. §11111(b)].

Kentucky law also provides legal protections and immunity for those who participate in peer review. KRS 311.377 contains eight subsections, the first five of which are most important.

(1) “Any person who applies for, or is granted, medical staff privileges, . . . shall be deemed to have waived . . . any claim for damages or any good faith action taken by any person who is a member, participant in or employee of, or who furnishes information, professional counsel, or services to any committee, board, commission or other entity . . . performing the designated function of review of credentials or retrospective review and evaluation of the competency of professional acts or conduct of other healthcare personnel.”

The main purpose of KRS 311.377(1) is to protect peer review participants and organizations by conferring immunity on persons and organizations who conduct good faith peer review from any claim for damages by a physician who is aggrieved by the peer review process.

(2) “. . . the proceedings, records, opinions, conclusions and recommendations of any committee, board, commission, medical staff, professional standards review organization, or other entity, as referred to in subsection (1) . . . shall be confidential and privileged and shall not be subject to discovery, subpoena, or introduction into evidence in any civil action in any court . . .”

In the case of Sisters of Charity Health Systems, Inc. d/b/a Flaget Memorial Hospital v. Larry D. Raikes, Judge, Nelson Circuit Court, et al, the Kentucky Supreme Court ruled that peer review participants have no present, valid expectation that their input into peer review proceedings will be shielded from discovery in a medical malpractice suit. Subsection (2) of the statute does continue to have some meaning and effect, but only as it pertains to lawsuits by a physician against peer reviewers; not as it pertains to lawsuits against defendants in medical malpractice cases.

(3) “Nothing in subsection (2) . . . shall be construed to restrict or limit the right to discover or use in any civil action . . . any evidence, document or record which is subject to discovery independently of the proceedings of the entity to which subsection (1) . . . refers.”

(4) “No person who presents or offers evidence in proceedings described in subsection (2) . . . or who is a member of any entity before which such evidence is presented . . . may refuse to testify in discovery or upon a trial of any civil action as to any evidence, document or record described in subsection (3) . . . or as to any information within his own knowledge except as provided in subsection (5) . . .”

Subsections (3) and (4) of the statute make it clear that no confidentiality or privilege attaches to any evidence or document used in a peer review proceeding if that evidence or document was independently discoverable. In other words, a physician's notes in a patient's medical record or an operative report in the medical record did not attain a protected status from discovery in a medical malpractice lawsuit merely because those documents might also have been used during the course of a peer review proceeding. Thus, privilege and confidentiality extend only to such things as the minutes or other documents prepared specifically as a result of the peer review proceeding and not during the ordinary course of patient care. Also, according to subsection (4), a participant in peer review proceedings who had independent knowledge obtained outside the peer review process could not refuse to testify as to that independent knowledge in a medical malpractice case.

(5) “No person shall be permitted or compelled to testify concerning his testimony or the testimony of others except that of a defendant given in any proceeding referred to in subsection (2) . . . or as to any of his opinions formed as a result of such proceeding.”

Subsection (5) of the statute protects the peer reviewer against being compelled to testify, in any case, about his own testimony or his opinions formed, or the testimony of others (except a defendant in a malpractice case) during the course of the peer review proceeding. Peer reviewers may invoke protection against being compelled to testify about their own opinions formed or expressed, or the testimony of others (except a defendant) in the conduct of the peer review proceedings. However, if the peer reviewer's statements or opinions are reduced to writing in the minutes of the peer review proceedings, the minutes will be subject to discovery. As a practical matter, the effect of subsection (5) is to protect peer reviewers from the annoyance and inconvenience of being compelled to testify on matters about which they learned only through the peer review process. [\(Back\)](#)

Physician Assistants

A physician assistant is defined by statute as a person who is licensed and has graduated from a physician assistant or surgeon

assistant program accredited by the Accreditation Review Commission on Education for Physician Assistants or its predecessor or successor agencies and has passed the certifying examination administered by the National Commission on Certification of Physician Assistants or its predecessor or successor agencies. It also includes those who possessed a current physician assistant certificate issued by the Kentucky Board of Medical Licensure (KBML) prior to July 2002. [KRS 311.840(3)]

Physician Supervision

A physician assistant may not practice medicine or osteopathy independently. Each physician assistant must practice under physician supervision. [KRS 311.858(8)] A physician may not supervise a physician assistant without approval of the KBML. Failure to obtain such approval, as well as failure to follow all requirements of supervising physician assistants, is considered unprofessional conduct. [KRS 311.854(1)]

To be approved by the board as a supervising physician, a physician must:

- (a) Be currently licensed and in good standing with the KBML;
- (b) Maintain a practice primarily within Kentucky;
- (c) Submit a completed application and fee to the KBML. [KRS 311.854(2)]

Prior to a physician assistant performing any service or procedure beyond those described in the initial application submitted to the KBML, the supervising physician must supplement that application with information that includes but is not limited to:

- (a) A description of the additional service or procedure;
- (b) A description of the physician assistant's education, training, experience, and institutional credentialing;
- (c) A description of the level of supervision to be provided for the additional service or procedure; and
- (d) The location or locations where the additional service or procedure will be provided.
- (e) Any changes to the specific parameters for review of countersignatures. [KRS 311.854(3)]

A physician may enter into supervision agreements with no more than four (4) physician assistants and shall not supervise more than four (4) physician assistants at any one (1) time. Application for board approval to be a supervising physician must be obtained individually for each physician assistant. [KRS 311.854(5)]

A supervising physician must:

- (1) Restrict the services of a physician assistant to services within the physician assistant's scope of practice and to the provisions of the law;
- (2) Prohibit a physician assistant from prescribing or dispensing controlled substances;
- (3) Inform all patients in contact with a physician assistant of the status of the physician assistant;
- (4) Post a notice stating that a physician assistant practices medicine or osteopathy in all locations where the physician assistant may practice;
- (5) Require a physician assistant to wear identification that clearly states that he or she is a physician assistant;
- (6) Prohibit a physician assistant from independently billing any patient or other payor for services rendered by the physician assistant;
- (7) If necessary, participate with the governing body of any hospital or other licensed health care facility in a credentialing process established by the facility;
- (8) Not require a physician assistant to perform services or other acts that the physician assistant feels incapable of carrying out safely and properly;
- (9) Maintain adequate, active, and continuous supervision of a physician assistant's activities to assure that the physician assistant is performing as directed and complying with the requirements of the law and all related administrative regulations;
- (10) Review and countersign a sufficient number of overall medical notes written by the physician assistant to ensure quality of care provided by the physician assistant and outline the specific parameters for review of countersignatures in the supervision application. Countersignature requirements must be determined by the supervising physician, practice, or institution. "Practice" means a medical practice composed of two (2) or more physicians organized to provide patient care services, regardless of its legal form or ownership. "Institution" means all or part of any public or private facility, place, building, or agency, whether organized for profit or

not, that is used, operated, or designed to provide medical diagnosis, treatment, nursing, rehabilitative, or preventive care;

- (11) Reevaluate the reliability, accountability, and professional knowledge of a physician assistant two (2) years after the physician assistant's original licensure and every two (2) years thereafter and based on the reevaluation, recommend approval or disapproval of licensure or renewal to the KBML; and
- (12) Notify the board within three (3) business days if the supervising physician:
 - (a) Ceases to supervise or employ the physician assistant; or
 - (b) Believes in good faith that a physician assistant violated any disciplinary rule or regulation. [KRS 311.856]

A supervising physician who uses the services of a physician assistant in an office or clinic separate from the physician's primary office must submit to the KBML for approval a specific written request that describes the services to be provided by the physician assistant in the separate office or clinic, the distance between the primary office and the separate location, and the means and availability of direct communication at all times with the supervising physician. [KRS 311.860(2)]

Until May 31, 2014, a newly graduated physician assistant may not practice medicine or osteopathy in a location separate from the supervising physician or credentialing facility until the physician assistant has three (3) continuous months of experience in a nonseparate location. Beginning on June 1, 2014, the three (3) continuous months of experience in a nonseparate location will no longer be required. [KRS 311.860(3)] A "nonseparate location" includes the following if the supervising physician is available in person or via telecommunication at all times:

1. Hospitals in which patients of the supervising physician are receiving care, subject to the rules and regulations of the governing body of the hospital;
2. Nursing homes in which the supervising physician has patient care responsibilities, subject to the rules and regulations of the governing body of the nursing home;
3. The homes of patients of the supervising physician if the home visits are related to patient care, and
4. School health fairs, wellness clinics, or similar events where the supervising physician is responsible for providing oversight. [KRS 311.860(1)]

The supervising physician or credentialing facility has oversight of the "nonseparate location" requirements as stated above. [KRS 311.860(1)(b)]

Except for physician assistants practicing as anesthesiology assistants, a physician assistant may perform services in a location separate from the supervising physician if the supervising physician is continuously available via telecommunication and the physician's primary office seeks a written request from the KBML as described above or a waiver has been granted by the KBML. [KRS 311.860(4)]

Scope of Practice

A physician assistant may perform medical services and procedures within the scope of medical services and procedures described in the initial or any supplemental application received by the KBML and is considered an agent of the supervising physician in performing such medical services. [KRS 311.858(1)] A physician assistant may:

