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
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**Cynthia Marcotte Stamer**, P.C., a member of the law firm of Glast, Phillips & Murray, P.C, has more than 20 years
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