

April 27, 2007

Federal and Texas Requirements for Disclosure of Physician Ownership in Hospitals, ASCs and Other Health Care Facilities

The purposes of this Health Care Alert are to: 1) summarize recently proposed federal regulations which will require physician disclosure of ownership interests in hospitals to patients; 2) remind health care providers of existing Texas laws requiring disclosure of ownership interests and 3) suggest best practices for disclosure of ownership interests.

Proposed Federal Regulations Requiring Physician-Owned Hospital Disclosure

The Center for Medicare and Medicaid Services (“CMS”) proposed rule responds to the Deficit Reduction Act provision addressing the annual disclosure of investment information and the report of the U.S. Department of Health and Human Services (“DHHS”) to Congress stating DHHS would adopt a disclosure requirement for hospitals regarding physician ownership.

The proposed regulations will require physician-owned hospitals to provide written notice to patients disclosing the hospital is physician-owned and provide a list of physician-owners upon request. The regulations define “*physician-owned hospital*” as a participating hospital in which a physician or physicians have ownership or investment interests. After receiving comments, the proposed regulations may create exceptions based on the size or type of physician ownership or investment interests.

The proposed regulations may be enforced through expanded reporting on Medicare provider enrollment agreements or through changes to Medicare conditions of participation. Medicare Provider Enrollment Form 855A currently requires disclosure of all persons who have a five percent or greater direct or indirect ownership interest in a provider corporation. Also, persons owning any partnership interest in a provider must disclose their ownership regardless of the type of partnership owning the provider or the partnership percentage owned.

The DHHS Secretary currently has the authority to require the disclosure of a Medicare provider’s ownership under Medicare law and regulations. The 2004 final Stark rules removed a proposed periodic physician ownership and compensation arrangement reporting requirement and now requires the information to be maintained by the hospital and provided to CMS on request. The DHHS Office of Inspector General (“OIG”) has recommended how to maintain compensation arrangements’ information for potential disclosure in its Compliance Program Guidance for Hospitals and required such maintenance of information in several corporate integrity agreements. The new CMS regulations will only apply to hospitals, but it is worth noting the Anti-Kickback Safe Harbor for ambulatory surgery centers (“ASC”) already requires physician-owners to disclose ASC ownership interests to patients prior to a referral to a physician-owned ASC.

The proposed regulations will require hospital medical staff bylaws to be updated by requiring physician-owners to disclose ownership interests to patients at the time of a referral to the hospital. The required change to hospital bylaws would require physicians to comply with the disclosure requirement in order to continue medical staff membership. To enforce the proposed regulations, hospitals that do not have procedures in place to notify patients of physician ownership may be denied new Medicare provider agreements. CMS would terminate existing provider agreements with hospitals that do not comply with the proposed changes to medical staff bylaws.

More information is available on the proposed regulations at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1533-P.pdf>.

Physician Disclosure of Ownership in “Specialty Hospitals” – Texas Occupations Code § 105.002

Texas law requires physicians to disclose in writing and inform a patient of a financial interest and alternative facilities prior to directing a patient to a specialty hospital (referred to as a “*niche hospital*” in the statute) in which the physician or his or her family member has a financial interest. The statute defines a “*niche hospital*” as a hospital that classifies at least two thirds of its Medicare patients in no more than two diagnosis related groups or surgical diagnostic related groups and specialize in cardiac, orthopedic, surgical, or women’s health. Niche hospitals do not include public hospitals, rehabilitation hospitals, psychiatric hospitals, drug and alcohol treatment facilities, or facilities with fewer than ten annual claims per bed. Physicians that do not make the required disclosures to their patients commit unprofessional conduct.

Failure to Disclose Physician Ownership in Health Care Facility – 22 Texas Administrative Code § 190.8(2)(H)

Texas regulations state a licensed physician commits unprofessional and dishonorable conduct if the physician refers patients to a health care facility without disclosing the physician’s ownership interest in the facility to the patient. Failure to disclose the physician’s ownership to the patient at the time of referral may be considered a violation of the Texas Medical Practice Act.

Failure to Disclose Financial Remuneration – Texas Occupations Code § 102.006

Texas law prohibits a person from soliciting patients for a provider licensed, certified or registered by a state health care regulatory agency in return for payment or remuneration. To prevent prosecution for a permitted arrangement (such as one protected by a federal Anti-Kickback safe harbor), the person must disclose at the time of initial contact the nature of the relationship between the person and the provider and that the person will receive remuneration for securing or soliciting patients. Failure to comply with this statute may result in disciplinary action against licensed providers and potential civil or criminal offenses.

Mental Health and Chemical Dependency Facilities: Disclosure of Affiliation – Texas Health & Safety Code § 164.010

All persons must disclose an affiliation between a mental health or chemical dependency treatment facility and its soliciting agents, employees, or contractors prior to soliciting a patient source or prospective

patient for the services of the treatment facility. Violations of this statute may result in civil fines or penalties and result in disciplinary actions against licensed healthcare providers.

Physicians' Use of the Internet – 22 Texas Administrative Code § 174.4

Texas regulations address the disclosures and information required for Texas physicians' operating medical practice internet sites. Among other disclosures, the physician's website must disclose: 1) ownership of the site; 2) fees for online services and consultation -including how payment is made; and 3) financial interest in any information, products or services. Physicians are also prohibited from receiving direct remuneration or incentives for advertising or promoting goods or products on the website.