- Initiate evaluation and treatment in emergency situations without specific approval.
- Prescribe and administer all nonscheduled legend drugs and medical devices as delegated by the supervising physician. A physician assistant who is delegated prescribing authority may request, receive, and distribute professional sample drugs to patients.
- A physician assistant must not submit direct billing for medical services and procedures performed by the physician assistant.
- Perform local infiltrative anesthesia if it is in the scope of medical services and procedures described in the application, but a physician assistant may not administer or monitor general or regional anesthesia unless additional requirements are met (see below).
- Perform services in the offices or clinics of the supervising physician. A physician assistant may also render services in hospitals or other licensed health care facilities only with written permission of the facility's governing body, and the facility may restrict the physician assistant's scope of practice within the facility as deemed appropriate by the facility. [KRS 311.858]

Anesthesiology Assistant

A physician assistant who was practicing as an anesthesiology assistant in Kentucky prior to July 2002 may continue to practice if the physician assistant:

- (a) Met the practice, education, training, and licensure requirements specified in the law;
- (b) Is a graduate of an approved program accredited by the Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs that is specifically designed to train an individual to administer general or regional anesthesia; and
- (c) Is employed by a supervising physician in anesthesia. [KRS 311.862(1)]

“Supervising physician in anesthesia” means a physician licensed by the KBML who has completed postgraduate training in anesthesiology at an anesthesiology program accredited by the Accreditation Council for Graduate Medical Education or its equivalent. [KRS 311.840(5)]

A physician assistant who has not practiced as an anesthesiology assistant in Kentucky prior to July 2002 must meet the following requirements prior to practicing as an anesthesiology assistant:

- (a) Graduation from an approved four (4) year physician assistant program as specified in subsection (1)(b) of this section and graduation from another two (2) year approved and accredited program that consists of academic and clinical training in anesthesiology;
- (b) Compliance with the practice, education, training, and licensure requirements specified in the law; and
- (c) Employment with a supervising physician in anesthesia. [KRS 311.862(2)]

A physician assistant practicing as an anesthesiology assistant may not administer or monitor general or regional anesthesia unless the supervising physician in anesthesia:

- (a) Is physically present in the room during induction and emergence;
- (b) Is not concurrently performing any other anesthesiology procedure; and
- (c) Is available to provide immediate physical presence in the room. [KRS 311.862(3)]

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Physician Self Treatment, Family Members

KRS 311.597(1)(c) prohibits physicians from prescribing or dispensing medication for the physician’s personal use or for the use of the physician’s immediate family members when the physician knows or has reason to know that an abuse of controlled substances is occurring or may result from the prescription or dispensing of the medication.

Code of Medical Ethics Opinion 8.19 discourages self-treatment and treatment of immediate family members of physicians by stating: “Physicians generally should not treat themselves or members of their immediate families.” Such treatment may be appropriate in cases of emergency or isolated settings where there is no other qualified physician. There are also situations in which routine care is acceptable for short-term, minor problems.

As for physicians issuing prescriptions to themselves or family members, Opinion 8.19 states: “Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members.” [\(Back\)](#)

Physician/Patient Relationship—Termination

Code of Medical Ethics Opinions 8.115 and 9.12 discuss abandonment of patients and the termination of the physician/patient relationship. In order to avoid an allegation of abandonment, once a physician undertakes to treat a patient, he or she must continue to provide care unless one or more of the following occurs:

1. The patient's condition is such that care is no longer reasonably required;
2. The patient terminates the physician-patient relationship;
3. The physician agreed to treat only a specific ailment or injury, or agreed to treat only at a certain time or place;
4. The physician properly notifies the patient of withdrawal from care, and allows sufficient time for the patient to obtain another physician.

If a physician withdraws from caring for a patient, the physician should notify the patient in writing. The reason for the decision to withdraw from care may be included in the letter to the patient at the physician's discretion. As appropriate, the physician may advise patients with chronic conditions whether ongoing medical attention is needed; mention medication requirements; reinforce earlier health care recommendations; etc. Advise your receptionist and all pertinent office staff of the termination of the particular patient so that after the specified grace period a new appointment is not offered to the patient, thereby inadvertently reestablishing the physician-patient relationship.

Set out on the following page is a sample letter that may be adapted by a physician for discharging a patient from care and permanently withdrawing as the patient's physician.

It should also be noted that most third-party payer contracts require a physician to obtain the permission of the third-party payer prior to terminating a patient's care. Physicians should review their contracts and find out the particular requirements.

SAMPLE LETTER OF WITHDRAWAL FROM CARE

(Termination of Physician/Patient Relationship)

Date

Dear (Patient's Name) :

I find it necessary to inform you that I can no longer take responsibility for your medical care. [The reasons for the physician's withdrawal may be included at the physician's discretion. In some cases, it may be prudent not to offer the patient a specific reason]

As you may require medical attention in the future, I suggest that you promptly seek the services of another physician. (As appropriate, the physician may advise the patient with a chronic condition whether ongoing medical attention is needed; mention medication requirements; reinforce earlier health care recommendations; etc.) If you are not familiar with other physicians in this area (or specialty) you may wish to contact the county medical society for a referral.

I shall be available to attend to your emergency medical needs for the next (stipulate a reasonable time for the patient to obtain another physician; periods of 10, 15, or 30 days are commonly used). This will allow you ample opportunity to obtain the services of another physician.

When you have selected a new physician, I will be happy to make available to his or her office a copy of your medical record (or a summary of your treatment) upon receipt of your written authorization. [Remember, a patient is entitled to one free copy of his or her medical record. You may charge for additional copies. See the discussion under the Medical Records section of this booklet]

Very truly yours,

Physician's Name
and signature

(THIS LETTER SHOULD BE SENT BY CERTIFIED MAIL, WITH RETURN RECEIPT REQUESTED. A COPY OF THIS LETTER AND THE RETURNED RECEIPT SHOULD BE KEPT IN THE PATIENT'S MEDICAL RECORD.)

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Prescriptions

A physician may not prescribe or dispense any medication with the knowledge that it will be used or is likely to be used other than medicinally; with the intent to evade any law with respect to the sale, use or disposition of the medication; for the licensee's own use or the use of his family when he knows or should know that the abuse of controlled substances is likely to occur; or in such amounts that the physician should know that the amounts are excessive under accepted medical practice [KRS 311.597(1)].

No person may knowingly obtain or attempt to obtain a prescription for a controlled substance without having formed a valid practitioner-patient relationship with the practitioner from whom the person seeks to obtain the prescription [KRS 218A.140(3)]. Such a relationship exists when the practitioner or his designee has conducted at least one good faith prior examination, which includes an in-person medical examination at which time the patient is physically examined and a medical history of the patient is obtained [KRS 218A.010(14) & KRS 218A.010(33)].

A physician may prescribe a legend drug for a legitimate medical purpose and in the course of professional practice [KRS 217.182(3)]. A physician may also prescribe a controlled substance for a legitimate medical purpose and in the course of professional practice [KRS 218A.170(3)(a)]. A prescription may not be issued for a practitioner to obtain a controlled substance for the purpose of general dispensing or administering to patients [KRS 218A.180(3)(b)]. A legend drug is defined as a drug defined by the Federal Food, Drug and Cosmetic Act, as amended, and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription" [KRS 217.015(28)]. A controlled substance is defined as methamphetamine or a drug, substance, or immediate precursor in schedules I through V and includes a controlled substance analog [KRS 218A.010(6)]. All prescriptions for controlled substances must be written on prescription blanks that provide protection from forgery [KRS 218A.204]. A physician or an employee of the physician may seize and retain any prescription which he has reasonable suspicion to believe is forged, altered or deceitful [KRS 217.214(1)]. Physicians who are residents of and actively practice in a state other than Kentucky may prescribe legend drugs and controlled substances as long as they meet all other requirements for prescribing such drugs in Kentucky and they are licensed and have prescriptive authority under the professional licensing laws of another state, unless the physician's Kentucky license has been revoked, suspended, restricted, or probated in which case the terms of the Kentucky license shall prevail [KRS 217.015 and KRS 218A.010].

When a pharmacist receives a prescription for a brand name drug, the pharmacist must select a lower-priced therapeutically equivalent drug (generic) which the pharmacist has in stock, unless otherwise instructed by the patient or by the patient's physician. [KRS 217.822]

When a pharmacist receives a prescription for a brand name biological product, the pharmacist shall dispense a lower-priced interchangeable biological product, if there is one in stock, unless otherwise instructed by the patient or by the patient's prescribing physician. Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must communicate to the physician the specific product provided to the patient, including the name of the product and the manufacturer. Such communication must be conveyed by making an entry that is electronically accessible to the prescribing practitioner through: an interoperable electronic medical records system; an electronic prescribing technology; a pharmacy benefit management system; or a pharmacy record. Otherwise, the pharmacist must communicate the biological product dispensed to the physician using facsimile, telephone, electronic transmission, or other prevailing means. Communication received by the physician from the dispensing pharmacist or the pharmacist's designee must be treated in accordance with the standards of acceptable and prevailing practice of the physician and the following as they relate to patient records: the principles of ethics of the American Medical Association; and the code of ethics of the American Osteopathic Association. [KRS 217.822]

When, in the professional opinion of a physician, the physician determines that an equivalent drug (generic) or interchangeable biological product is medically inappropriate, the physician shall prescribe the pharmaceutical product that the physician determines to be medically appropriate with the indication "do not substitute" and no substitution shall be made without the physician's approval [KRS 304.17A-535(3)][KRS 217.822(4)].

