

## Texas Hospital Settles Self-Disclosed Violation of Stark Law, Signs CIA

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On March 17, 2008, Hardeman County Memorial Hospital, a 24 bed critical access hospital in rural Quanah, Texas, reached a settlement agreement with the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) and the Department of Justice regarding an 11 year long violation of the Stark law. Because it imposes heavy handed sanctions for unintentional and self-reported Stark law violations, the Hardeman County Memorial Hospital settlement agreement and corporate integrity agreement (“CIA”) sends a strong signal to health care providers that the Federal government’s increasingly hard-line approach to Stark and other federal health law violations extends to inadvertent, as well as deliberate violations of these requirements. Accordingly, like the March 14, 2008 criminal sentencing of the former chief executive officer of a Plainview, Texas medical clinic, the settlement agreement drives home the critical need for health care providers and their leaders to maintain and administer effective compliance and audit programs to mitigate their exposure to criminal and civil prosecution under a wide range of federal health care fraud and other laws.

Briefly, the Stark law (42 U.S.C. § 1395nn) prohibits a physician from making referrals of patients to a health care provider, if that physician has a “financial relationship” with the provider accepting the referral, unless the financial relationship falls into a specified exception. If the relationship does not fall into an exception, then any claims made by the provider that accepted the referral are considered “tainted” claims. These “tainted” claims are thus violations of the Civil False Claims law (31 U.S.C. § 3729), which requires that claims to federally-funded health care programs comply with applicable laws and regulations. Under the Civil False Claims law, not only must the claims be repaid, but the provider who submitted them may also be subject to penalties of up to \$11,000 per violation, plus treble damages.

In 2005, the hospital notified the OIG that it had discovered a physician relationship that potentially violated federal law. During a review of physician relationships conducted by new management, it was discovered that Hardeman had a physician lease arrangement where the physician was not paying rent. In addition to rent-free space in a clinical building owned by the hospital, the physician also received free utilities. The violation occurred from 1994 through 2005. The hospital self-disclosed this violation, utilizing the OIG’s Voluntary Self-Disclosure Protocol (<http://www.oig.hhs.gov/fraud/selfdisclosure.html>). The OIG launched an investigation. The hospital cooperated fully with the OIG in the investigation. As a result of the data provided by the hospital, the government concluded that the hospital had been paid substantial sums by the Medicare program for providing services and items to patients who had been referred by the physician who received free rent. After negotiations, the parties agreed to a repayment of \$398, 230.56. Because Hardeman County Memorial Hospital was experiencing ongoing financial difficulties, the U.S. Government agreed to reduce the settlement amount and to allow the hospital to make payments over two years.

Nonetheless, the administrator of the hospital was unhappy with the outcome. By using the OIG’s Voluntary Self-Disclosure Protocol, the hospital did the right thing, as has been so often urged by the government, yet it did not seem to obtain many benefits from self-disclosing. The outcome seems to be unduly harsh for a struggling rural hospital that attempted to do the right thing by disclosing the violation. Additionally, because the hospital is located in a rural county and the next closest hospital is approximately 80 miles away, it would seem to lessen any requirement of referrals. As the hospital administrator noted, where else was the physician to refer patients? In addition, Furthermore, it appears that the physician will not be required to repay the government for tainted claims, nor will the physician be required to enter into a CIA.

In conjunction with the settlement agreement, Hardeman County Memorial Hospital entered into a 3 year Corporate Integrity Agreement (“CIA”). In addition to implementing the other aspects of full-fledged compliance program, the CIA requires the hospital to provide 3 hours of training initially to “Arrangements Covered Persons” and 2 hours annually thereafter. “Arrangements Covered Persons” is defined as all individuals involved with any transaction or arrangement that might implicate the Stark law or the federal Anti-kickback Statute (43 U.S.C. § 1320a-7b).

But perhaps the most onerous provision in the CIA is the requirement that the hospital create a database to track all arrangements and ensure that they do not violate the Stark or Anti-kickback laws. To that end, the database must include the names of all parties involved in the arrangement; the type of arrangement (e.g., lease agreement, medical directorship, etc.);

the term of the arrangement, including effective dates and expiration dates and any automatic renewal provisions; the amount of compensation to be paid and the means of payment; methodology for determining compensation, including methodology used to determine fair market value of the compensation; whether the amount of compensation varies with the volume or value of referrals between the parties; ensuring that the arrangement is in writing, contains a certification that the parties will not violate the Stark or Anti-kickback laws with regard to the arrangement, and all individuals who meet the definition of "Covered Persons" must comply with the hospital's compliance plan, including obtaining the required training; and whether the arrangement satisfies the requirements of a Stark law exception or an Anti-kickback statute safe harbor. Each year, the Independent Review Organization required by the CIA must review the hospital's Arrangements database and underlying policies and procedures and ensure that the requirements have been met. The IRO must report to the OIG annually on its findings and any corrective actions taken.

In addition to creating the database, the hospital must also track and log all remuneration to and from all of the parties included in the database; require physicians to complete time and service logs and track these to ensure that physicians are providing the services required under the relevant arrangements; monitor the use of leased space, medical equipment, medical supplies and other patient care items; and implement a written review and approval process for all arrangements, including review by outside legal counsel. These requirements will not be cheap or easy to implement for a financially ailing rural hospital with limited staff resources. In addition, these requirements will force physicians on the medical staff and vendors to effectively implement their own compliance program, to the extent that they do not have compliance program elements, just to be able to refer and service patients to the hospital. Hardeman County Memorial Hospital's CIA will thus have a ripple effect throughout the community.