Worker's Compensation – Texas Labor Code § 413.041 & 28 Texas Administrative Code § 180.24

Every health care practitioner that registers with the Texas Department of Insurance, Division of Worker's Compensation must disclose the name of health care providers in which the practitioner has a financial interest. Financial interests include a health care practitioner's or their family member's ownership or investment interests and direct or indirect compensation relationships (including employment relationships) with a health care provider. Failure to disclose financial interests may result in fines, the loss of reimbursement rights, and refunds of fees billed during the period of nondisclosure.

Physician Health Care Facility Ownership Disclosure – Texas Medical Association Board of Councilors Opinion, Winter 2007

Physicians have an affirmative ethical obligation to disclose his or her ownership of a health care facility to a patient prior to the patient's admission or utilization of the facility. The ethical opinion suggests physicians should make a list of alternative facilities available upon patient request. Opinions from the Board of Councilors are intended to provide guidance to Texas physicians on responsible ethical behavior.

Best Practices – Methods to Disclose Physician Ownership

If the criteria of an applicable Stark exception and/or Anti-Kickback safe harbor are complied with by a physician and a hospital with respect to ownership interests and compensation arrangements, the likelihood of the financial relationship producing any aspect of fraud or abuse of a federal health care program is greatly diminished. Patient freedom of choice of provider under Medicare and Medicaid must still be protected and informed decision-making by the patient enhanced according to both CMS and the OIG even with such compliance. Requiring disclosure of physician ownership in the health care facility is the OIG's and CMS's response to preserving these principles. CMS states physician ownership disclosure is in the interest of the health and safety of hospital patients because disclosure will permit individuals to make more informed choices regarding their treatment and evaluate whether a physician's ownership in the hospital portends a conflict of interest that is not in their best interest. However, the OIG does not believe disclosure of an ASC ownership interest provides sufficient assurance of informed decision-making as patients are not sufficiently warned of the possible effect of financial considerations on physicians' independent medical judgments. According to the OIG, bare disclosure of ASC ownership makes no mention of this potential conflict of interest between financial incentives and physician behavior.

Neither CMS or the OIG provide much direction on the method of disclosure of physician ownership or how to bridge the gap between notice of physician ownership and providing information on the pros and cons of physician financial interests and incentives. Information for informed decision-making relating to informed consent for a hospital or ASC surgical procedure is typically presented in a manner that best related to the decisions and concerns patients face, at the time they face them, and allows patients to learn more over time as questions arise. Hospitals and physicians will need to decide if they want to provide a similar opportunity for patients in the physician ownership disclosure process to receive information on the potential conflict of interest.

Signs and notices at the hospital and the physicians' practices that state the hospital is owned by physicians, the names of physician investors and that further details are available on request likely satisfy the OIG and CMS disclosure requirements. If a patient inquires about other hospitals and ASCs, physicians should be prepared to present an alternative choice to assure freedom of choice of provider. An explanation of the potential positive and negative effects of physician investment may be offered by the physician, hospital, or ASC, orally or in writing, to the patient who inquires about the risks of being referred for unnecessary services or overutilization in a physician-owned facility versus the benefits of a physician actively engaged in oversight of quality improvement and cost containment due to the physician's ownership interest in the hospital or ASC.

If you would like assistance or more information regarding implementing physician ownership disclosure requirements, please contact one of the Haynes and Boone Health Care Practice Group attorneys listed below.

Stephen P. Allison
(210) 978-7416
stephen.allison@haynesboone.com

Stacy L. Brainin
(214) 651-5584
stacy.brainin@haynesboone.com

Felicity A. Fowler
(713) 547-2072
felicity.fowler@haynesboone.com

Earl Harcrow
(817) 347-6646
earl.harcrow@haynesboone.com

David N. Heard
(214) 651-5563
david.heard@haynesboone.com

Michael L. Hood
(214) 651-5673
michael.hood@haynesboone.com

Jeffrey P. King
(512) 867-8413
jeff.king@haynesboone.com

Lewis A. Lefko
(214) 651-5608
lew.lefko@haynesboone.com

Thomas W. Mayo
(214) 651-5768
thomas.mayo@haynesboone.com

Michael McCabe
(214) 651-5126
michael.mccabe@haynesboone.com

Bill Morrison
(214) 651-5018
bill.morrison@haynesboone.com

If you receive this Health Care Alert by mail and would prefer to receive it electronically, please e-mail Lewis Lefko at lew.lefko@haynesboone.com. Please visit our website at www.haynesboone.com for other recent Health Care Alerts.

Haynes and Boone LLP and its Health Care Practice Group congratulates authors *Thomas Wm. Mayo and Tara E. Kepler* on the publishing of their book *Telemedicine: Survey and analysis of Federal and State Laws* by the American Health Lawyers Association. Tom is Of Counsel to the Health Care Practice Group and is Associate Professor at the Southern Methodist University Dedman School of Law and Director of SMU's Cary M. Maguire Center for Ethics and Public Responsibility. Tara is a health care and regulatory analyst for the Health Care Practice Group and will be graduating from the Texas Wesleyan School of Law in Fort Worth in December, 2007.