Every prescription order written by a physician for a controlled substance shall bear upon the prescription blank the name, telephone number, and business address of the prescribing practitioner. Likewise, in order to provide a pharmacist sufficient information to meet the communication requirements for interchangeable biological products, every prescription order written by a physician shall bear upon the prescription blank the name, telephone number, and business address of the prescribing practitioner in a clear and legible manner. [KRS 217.216]

KRS 218A.202 requires the Cabinet to implement a computerized monitoring system for controlled substances dispensed within the Commonwealth. This system is known as the Kentucky All Schedule Prescriptions Electronic Reporting (KASPER). Practitioners authorized to prescribe or dispense controlled substances are required to register with KASPER and maintain registration throughout the practitioner's term of licensure within Kentucky. All dispensers of controlled substances (in-state pharmacies, out-of-state pharmacies and practitioners who dispense from their office) are required to report specific information for each dispensation. There are very strict deadlines for such reports. If you dispense controlled substances, you should contact the Drug Control Branch for information about how to report. (Dispensing means supplying take-home doses; it does not include

single doses that the patient takes immediately nor does it include prescriptions that are written). The data submitted is stored in a high-security database and access to the information is strictly limited by statute. Drug Control uses the data to identify patients who appear to be drug seekers by obtaining prescriptions from multiple practitioners and pharmacies.

Practitioners are sometimes asked by patients to prescribe certain narcotics or other controlled substances. While most instances are legitimate, sometimes the practitioner may feel uncomfortable and wonder if the patient is a drug seeker who tries to obtain drugs from multiple practitioners. The KASPER program allows a physician to make a request to Drug Control and obtain a report. Practitioners and their employees will be able to use the report's data to confirm whether a patient is seeing other practitioners for controlled substances. Practitioners and their employees who obtain KASPER data may share the report with the patient or person authorized to act on the patient's behalf and place the report in the patient's medical record, with that individual report then being deemed a medical record subject to disclosure on the same terms and conditions as an ordinary medical record. Practitioners and/or their employees may also use KASPER data to review and assess practitioners' prescribing and dispensing patterns to ensure accuracy and completeness of the information contained within KASPER. [KRS 218A.202]

Prescribing and Dispensing Standards

In the aftermath of 2012 House Bill 1, KMA published a detailed overview of statutes and regulations adopted by the Kentucky General Assembly, Kentucky Board of Medical Licensure (KBML), and the Cabinet for Health and Family Services' Office of Inspector General (OIG) that impact physicians' ability to prescribe, dispense, and administer controlled substances. The summary is divided into sections outlining, among other items, requirements pertaining to documentation, patient education, continuing medical education, data reporting, and appropriate prescribing and dispensing. [KRS 218A.172, KRS 218A.202, KRS 218.205, 201 KAR 9:220, 201 KAR 9:260, 201 KAR 9:310, 902 KAR 55:110] These requirements went into effect on March 4, 2013. To access the summary, [click here](#).

The information prepared by KMA is merely a summary of certain portions of the controlled substance statutes and regulations. Physicians should review the actual statutes and regulations, as this summary is not comprehensive nor intended to take the place of reading those laws. A link to the revised statutes and regulations can be found on the KBML's website and the OIG's website. The information provided in this summary should not be considered legal advice or a legal opinion. For specific legal advice, please consult an attorney familiar with such issues.

Naloxone

A physician may, directly or by standing order, prescribe or dispense naloxone to a person or agency who the physician believes is capable of administering the drug for an emergency opioid overdose. [KRS 217.186]

A prescription for naloxone may include authorization for administration of the drug to the person for whom it is prescribed by a third party if the prescribing instructions indicate the need for the third party upon administering the drug to immediately notify a local public safety entity. [KRS 217.186]

A person or agency, including a peace officer, jailer, firefighter, paramedic, EMT, or an authorized school employee, may receive a prescription for naloxone, possess naloxone and any equipment needed for administration, and administer naloxone to an individual suffering from an apparent opiate-related overdose. [KRS 217.186]

A pharmacist who holds a separate certification issued by the Kentucky Board of Pharmacy may, without a prescription, initiate the dispensing of naloxone but only if certain requirements are met, including the pharmacist's adherence to a physician-approved protocol established by the Kentucky Board of Pharmacy in consultation with the Kentucky Board of Medical Licensure before dispensing the drug. [KRS 217.186] ([Back](#))

Professional Courtesy

Professional courtesy is the practice of providing free or reduced cost medical services to another physician or the physician's family. Some physicians also provide professional courtesy to others in the medical field including nurses, office personnel, and hospital employees. It is usually provided by either waiving the patient's copay or deductible, or by providing services at no charge. As discussed below, either of these types of professional courtesy can create legal problems for physicians.

Professional Courtesy as a False Claim

The most dangerous area for physicians to be caught in allegations of fraud and abuse is in the submission of claims. If a physician claims additional payments from the government above what is allowed for a particular service, it may be a violation of federal law. The federal False Claims Act prohibits a person from knowingly submitting false or fraudulent claims in order to secure payment from a federal healthcare program [31 U.S.C. §3729]. The law was passed during the American Civil War to ensure that government contractors could be prosecuted for submitting inflated claims for payment of goods provided to the government. In the past, this law was used against other government contractors, but it has recently become very popular in the health care field because of the number of health care claims submitted to the government each year. The penalties for violating this law include a civil penalty of up to \$10,000 for each violation (\$10,000 for each claim submitted); treble damages (three times the amount of the claim); and, payment of the costs associated with bringing the action.

So how can giving a colleague professional courtesy violate the False Claims Act? Most professional courtesy is given by charging the patient “insurance only,” in which any deductible or copayment is waived and the office accepts whatever the insurance company is obligated to pay. According to the government, any waiver of a copay or deductible for anyone participating in a federal healthcare program may constitute a violation of the federal False Claims Act. How? Waivers of coinsurance and deductibles may be a misstatement of the actual charge for a service. For example, if a physician’s charge for a service is \$100 and he agrees to accept 80% from Medicare, he is to receive \$80 from Medicare and bill the remainder to the patient. But if he waives the \$20 co-payment, he has reduced his charge to \$80. The carrier, therefore, should be paying 80% of \$80, rather than 80% of \$100. This theory was outlined in a government “fraud alert” issued in 1991 [See the section in this book entitled *Fraud Alerts*]. There is no exception under this theory for professional courtesy. In fact, the government and legal commentators have consistently maintained that professional courtesy violates the law.

The federal False Claims Act only applies to claims submitted to a federal healthcare program. If professional courtesy in the form of “insurance only” is given to someone who has private insurance, as opposed to government sponsored insurance, is waiving copays or deductibles still illegal? Perhaps. Kentucky state law prohibits false claims from being submitted to private insurance carriers [KRS 304.47.020]. If the same analysis regarding how professional courtesy violates federal law is applied to state law, thus extending the analysis to private insurance carriers, the practice would be illegal.

Is there any way to get around this law? One way is to give professional courtesy in the form of “free care,” which means the services provided to a colleague are given in exchange for no payment of any kind. If the insurance company or federal program is not billed, there is no claim submitted that may be considered “false.” Thus, free professional courtesy may be all right, *unless* it’s given to a colleague who is in a position to refer patients to the physician who provided the free care. In that case, such professional courtesy may violate the federal Anti-Kickback law.

Professional Courtesy as a Kickback

The federal Anti-Kickback law prohibits medical providers, as well as patients, from offering, paying, soliciting or receiving “remuneration” (i.e.—kickbacks) to induce business for which payment is made under a federal health care program [42 U.S.C. §1320a-7b(b)]. In other words, no one can give or receive money to refer a person, or be referred, to a provider if payment for the services is going to be made by a federal health care program.

What is considered to be a “kickback” has been interpreted quite broadly. One federal appeals court has said, “If one purpose of the payment was to induce future referrals, the Medicare statute has been violated” [U.S. v. Greber, 760 F2d 68 (3rd Cir. 1985)]. The Departmental Appeals Board has also ruled that a kickback is “anything of value,” which could be interpreted to mean cash, donuts or free medical care [Inspector General v. Hanslester Network, CCH Medicaid and Medicare Guide § 39,566, Departmental Appeals Board, Appellate Division, Dec. No. 1275 (Sept. 18, 1991)]. The government’s use of the Anti-Kickback law in prosecuting physicians has become very popular in the last few years. Several investigations have led to prosecutions and convictions of physicians.

How can professional courtesy in the form of free care violate this law? According to the Anti-Kickback statute, no one may give or receive anything of value in exchange for a referral. If a physician provides free or discounted care to another physician who is in a position to provide referrals to the treating physician, it may be looked upon as providing something of value to the physician in exchange for a referral.

Government comments on professional courtesy

On April 26, 2000, the federal government issued new regulations discussing the issue of waiving copays and deductibles, as well as professional courtesy. The new regulation clearly states that an illegal kickback under federal law “would include both the waiver of all or part of deductible and coinsurance amounts, and the transfer of items and services for free or for other than fair market value.”

There are, however, situations in which a waiver of a copay or deductible might not be in violation of the law. The regulation says that “Congress exempted...Waivers of coinsurance and deductible amounts that are not advertised or solicited, are not routine, and are made either after a good faith, individualized determination of financial need or after reasonable collection efforts have failed...”

Thus, waivers of copays and deductibles may be allowed if they are made on the basis of “financial need.” The regulation does not specifically define “financial need,” but does state the following:

“We are not specifying any particular method of determining financial need because we believe what constitutes ‘financial need’ varies depending on the circumstances. What is important is that providers make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality. We do not believe that it is appropriate to apply inflated income guidelines that result in waivers of copayments for persons not in genuine financial need.”