Announced a mere three days after a Texas federal court sentenced former CEO Angela Edwards to 2 ½ years in prison and ordered her to pay \$370,657 in restitution for her intentional involvement in health care fraud, the Hardeman Memorial Hospital settlement and CIA demonstrates the Federal government's serious commitment to enforcement of federal health care laws even with respect to inadvertent violations of health care laws and even in small and rural settings. Therefore, all health care providers receiving patient referrals from physicians should spend diligent and well-document time and effort ensuring their ability to demonstrate full compliance with the Stark and Anti-kickback laws and implementing regulations, as well as other Federal health care laws. Health care providers should seek consult with qualified legal counsel within the scope of attorney-client privilege about the adequacy of their current policies and procedures and the development, implementation and enforcement of appropriate policies and practices to manage exposures to health care fraud or other liabilities taking into account the specific nature and scope of that health care provider's health care operations. As part of this process, health care providers should work with their legal counsel within the scope of attorney-client privilege to decide and implement appropriate oversight and audit procedures and processes for investigating and addressing any issues that might arise in connection with an audit. While each health care provider generally should work with their legal counsel to define the scope and other particulars of such audit, every health care provider as part of this effort generally should undergo a periodic assessment by outside counsel of the adequacy of its Stark compliance efforts.

For assistance in reviewing and updating your Stark, Anti-kickback, or other corporate compliance policies, practices or program, assessing the strength of your controls in addressing these laws or other healthcare laws and regulations, or in addressing other compliance or health care concerns, please contact Cynthia Marcotte Stamer at [cstamer@solutionslawyer.net](mailto:cstamer@solutionslawyer.net), 972-419-7188, or Heidi Kocher at [hkocher@solutionslawyer.net](mailto:hkocher@solutionslawyer.net), 972-419-7107.

### *About Cynthia Marcotte Stamer & Heidi Kocher*

**Cynthia Marcotte Stamer**, P.C., a member of the law firm of Glast, Phillips & Murray, P.C, has more than 20 years experience advising, and representing health care providers and other health industry clients about health care operations, reimbursement, regulatory and public policy, risk management, human resources, credentialing, technology, privacy, and other concerns. Her clients include hospitals, physicians, clinics, IPAs, PHOs, skilled nursing facilities, assisted living and home health, rehabilitation, imaging and other diagnostic services providers, DME, physician practice management companies and other management services organizations, health care technology, and other health industry clients. Recognized in the International Who's Who of Professionals and bearing the Martindale Hubble AV-Rating, Ms. Stamer is a highly regarded legal advisor and consultant, author and speaker, who regularly conducts management and other training on health care reimbursement and other health industry operational, regulatory, and public policy matters.

Chair of the American Bar Association (ABA) Health Law Section Managed Care & Insurance Interest Group and known for her practical, direct problem-solving approach, Ms. Stamer also applies her extensive industry experience in numerous professional and industry leadership roles. In addition to her ABA Health Law Section involvement, Ms. Stamer serves on the editorial advisory boards of and is a contributing author for the Bureau of National Affairs and other publications, served as the Compliance Committee Chair and a member of the Board of the National Kidney Foundation of North Texas Board of Directors, serves on the continuing education and conference planning committees of the ABA Joint Committee On Employee Benefits (JCEB), the HFMA Lone Star Chapter, TAHFA, the IRS TEGE Advisory Council, and numerous other health industry groups. She also is the past-president of the Alliance for Health Care Excellence, and founder of its Health Care Heroes and Patient Empowerment Programs. She also is active in numerous other industry organizations including the American Health

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Ms. Stamer is a widely published author and highly sought-after speaker nationally and internationally sought out for her strategic knowledge and insights on operational and technical health care risk management and operational concerns. A columnist for MD News and recurring author for various other health industry publications, Ms. Stamer's insights have been quoted by the Wall Street Journal, the Bureau of National Affairs (BNA), HIPAA Comply, Private Payer News, Modern Health Care, Managed Healthcare Executive, Health Leaders, Caring for The Elderly Magazine, For The Record, the Dallas Morning News, Spencer Publications, the Dallas Business Journal, the Houston Business Journal, and a various other national and local publications. Ms Stamer is the author of 100s of publications on health industry matters including numerous highly regarded works published by the American Bar Association, Aspen Publishers, BNA, the American Health Lawyers Association, the Medical Group Management Association, Government Institutes, Inc., Decision Health and others.

**Heidi Kocher** has over 10 years experience in healthcare law, having represented many kinds of healthcare providers, from small DME companies to large national health care organizations. Prior to returning to private practice, Ms. Kocher was in-house at one of the largest national hospital companies. Her wide-ranging experience includes advising corporate and individual clients on the myriad federal and state fraud and abuse laws, such as Stark, the Anti-kickback statute, and False Claims Act, structuring mergers, acquisitions, joint ventures, employment agreements, and other deals, developing compliance programs and plans, interfacing with fiscal intermediaries, carriers, and other payers, resolving reimbursement issues, conducting investigations, assisting with preparing for and responding to JCAHO surveys, obtaining advisory opinions from the OIG, and representing providers in relation to federal and state agencies. She has worked with hospitals, physicians, mid-level practitioners, pharmacies, DME companies, LTACs, SNFs, home health and hospice agencies, inpatient rehab facilities, clinical laboratories, as well as allied health practitioners. She is active in the Health Care Compliance Association, and has written numerous articles and provided training on various healthcare law topics.

For more information about Ms. Stamer and Ms. Kocher, a listing of selected publications and other health industry links, information about workshops and other training and other health industry information and resources or other details about Cynthia Marcotte Stamer, P.C. and Glast, Phillips & Murray, P.C., see [CynthiaStamer.com](http://CynthiaStamer.com) or contact Ms. Stamer or Ms. Kocher.

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