The regulation also addresses the issue of what constitutes “reasonable collection efforts.”

“Reasonable collection efforts’ are those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients. If the patient has an insurer providing secondary coverage that refuses to pay a copayment amount, the provider should attempt to collect from the patient, unless the provider has contractually agreed with the insurer not to balance bill the patient. In that case, the insurer remains liable for the copayment.”

The government also commented on the legality of “professional courtesy”:

“With respect to ‘professional courtesy,’ we note that traditionally the term means free care (i.e., no charge is made to anyone), not care provided on an “insurance only” basis. Generally, a routine practice by a physician of waiving the entire fee for services provided to other physicians without regard to the potential for referrals is not a problem under section 231(h) of HIPAA or the anti-kickback statute. However, waivers of Medicare or other Federal health care program copayments for non-indigent persons, whether physicians or any other groups, are problematic.”

In 2004, the federal government instituted regulations dealing with the federal Stark Law and those regulations further specify when physicians and others may provide professional courtesy. For purposes of the regulation, “professional courtesy” is defined as “the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.” In order to provide professional courtesy, the regulation sets out the conditions that must be met:

- a) The professional courtesy must be offered to all physicians on the entity’s staff or in the entity’s local community without regard to the volume or value of referrals or other business generated between the parties;
- b) The items or services provided are routinely provided by the entity;
- c) The entity’s professional courtesy policy is set out in writing and approved in advance by the governing body of the entity;
- d) The professional courtesy is not offered to anyone who is a federal health care program beneficiary unless there is a showing of financial need;
- e) If the professional courtesy involves any whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of that reduction so that the insurer is aware of the arrangement; and
- f) The professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

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Prompt Payment Laws

Kentucky’s prompt payment law applies to all health care claims incurred after July 14, 2000. An insurer may not request or require a physician to pursue any other course of action regarding the payment of health care claims outside of the provisions of this law [KRS 304.17A-726].

Claims Submission

The uniform health insurance claim form for physicians consists of the HCFA 1500 data set or its successor and an insurer may not require a provider to use a different claim form [KRS 304.14-135].

Beginning on January 1, 2001, upon issuance, delivery, or renewal of a health benefit plan in Kentucky, an insurer must clearly indicate on each covered person’s identification card the mailing address where a claim for payment is to be sent and issue new identification cards or an appropriate sticker to covered persons no later than thirty (30) calendar days following the effective date of any change in that address. Identification cards must also identify whether the covered person has health maintenance organization (HMO), point of service (POS), preferred provider organization (PPO), or indemnity fee for service (FFS) coverage [KRS 304.17A-718].

In contracts with providers or in the provider manual or other document that sets forth the procedures for filing claims, an insurer must disclose to providers:

- (a) The mailing or electronic address where claims should be sent for processing;
- (b) The phone number for a provider to call regarding claims;
- (c) Any entity to which the insurer has delegated claim payment functions; and
- (d) The address of any separate claims processing centers for specific types of services.

An insurer must provide, no less than thirty (30) calendar days, prior written notice of any changes to such information to its contracted providers [KRS 304.17A-710].

If an insurer requires a provider to submit health claim attachments to the claim before the claim will be paid, the insurer must identify the specific required health claim attachments in its provider manual or other document that sets forth the procedure for filing claims with the insurer. The insurer must provide sixty (60) days' advance written notice of modifications to the provider manual that materially change the type or content of the health claim attachments or other documents to be submitted [KRS 304.17A-706(2)(a)].

If an insurer conducts a retrospective review of a claim and requires an attachment not specified in the provider manual or other document that sets forth the procedure for filing claims, the insurer must:

- Notify the provider, in writing or electronically within the claims payment time frame of the service that will be retrospectively reviewed and the specific information needed from the provider regarding the insurer's review of a claim;
- Complete the retrospective review within twenty (20) business days of the insurer's receipt of the medical information; and
- Add interest to the amount of the claim from the thirty-first day after the claim was received by the insurer through the date upon which the claim is paid [KRS 304.17A-706(2)(c)].

[If the provider, however, fails to submit the information requested regarding a retrospective review within 15 business days from the date of the receipt of the notice, the insurer is not required to pay interest. (KRS 304.17A-706(2)(d))]

If a claim or portion thereof is contested by an insurer on the basis that the insurer has not received information reasonably necessary to determine insurer liability for the claim or portion thereof, or if the insurer contests the claim on the reasonable and documented belief that the claim involves the coordination of benefits or questions of pre-existing conditions, the insurer must, within the applicable claims payment time frame, provide written or electronic notice to the provider, covered person, group policyholder or other insurer, as appropriate, with an itemization of all new, never-before-provided information that is needed. [KRS 304.17A-706(3)(a)] The insurer must pay or deny the claims within thirty (30) calendar days of receiving the additional information [KRS 304.17A-706(3)(c)]. If the provider, however, fails to submit the information requested within 15 business days from the date of the receipt of the notice, the insurer may deny the claim. [KRS 304.17A-706(3)(b))] Any claim denied for such failure to submit the requested information may be resubmitted by the provider and any resubmitted claim may not be denied on the basis of timeliness if the resubmitted claim is made with the timeframe for submitting claims established by the insurer beginning on the date of denial. [KRS 304.17A-706(3)(b))]

Acknowledgment of Claims

Within forty-eight (48) hours of receiving an electronic claim, an insurer must acknowledge the date of receipt of the claim by an electronic transmission [KRS 304.17A-704(1)(a)].

Within twenty (20) calendar days of receiving a non-electronic claim, an insurer, its agent or designee must acknowledge the date of receipt of the claim to the provider, its billing agent or designee that submitted the claim. For claims containing all necessary information and having no errors, the insurer must make available confirmation of receipt of the claim to the provider, its billing agent, or designee that submitted the claim. Acknowledgment may be in writing or the insurer may list the claim and the date it was received on a file that can be accessed electronically by the provider, its agent or designee. Claims that contain errors or lack necessary information must be acknowledged by an electronic transmission or in writing [KRS 304.17A-704(1)(b)].

At the time of acknowledgment, an insurer must notify the provider, its agent or designee in writing or electronically, of all information that is missing from the billing instrument or any errors in the billing instrument which preclude it from being a clean claim [KRS 304.17A-704(2)]. When an insurer has notified a provider that a claim contains errors, upon receipt of a corrected claim, the insurer must adjudicate the corrected claim within the applicable claims payment time frame for a clean claim [KRS 304.17A-704(3)]. By January 1, 2001, insurers must have in place a mechanism to inform providers of the status of a claim either through notation on the remittance or by allowing providers to check claim status electronically at any time following submission of the claim to the insurer [KRS 304.17A-704(4)].

Claims Payment Timeframe

An insurer must reimburse a provider for a clean claim or send a written or an electronic notice denying or contesting

the claim within thirty (30) calendar days from the date that the claim is received by the insurer or any entity that administers or processes claims on behalf of the insurer [KRS 304.17A-702]. A “clean claim” is defined as a properly completed billing instrument, paper or electronic, including the required health claim attachments [KRS 304.17A-700(3)].

Within the applicable claims payment time frame, an insurer must:

- (a) Pay the total amount of the claim in accordance with any contract between the insurer and the provider;
- (b) Pay the portion of the claim that is not in dispute and notify the provider, in writing or electronically, the reasons the remaining portion of the claim will not be paid; or
- (c) Notify the provider, in writing or electronically, of the reasons no part of the claim will be paid [KRS 304.17A-702(2)].

If an insurer fails to provide a utilization review decision within 24 hours after being contacted for a requested review of continued hospitalization of a covered person, or if the covered person’s provider is unable to contact the insurer after 3 documented attempts during a 4 consecutive hour period during normal business hours, the insurer is prohibited from denial or reduction of payment for a covered service [KRS 304.17A-716].

When an Insurer May Delay Payment

An insurer may contest a clean claim only in the following instances:

- (a) The insurer has reasonable documented grounds to believe that the clean claim involves a preexisting condition, coordination of benefits or that another insurer is primarily responsible for the claim;
- (b) The insurer will conduct a retrospective review of the services identified on the claim;
- (c) The insurer has information that the claim was submitted fraudulently; or
- (d) The covered person’s or group’s premium has not been paid [KRS 304.17A-706(1)].

An insurer may not require a provider to appeal errors in payment where the insurer has not paid the claim according to the contracted rate. Miscalculations in payments made by the insurer must be corrected and paid within thirty (30) calendar days upon the insurer’s receipt of documentation from the provider verifying the error [KRS 304.17A-708(1)].

Recoupment by Insurer

Except for overpayments which are a result of an error in the payment rate or method, an insurer that determines that a provider was overpaid must, within twenty-four (24) months from the date that the insurer paid the claim, provide written or electronic notice to the provider of the amount of the overpayment, the covered person’s name, patient identification number, date of service to which the overpayment applies, insurer reference number for the claim, and the basis for determining that an overpayment exists. Electronic notice includes E-mail or facsimile where the provider agreed in advance in writing to receive such notices. The insurer must either

- (a) Request a refund from the provider; or
- (b) Indicate on the notice that, within thirty (30) calendar days from the postmark date or electronic delivery date of the insurer’s notice, if the insurer does not receive a notice of provider dispute, the amount of the overpayment will be recouped from future payments.

If a provider disagrees with the amount of the overpayment, the provider must within thirty (30) calendar days from the postmark date or the electronic delivery date of the insurer’s written notice dispute the amount of the overpayment by submitting additional information to the insurer. If a provider files a dispute, no recoupment shall be made until the dispute is resolved. If a provider does not dispute the amount of the overpayment and does not provide a refund, the insurer may recoup the amount due from future payments. All disputes submitted by providers must be processed in accordance and completed within thirty (30) days with the insurer’s provider appeals process. An insurer may recover an overpayment resulting from an error in the payment rate or method by requesting a refund from the provider or making a recoupment of the overpayment from the provider. A provider may dispute such recoupment in accordance with the provisions contained in KRS 304.17A-708. If an insurer chooses to collect an overpayment made to a provider through a recoupment against future provider payments, the insurer must, within twenty-four (24) months from the date that the insurer paid the claim and at the actual time of recoupment, give the provider written or electronic documentation that specifies:

- (a) The amount of the recoupment;
- (b) The covered person’s name to whom the recoupment applies;
- (c) Patient identification number; and
- (d) Date of service [KRS 304.17A-714(6)].

An action or request for reimbursement for any overpayment of a health insurance claim pursuant to any health insurance contract shall be brought not more than two (2) years from the date the claim was filed. No insurer can make any claim or seek recovery for reimbursement for any overpayment pursuant to any health insurance contract from any person more than two (2) years after the claim was filed, unless the claim was false or fraudulent [KRS 304.14-135].

Penalties and Interest

An insurer that fails to pay, deny, or settle a clean claim in accordance with this law must pay interest according to the following schedule on the amount of the claim that remains unpaid:

- (a) For claims that are paid between one and thirty days from the date that payment was due, interest at a rate of twelve percent (12%) per annum shall accrue from the date payment was due;
- (b) For claims that are paid between thirty-one days and sixty days from the date that payment was due, interest at a rate of eighteen percent (18%) per annum shall accrue from the date payment was due; and,
- (c) For claims that are paid more than sixty days from the date that payment was due, interest at a rate of twenty-one percent (21%) per annum shall accrue from the date that payment was due [KRS 304.17A-730(1)].

When paying a claim after the time required, the insurer must add the interest payable to the amount of the unpaid claim without the necessity for any claim for that interest to be made by the provider filing the original claim [KRS 304.17A-730(2)]. [\(Back\)](#)

Sexual Harassment

Federal law prohibits sexual harassment in the workplace and generally applies to a person or entity that regularly employs fifteen or more persons [42 U.S.C. §2000e(b)]. Kentucky law also prohibits sexual harassment and applies to persons or entities that employ eight or more persons [KRS 344.030].

Both state and federal law make it an unlawful employment practice to discriminate against an individual with respect to hiring, discharging, establishing compensation, terms, and conditions or privileges of employment, because of such individual's sex. These laws prohibit not only discrimination based on gender, but also sexual harassment in the workplace. Physician employers have a duty to protect employees from sexual harassment by the employer, fellow employees, and even non-employees in the employment setting. Employers also have an affirmative duty to ensure that the workplace is free of sexual harassment. Sexual harassment that is either perpetrated or tolerated by an employer is prohibited.

The courts have defined two general categories of sexual harassment:

"Quid pro quo" sexual harassment occurs if submission to the conduct is an explicit or implicit term or condition of employment, or if submission to or rejection of the conduct is used as a basis for an employment decision affecting the person rejecting or submitting to the conduct. In other words, an employment decision cannot be based on whether the employee submitted to sexual conduct.

"Hostile or offensive environment" sexual harassment occurs if the conduct is used as a basis or effect of substantially interfering with an affected person's work performance or creating an intimidating, hostile or offensive work environment.

"Sexually harassing conduct" consists of unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature. Such conduct may include, but is not limited to, sexual propositions or threats, making sexual gestures, making sexually suggestive or derogatory remarks, slurs or jokes, displays of sexually suggestive pictures or cartoons, and many forms of unwelcome physical touching.

A single sexual advance may create a "quid pro quo" case of harassment if the advance is linked to the granting or denial of employment benefits. However, to create a valid claim of "hostile environment" harassment, an employee must show that the conduct was sufficiently severe and/or pervasive so as to alter the conditions of employment and create an offensive working environment. Whether a hostile environment has been created is to be determined from the viewpoint of the "reasonable" person.

An employer, as well as the harasser, may be held liable for harassment, depending on the circumstances. To help prevent harassment, as well as to protect an employer from liability, the courts and federal agencies suggest that an employer have an explicit policy against sexual harassment that is clearly and regularly communicated to employees and effectively implemented. The employer should affirmatively raise the subject with all supervisory and non-supervisory employees, express strong disapproval, and explain sanctions for harassment. The employer should also have a procedure for resolving sexual harassment complaints. The procedure should be designed to "encourage victims of harassment to come forward" and should not require a victim to complain first to the offending supervisor. It should ensure confidentiality as much as possible and provide effective remedies, including protection of victims and witnesses against retaliation.

Physicians should also note that under both federal and state law, it is unlawful for an employee to be retaliated against for making a complaint of sexual harassment. Under federal law, the employer can be held liable for any retaliation. Under state law, however, both employers and individuals can be held liable for retaliation of an employee who has complained of sexual harassment. In addition, there may be other state common law claims an employee may assert against an individual such as assault

and battery or outrageous conduct. Therefore, it is imperative that before any employment action is taken against an employee who has complained of sexual harassment, legal counsel should be consulted as to the appropriateness, as well as the timing of such action.

The *Code of Medical Ethics* Opinion 3.08 also prohibits sexual harassment between medical supervisors and trainees. This prohibition includes consensual sexual relationships, which are considered to be unacceptable “regardless of the degree of supervision in any given situation.”

The *Code of Medical Ethics* Opinion 8.14 prohibits “sexual contact that occurs concurrent with the physician-patient relationship...” Physicians should terminate the physician-patient relationship “before initiating a dating, romantic, or sexual relationship with a patient.” A physician may not have a sexual or romantic relationship with a former patient “if the physician uses or exploits trust, knowledge, emotions, or influence derived from the previous relationship.”

What follows is a sample sexual harassment policy for a physician office. Physicians should tailor the policy to fit their own practices, especially when developing mechanisms for reporting instances of sexual harassment.

This information, as well as the sample harassment policy, does not constitute legal advice. If physicians have specific questions regarding these issues, they should seek the advice of qualified legal counsel.

SAMPLE ANTI-HARASSMENT POLICY FOR PHYSICIAN PRACTICE

It is the policy of [the Practice] to strive to maintain a working environment for its employees which is free from sexual harassment by supervisors, co-workers or third parties. [The Practice] will not tolerate any act of sexual harassment by any person in violation of this policy.

Sexual harassment is defined as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature when:

1. Submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment;
2. Submission to or rejection of any such conduct by an individual is used as a basis for employment decisions; or
3. Such conduct has the result of unreasonably interfering with an individual's work performance or creating an intimidating or offensive working environment.

It is the responsibility of all employees to conduct themselves in ways that ensure that others are able to work in an atmosphere free from sexual harassment. It is the responsibility of all employees to comply with this policy in all respects and at all times. It is the further responsibility of all employees to bring to [the Practice's] attention any evidence of sexual harassment, and to promptly report any act or event that is believed to be a violation of this policy (or that may be a violation of this policy) so that the matter can be investigated as soon as practicable and appropriate action taken.

Anyone having knowledge of alleged harassment is encouraged to report the matter to [the Practice] immediately. Reports that should be confirmed in writing are encouraged to be as specific as possible, detailing the nature, date and place of all occurrences, witnesses and any adverse impact. Reported information will be maintained on as confidential a basis as possible, consistent with any legal obligations.

No employee shall be subject to any form of reprisal or retaliation for having made a good faith complaint under this policy.

Any employee who is determined to have violated this policy by engaging in or condoning the sexual harassment of a fellow employee, or retaliating against a fellow employee due to a complaint of sexual harassment, will be subject to immediate discipline up to and including termination of employment.

All allegations of harassment shall be immediately investigated and, if confirmed, will result in appropriate remedial action. ([Back](#))

Silent PPOs

“Silent PPO” – An Overview

In a typical “Silent PPO”, the managed care organization [MCO] that has signed a participation agreement with a physician assigns or “rents” its physician network to third parties, such as other MCOs, preferred provider organizations [PPO], insurance

companies, and third party administrators without the knowledge or consent of the physician. The third party, in turn, takes the fee discount agreed to between the physician and the “sharing” MCO even though the physician does not have any contract with that third party.

There are three scenarios in which such third parties might apply a discount to physician fees:

1. A physician enters into a participating provider agreement with an MCO which provides that the physician will accept certain negotiated discounted rates as reimbursement for services provided under the contract. The participation agreement also permits the MCO to enter into separate contractual agreements with other payer sources whereby the other payer source “rents” the MCO’s provider network and the participating providers agree to accept the negotiated discounted rates from those other payers.
2. Same situation as discussed above, except the participation agreement does NOT specifically authorize or mention the MCO’s ability to enter into contractual arrangements with other payer sources and/or does NOT require the physician to accept discounted reimbursement from other payer sources.
3. A third party payer may attempt to reimburse a physician at a discounted rate, even though the payer does not have a direct contractual relationship with the physician and does not rent an MCO provider network in which the physician is a participating provider.

Each of these scenarios is discussed in more detail below.

Scenario #1 – Legitimate Network Leasing

In many instances, participating provider agreements contain language which allow the MCO to lease its network of physicians to other PPOs, insurance companies, or health plans. In the past, such leasing arrangements were set up without the knowledge of the physician who contracts with the MCO.

With the support of the KMA, the 2000 General Assembly adopted measures to ensure that a physician effectively agrees to a discount before it is applied. KRS 304.17A-728 generally prohibits reimbursement on a discounted fee basis unless the products and markets applicable to the discount are properly identified in a contract. The statute provides in relevant part:

- (1) A provision identifying the products and markets applicable to any discount as provided in the contract shall be required of all contracts with a:
 - (a) Provider or an organization of providers; or
 - (b) Preferred provider organization that has a network of preferred providers and the organization has contracted with the health care preferred provider.
- (2) An insurer or entity shall not reimburse on a discounted fee basis unless the disclosure is provided in the contract with:
 - (a) A provider or organization of providers; or
 - (b) An organization that has a network of preferred providers and the insurance entity has the written consent of the health care preferred providers.

How do you know if the MCO with which you contracted is in compliance with this law? It is important that you review the underlying participating provider agreement or PPO contract. Check to see if any agreement contractually requires you to accept payments from “other payers,” including the other payer at issue in the particular case. If it does, ensure that the reimbursement you received from the other payer is consistent with the negotiated rate in the underlying contract. You might also consider the following suggestions and negotiating techniques:

- Verify that your participation agreement with the MCO properly identifies the products and markets applicable as required by Kentucky statutes.
- Look for the key definitions that identify the financially responsible party, such as “payer”, “groups”, and “clients”. Avoid contract clauses that define the financially responsible party simply by reference to a separate contract entered between the MCO and a non-specific third party. Consider the following examples of defined terms and clauses in participating provider agreements which could require you to accept discount rates from payer sources in addition to the MCO with which you are contracting:

Example #1

- **Definitions**
 - Covered Services: Those medically necessary services which a Member is entitled to receive under the terms and conditions of a Plan

- Member: An individual covered by or enrolled in a Plan
- Payor: An employer, insurer, health maintenance organization, labor union, organization or other person or entity which has agreed to be responsible for funding benefit payments for Covered Services provided to Members under the terms of a Plan
- Plan: Any health benefit product, plan or product issued, administered, or serviced by Company or one of its affiliates, including but not limited to, HMO, preferred provider organization, indemnity, Medicaid, Medicare and Workers' Compensation.
- **Terms**
 - Provision of Services: Provider agrees to render to Members medical services which are Covered Services under Members' Plans.

Example #2

- **Definitions**
 - Covered Services means those health care services provided to a Participant in accordance with a Service Agreement
 - Participant means any individual, or eligible dependent of such individual, whether referred to as "Insured", "Subscriber", "Member", "Participant", "Enrollee", "Dependent", or otherwise, who is eligible for Covered Services pursuant to a Service Agreement
 - Payor means Company or such other entity which, pursuant to a Service Agreement, funds, administers, offers or insures Covered Services and which has agreed to act as a Payor in accordance with this Agreement
 - Service Agreement means those agreements among Company and a employer, insurer, labor union, trust or other organization or entity, or an individual, that specifies services to be provided to or for the benefit of, or arranged for or reimbursed to or for the benefit of Participants, the terms and conditions under which those services are to be provided or reimbursed.
- **Terms**
 - Provider shall accept the rates set forth in this Agreement as payment in full for all services provided to Participants pursuant to this Agreement.
 - Company shall, upon specific request by Provider, identify the Payor responsible for payment of Covered Services.
 - Company shall contract, directly or indirectly, with Payors who agree to pay in accordance with this Agreement for Covered Services rendered by Provider
 - If the contract contemplates that additional payers will be added later, consider requesting some sort of advance notice of the additions and the right to refuse participation with a particular payer. You may find that you already have a contract with the proposed payer and that contract may provide for a higher fee.
 - When negotiating the terms of your participation agreement with an MCO, consider identification of the specific payer and the payer's plans to which the discount will apply. For example:
- The term ["Payer"*] does not include any entity or person that is not identified as such by specific name, either in this Agreement or in accordance with the notice and approval procedures required by this Agreement. Under no circumstances shall the rates negotiated in this Agreement be extended to or for the benefit of any entity or person that is not identified and approved in such manner.
 - (*Insert the Agreement's defined term that designates the entity that is financial responsible for the claims.)
 - Review the MCO contract for terms that might permit the MCO to freely assign the contract or discounts. These provisions may be hidden in the boilerplate language of "Miscellaneous Provisions" that are often found at the end of the contract.
 - Monitor the EOB's issued by the payers. See below.
 - See if the PPO discloses any discounts applicable to a PPO patient at the time the physician verifies coverage.

Scenario #2 – Illegal Network Leasing

As discussed above, Kentucky law provides that any contract between a payer and a physician must contain a provision identifying the products and markets applicable to any discount. *An attempt by an MCO, therefore, to sell your negotiated discounts*

may be a breach of your MCO contract or violate Kentucky insurance laws if the product is not properly identified, or if your MCO contract does not contemplate other payers having access to the negotiated discount rates. If there is a breach, you may have legal rights against the MCO in addition to claims against the third party that attempts to take an unauthorized discount. Assistance from legal counsel may be required to assert your claims for relief under these principles.

Kentucky law also requires an insurer to pay, deny or settle a clean claim within 30 days after the date that the claim is received by the insurer or any entity that administers or processes claims on behalf of the insurer. If an insurer fails to pay, deny or settle a clean claim as required by Kentucky law, it must pay interest on the amount of the claim that remains unpaid after the statutory deadline. One might assert that the amount of an unauthorized discount that remains unpaid is subject to interest at the statutory rate.

If an MCO has leased a negotiated discount without authority, physicians can complain to the Kentucky Office of Insurance. The Office of Insurance may assess fines for noncompliance with Kentucky's Silent PPO and prompt payment statutes. The fines may be as much as the greatest of \$1,000 per day, or 10% of the amount of the unpaid claim amount, for each day that a clean claim remains unpaid in violation of the statutes. Under certain circumstances the fines may be even more. Also, a Silent PPO may constitute a violation of the Unfair Claims Settlement Practices Act. Complaints may be submitted to the Office of Insurance via the internet at insurance.ky.gov/online_complaint.aspx or by contacting the Office of Insurance at:

Kentucky Office of Insurance
Health Insurance Policy & Managed Care Division
P.O. Box 517
Frankfort, KY 40602-0517
(502) 564-6088
(502) 564-2728
TDD: 800-462-2081
Toll Free: 800-595-6053

Scenario #3 – Payer Inappropriately Claims Discounts

A Silent PPO may arise where the patient's insurance coverage is of a type or from an entity that does not have its own participating physician network, such as an auto/liability insurer, a small health insurer, a worker's compensation insurer, or an employer's self-insured plan. After the physician treats the patient, the physician bills the patient's payer his/her usual and customary charge. The payer, in anticipation of receiving claims for medical services, may do one of two things, or even both:

1. It purchases or leases a network "discount database" that contains the physician's name and discounted rates from a contracting agent; and/or
2. It engages a "repricer" or discount broker that itself has amassed an expansive discount database containing many networks, potentially including most, if not all, the networks the physician has agreed to participate in at discounted rates.

The payer or repricer then searches the database for the physician's name and lowest discounted rate. Based on what is found in the database, the claim is then "repriced" to reflect that discounted charge. The physician subsequently receives reimbursement at less than full payment. Always compare the explanation of benefits with the patient's insurance information. The explanation of benefits possibly references the discount with the entity with whom the physician agreed to accept that reduced rate, even though the patient may not be covered by that entity. Unfortunately, many physicians accept the reimbursement without challenge, not knowing that it was discounted inappropriately.

When discounts are in question, contact the payer and ask them to justify. Follow up in writing. Challenge the payer to prove it is entitled to the discount or demand payment of your full fee.

How To Spot a Silent PPO

Certain payers, i.e., those not likely to have their own networks, may be likely to engage in silent PPO activities. Thus, self-insured employers, automobile, or liability insurers and even health insurers that do not contract directly with providers may be purchasing or leasing provider networks for the purposes of paying for medical services. You should pay particular attention to "indemnity insurers" such as car insurance carriers as they may attempt to apply a silent discount. In addition, watch for unfamiliar payers or particularly large claims. Also check to see if a discount is taken when you cannot clearly determine from the patient's insurance card that the patient's plan is one with which you have contracted.

Many payers rely on the expectation that the physician's office will simply post the payment without verifying the existence of a proper discounted participation arrangement. Monitor the EOB's issued by the payers. Verify that any discount taken has been authorized. When reviewing EOBs, look for the following:

- The EOB should clearly specify through whom a discount is taken. If it indicates a network or payer with which you are not contracted, follow up may be warranted.

- Payments for services provided to a single patient coming from multiple PPO networks.
- Discrepancies in the EOB suggesting that silent PPO activity is occurring, such as an EOB which does not specify the source of the claimed discount, or an EOB which discloses a discount source that is different from those listed on the patient's insurance card,
- Whether you are receiving any indications (on the EOB, remittance advice, or even a letter) that a repricer is invoiced.
- Whether you are experiencing a high volume of retroactive reclassifications.

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Sports Physicals

Every local board of education must require an annual medical examination performed and signed by a physician, physician assistant, advanced practice registered nurse, or chiropractor, if performed within the professional's scope of practice, for each student seeking eligibility to participate in any school athletic activity or sport. The Kentucky Board of Education or any organization or agency designated by the state board to manage interscholastic athletics must not promulgate administrative regulations or adopt any policies or bylaws that are contrary to the provisions of this paragraph [KRS 156.070(2)(d)]. [\(Back\)](#)

Stark Laws

The following discussion was prepared by Theodore "Tad" Myre of the law firm of Wyatt Tarrant & Combs.

The so-called "Stark Law" (42 U.S.C. §1395nn) is a federal statute that precludes billing the government for certain "designated health services" where a physician who refers for such services (or an immediate family member of the physician) has a financial relationship with the service-providing entity and that financial relationship is not structured to fit within the requirements of the statute.

The Stark Law is a pervasive statute that, one way or another, impacts all physicians who treat government-pay patients. Any group practice that offers such ancillary services as lab and x-ray must comply with the complex requirements of this law or else face the prospect of devastating penalties. A bad motive is not a prerequisite to running afoul of this law, and consequently there is a higher likelihood of innocent mistakes, especially in view of the law's complexity. The statute itself is bare-boned, with all detail to be set out in regulations, which, as of early December 2000, had not yet been issued in final form. The initial set of proposed regulations, issued in 1998, produced a great deal of consternation in the provider community due to their unduly restrictive nature, their complexity, and their lack of tolerance for many otherwise unobjectionable arrangements that are common in the health industry.

Designated Health Services

In order for the law to apply, the physician must refer to a provider of one (or more) of the eleven "designated health services", which include:

1. Clinical laboratory services.
2. Physical therapy services.
3. Occupational therapy services.
4. Radiology, including magnetic resonance imaging, computerized tomography scans and certain ultrasound services.
5. Radiation therapy services and supplies.
6. Durable medical equipment and supplies.
7. Parenteral and enteral nutrients, equipment and supplies.
8. Prosthetics, orthotics and prosthetic devices and supplies.
9. Home health services and supplies.
10. Outpatient Prescription Drugs
11. Inpatient and outpatient hospital services.

While these services are easily listed, there are many detailed rules that define the scope of each, and there are separate rules and exceptions that apply to many of these services. Note also that not all of the "designated health services" are in fact services, for this definition also encompasses a multitude of "goods," including supplies.

Physician Referral

In order to be subject to the law, there must be a physician referral. The term “referral” is broadly defined not only to include the ordering of items or services, but also other actions by a physician, such as a request for consultation, the adoption of a “plan of care” and a certification for care, that result in the provision of a designated health service. It is the extension of this term to the ordering of services that causes the statute to cover activities that begin and end within a physician practice, such as the ordering of lab and x-ray tests to be performed in the physician’s own practice.

Financial Relationship

The Stark Law will apply if the referring physician has a financial relationship with the designated health services provider. It takes very little to satisfy this condition. Indirect financial arrangements, e.g., through one or more entities, are sufficient for the law’s application. In addition, a financial arrangement with an immediate family member of the referring physician, defined to include the physician’s husband or wife, parent, child and sibling, grandparent and grandchild (and their spouses), as well as certain in-laws. The law divides financial relationships into two broad categories, “ownership” and “compensation” relationships, with the most common form of relationship (and often the most difficult to spot) the latter of these. This delineation is largely for the purpose of applying the exceptions, discussed below.

Exceptions

Once the referral and financial relationship are found to exist, compliance with the law hinges upon satisfaction of a permitted financial relationship standard as set out in the statute and interpreted in the (proposed) regulations. These exceptions are as follows:

General Exceptions to both Ownership and Compensation Relationships:

- Physician services.
- In-office ancillary services.
- Prepaid plans.

Ownership Exceptions:

- Publicly traded securities and mutual funds
- Rural providers.
- Hospital ownership.

Compensation Exceptions:

- Office space lease.
- Equipment lease.
- Employment relationships.
- Personal service arrangements.
- Remuneration unrelated to designated health services.
- Physician recruitment.
- Isolated transactions.
- De minimis compensation exceptions.
- Payments by a physician for items and services.
- Fair market value compensation.

The standards for satisfying any single exception are set out in detail in the statute and the (proposed) regulations and are fairly exacting and unforgiving. The law gives no credit for satisfying substantially all of the requirements (for example, nine out of ten), and therefore a great deal of attention must be devoted to the specific standards.

Group Practices

As noted above, the law applies to lab and x-ray, and the ordering of a test within a physician practice constitutes a referral. Accordingly, unless an exception is available and adhered to, intra-group referrals can trigger the Stark Law penalty provisions. In this instance, the in-office ancillary services exception provides relief. The difficulty with this exception is that it is extremely complex. In addition, it mandates that a physician cannot receive direct credit for ordering covered ancillary services, but must share revenues from those services with other physicians in the group in ways that can have dramatic economic consequences. Any group that offers a designated health service must take determined and sometimes painful steps to ensure that it complies with this exception. Once the final regulations are issued, group practices will be required to attest, on an annual basis, and under penalty of perjury, that they satisfy certain elements of the “group practice” definition. Since the attestation will itself be a condition of maintaining group practice status, the failure to attest or an erroneous attestation could itself result in government sanction.

Sanctions

The penalties for violating the Stark Law include denial of payment (including mandatory reimbursement of wrongfully

billed monies), civil money penalties of up to \$15,000 *per service*, and in certain circumstances, exclusion from the Medicare program. In addition, the law imposes certain extensive reporting requirements. Failure to comply with the reporting requirements can result in a \$10,000 *per day* penalty as well as exclusion from the Medicare program. ([Back](#))

Sterilization

Kentucky law requires any physician who is requested to perform a nontherapeutic sterilization to counsel the person who requests the sterilization [KRS 212.343]. Before a physician performs a nontherapeutic sterilization, the patient must give written consent [KRS 212.345]. Physicians must then wait 24 hours following the written consent before performing the sterilization procedure. ([Back](#))

Suicide, Physician Assisted

Kentucky law makes it a felony for any person, including a physician, to cause or assist another person in committing or attempting to commit suicide [KRS 216.302]. KRS 216.304, however, exempts from prosecution any physician who administers, prescribes, or dispenses medications or procedures to relieve another person's pain, even if the medication or procedure may hasten or increase the risk of death, unless the medications are knowingly and intentionally administered or prescribed to cause death. A physician who withholds or withdraws a life sustaining procedure in compliance with Kentucky law is also exempt from prosecution. KRS 216.308 allows the Kentucky Board of Medical Licensure to revoke the license of any physician who assists in a suicide. ([Back](#))

Tuberculosis

KRS 215.590 requires every physician to report cases of Tuberculosis to the local health department. Physicians who perform a related drug susceptibility test on tubercle bacilli must report the results of the testing to the local health department. ([Back](#))

Utilization Review

"Utilization review" is defined as a review of the medical necessity and appropriateness of hospital resources and medical services given or proposed to be given to a covered person for purposes of determining the availability of payment. Areas of review include concurrent, prospective, and retrospective review [KRS 304.17A-600(18)]. Utilization review may be conducted by an insurer or a private review agent acting on behalf of an insurer. Any insurer or private review agent that conducts utilization review must be registered with the Department of Insurance [KRS 304.17A-607(1)]. A private review agent must provide the Department of Insurance with the names of the entities for which it is conducting utilization review [KRS 304.17A-607(4)].

An insurer or private review agent must have written procedures for determining whether a requested service, treatment, drug, or device is covered under the terms of a covered person's health benefit plan; making utilization review determinations; and making notification of its determinations [KRS 304.17A-603]. An insurer must afford participating physicians an opportunity to review and comment on all of its medical and surgical and emergency room protocols, as well as all of the insurer's protocols that are within the provider's legally authorized scope of practice [KRS 304.17A-607(1)(k)]. An insurer or private review agent must submit a copy of any changes to its utilization review policies or procedures to the Department of Insurance and no change to the policies and procedures will be effective or used until after it has been filed with and approved by the Commissioner of Insurance [KRS 304.17A-607(3)]. Upon request of any provider, authorized person, or covered person whose care is subject to review, the Department of Insurance must provide copies of policies or procedures of any insurer or private review agent [KRS 304.17A-613(6)].

Only licensed physicians can make a utilization review decision to deny, reduce, limit, or terminate a health care benefit or

deny, or reduce payment for a health care service because that service is not medically necessary, experimental, or investigational. Physicians must also supervise qualified personnel conducting case reviews [KRS 304.17A-607(1)(b)]. Insurers and private review agents who perform utilization review must also have available the services of sufficient numbers of practicing physicians in appropriate specialty areas to assure the adequate review of medical and surgical specialty and subspecialty cases [KRS 304.17A-607(1)(c)]. Insurers and private review agents must also provide a toll free telephone line for covered persons, authorized persons, and providers to contact the insurer or private review agent and be accessible to covered persons, authorized persons, and providers forty (40) hours a week during normal business hours [KRS 304.17A-607(1)(e)]. They must also be available to conduct utilization review during normal business hours and extended hours in Kentucky on Monday and Friday through 6:00 p.m., including federal holidays [KRS 304.17A-607(1)(f)].

An insurer must provide a utilization review decision relating to urgent and nonurgent care in accordance with federal law [KRS 304.17A-607(1)(h)]. A utilization review decision must also be provided within twenty-four (24) hours of receipt of a request for review of a covered person's continued hospital stay and prior to the time when a previous authorization for hospital care will expire [KRS 304.17A-607(1)(i)].

An insurer or agent must provide written notice of review decisions to the covered person, authorized person, and providers. An insurer or agent that denies coverage or reduces payment for a treatment, procedure, drug, or device must include in the written notice:

1. A statement of the specific medical and scientific reasons for denial or reduction of payment or identifying that provision of the schedule of benefits or exclusions that demonstrates that coverage is not available;
2. The state of licensure, medical license number, and the title of the reviewer making the decision;
3. Except for retrospective review, a description of alternative benefits, services, or supplies covered by the health benefit plan if any; and
4. Instructions for initiating or complying with the insurer's internal appeal procedure [KRS 304.17A-607(1)(j)].

A utilization review decision may not retrospectively deny coverage for health care services provided to a covered person when prior approval has been obtained for those services, unless the approval was based upon fraudulent, materially inaccurate, or misrepresented information [KRS 304.17A-611].

If an insurer fails to provide a utilization review decision within 24 hours after being contacted for a requested review of continued hospitalization of a covered person, or if the covered person's provider is unable to contact the insurer after 3 documented attempts during a 4 consecutive hour period during normal business hours, the insurer is prohibited from denial or reduction of payment for a covered service [KRS 304.17A-615].

Internal Appeals

Every insurer must have an internal appeal process [KRS 304.17A-617(1)]. The internal appeals process may be initiated by the covered person, an authorized person, or a provider acting on behalf of the covered person [KRS 304.17A-617(2)]. Such an appeal can be undertaken when there is an "adverse determination" by the insurer, or a "coverage denial" by the insurer. An "adverse determination" is a determination by an insurer that the health care services furnished or proposed to be furnished are not medically necessary, or are experimental or investigational [KRS 304.17A-600(1)(a)]. A "coverage denial" is an insurer's determination that a service, treatment, drug, or device is specifically limited or excluded under the covered person's health benefit plan [KRS 304.17A-617(1)]. An insurer must disclose the availability of the internal review process to the covered person in the insured's timely notice of an "adverse determination" or notice of a "coverage denial" [KRS 304.17A-617(1)].

Insurers or their designees must provide decisions to covered persons, authorized persons, and providers on internal appeals of adverse determinations or coverage denials within thirty (30) days of receipt of the request for internal appeal [KRS 304.17A-617(2)(a)]. Requests for "expedited appeals" must be rendered within three (3) business days of the receipt of the request [KRS 304.17A-617(2)(b)]. An expedited appeal is deemed necessary when a covered person is hospitalized or, in the opinion of the treating provider, review under a standard time frame could, in the absence of immediate medical attention, result in any of the following:

1. Placing the health of the covered person or, with respect to a pregnant woman, the health of the covered person or the unborn child in serious jeopardy;
2. Serious impairment to bodily functions; or
3. Serious dysfunction of a bodily organ or part [KRS 304.17A-617(2)(b)].

Internal appeal of an adverse determination can only be conducted by a licensed physician who did not participate in the initial review and denial. In the case of a review involving a medical or surgical specialty or subspecialty, the insurer or agent must, upon request by a covered person, authorized person, or provider, utilize a board eligible or certified physician in the appropriate specialty or subspecialty area to conduct the internal appeal [KRS 304.17A-617(2)(c)]. Those portions of the medical record that are relevant to the internal appeal must be considered and providers given the opportunity to present additional information [KRS 304.17A-617(2)(d)]. An insurer or agent that denies, limits, reduces, or terminates coverage for a treatment, procedure, drug, or device for a covered person must provide the covered person with an internal appeal determination letter that must include:

1. A statement of the specific medical and scientific reasons for denying coverage or identifying that provision of the schedule of benefits or exclusions that demonstrates that coverage is not available;
2. The state of licensure, medical license number, and the title of the person making the decision;
3. Except for retrospective review, a description of alternative benefits, services, or supplies covered by the health benefit plan, if any; and
4. Instructions for initiating an external review of an adverse determination, or filing a request for review with the Department of Insurance if a coverage denial is upheld by the insurer on internal appeal. [KRS 304.17A-617(2)(e)]

Where a “coverage denial” is involved, in addition to stating the reason for the coverage denial, the insurer must provide instructions for filing a request for review by the Department of Insurance. The department must establish and maintain a system for receiving and reviewing requests for review of coverage denials [KRS 304.17A-617(3)]. Physicians and other providers must provide to the Department of Insurance any information requested by the Department of Insurance that is germane to the review [KRS 304.17A-617(3)(c)].

Independent External Review

Every insurer must have an external review process that must be disclosed to the covered person in the insured’s timely notice of an adverse determination or notice of a coverage denial [KRS 304.17A-623(1)]. A covered person, an authorized person, or a provider acting on behalf of *and with the consent* of the covered person, may request an external review. [KRS 304.17A-623(2)] *[Note: While an “internal appeal” does not require the consent of the covered person to file such an appeal, consent of the covered person is required to file an “external appeal.” Physicians should be sure to obtain written consent from the patient prior to filing an external appeal]*

The insurer must provide for an external review of an “adverse determination” if the following criteria are met:

- (a) The insurer, its designee, or agent has rendered an adverse determination;
- (b) The covered person has completed the insurer’s internal appeal process;
- (c) The covered person was enrolled in the health benefit plan on the date of service or, if a prospective denial, the covered person was enrolled and eligible to receive covered benefits under the health benefit plan on the date the proposed service was requested; and
- (d) The entire course of treatment or service at issue will cost the covered person at least one hundred dollars (\$100) if the covered person had no insurance [KRS 304.17A-623(3)].

The request for external review must be made to the insurer within sixty (60) days of receiving notice that an adverse determination has been timely rendered under the insurer’s internal appeal process. As part of the request, the covered person must provide written consent authorizing the independent review entity to obtain all necessary medical records from both the insurer and any provider utilized for review purposes regarding the decision to deny, limit, reduce or terminate coverage [KRS 304.17A-623(4)].

The covered person will be assessed a one time filing fee of twenty-five dollars (\$25) to be paid to the independent review entity and which may be waived if the independent review entity determines that the fee creates a financial hardship on the covered person. The fee will be refunded if the independent review entity finds in favor of the covered person [KRS 304.17A-623(5)].

A covered person will not be afforded an external review of an adverse determination if:

- (a) The subject of the covered person’s adverse determination has previously gone through the external review process and the independent review entity found in favor of the insurer; and
- (b) No relevant new clinical information has been submitted to the insurer since the independent review entity found in favor of the insurer [KRS 304.17A-623(6)].

If a dispute arises between an insurer and a covered person regarding the covered person’s right to an external review, the covered person may file a complaint with the Department of Insurance [KRS 304.17A-623(8)].

External reviews will be conducted in an expedited manner by the independent review entity if the covered person is hospitalized, or if, in the opinion of the treating provider, review under the standard time frame could, in the absence of immediate medical attention, result in any of the following:

- (a) Placing the health of the covered person or, with respect to a pregnant woman, the health of the covered person or her unborn child in serious jeopardy;
- (b) Serious impairment to bodily functions; or
- (c) Serious dysfunction of a bodily organ or part [KRS 304.17A-623(10)].

For expedited external review, a determination must be made by the independent review entity within twenty-four (24) hours from the receipt of all information required from the insurer [KRS 304.17A-623(12)]. External reviews that are not expedited will be conducted by the independent review entity and a determination made within twenty-one (21) calendar days from the receipt of all information required from the insurer [KRS 304.17A-623(13)].

In making its decision, an independent review entity conducting the external review must take into account all of the

following:

- a. Information submitted by the insurer, the covered person, the authorized person, and the covered person's provider, including:
 1. The covered person's medical records;
 2. The standards, criteria, and clinical rationale used by the insurer to make its decision; and
 3. The insurer's health benefit plan.
- b. Findings, studies, research, and other relevant documents of government agencies and nationally recognized organizations, including the National Institutes of Health, or any board recognized by the National Institutes of Health, the National Cancer Institute, the National Academy of Sciences, and the United States Food and Drug Administration, the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services, and the Agency for Health Care Research and Quality; and
- c. Relevant findings in peer-reviewed medical or scientific literature, published opinions of nationally recognized medical specialists, and clinical guidelines adopted by relevant national medical societies [KRS 304.17A-625(1)].

The independent review entity must base its decision on the information submitted and also consider safety, appropriateness, and cost effectiveness [KRS 304.17A-625(2)]. The independent review entity must provide to the covered person, treating provider, insurer, and the Department of Insurance a decision that includes:

- (a) The findings for either the insurer or covered person regarding each issue under review;
- (b) The proposed service, treatment, drug, device, or supply for which the review was performed;
- (c) The relevant provisions in the insurer's health benefit plan and how applied; and
- (d) The relevant provisions of any nationally recognized and peer-reviewed medical or scientific documents used in the external review [KRS 304.17A-625(6)].

The decision of the independent review entity is binding on the insurer with respect to that covered person [KRS 304.17A-625(9)]. The covered person, insurer, or provider in the external review may submit written complaints to the Department of Insurance regarding any independent review entity's actions believed to be inappropriate [KRS 304.17A-625(16)].

If the covered person, authorized person, or provider has new clinical information regarding the covered person's internal appeal he or she must provide that information to the insurer prior to the initiation of the external review process. The insurer then has five (5) business days from the date of the receipt of the information to render a decision based on the new information [KRS 304.17A-619]. [\(Back\)](#)

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