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Submitter Information

Name: Richard Morrison
Address:
Orlando, FL, 32803

General Comment

RE: Physician Self-Referral Disclosure Protocol (CMS-10328)

Adventist Health System welcomes the opportunity to comment on the information collection burden associated with the Self-Referral Disclosure Protocol (SRDP). The SRDP set forth a process for physicians to self-disclose actual or potential violations of the physician self-referral statute (Stark Law) and permits reduced liability for any Stark Law violations. While Adventist Health System supports the opportunity for physicians to self-disclose, this request for information is problematic. Penalties associated with Stark Law do not differentiate between technical errors and fraudulent activity. A misinterpretation of Stark Law, or a coding error, could result in a potential, or actual, violation not being reported. The requirement that overpayments must be reported and returned 60 days after the date the over-payment was identified is problematic, specifically in regards to technical errors. Once a technical error is identified, such as a coding inaccuracy, it may take more than 60 days to identify the extent of the over-payment. There must be a more reasonable time frame to ensure compliance.

The original intent of Stark Law was to curb the waste and abuse of the federal health care system through the restriction of physician Medicare patient referrals for Designated Health Services (DHS) to another entity with which the physician, or an immediate family member, has a financial relationship. This was initially implemented through barring self-referrals for clinical laboratory services. Since the inception of the law, Stark has grown to include 10 additional types of health services with 23 exceptions, each with a complex set of regulations. This has created an intricate

regulatory environment within which hospitals and physicians are expected to nimbly navigate.

The complexity of this regulatory infrastructure continues to be exacerbated by the redefinition of what constitutes value in health care. Today, the Triple Aim arguably delineates the definition of value—to deliver more efficient care with improved patient outcomes to a larger population base. This is driving the health care reimbursement system away from Fee-for-Service (FFS) towards value-based payments. This critical change in the reimbursement system requires a mirrored shift in the governing regulatory regime as regulatory burdens, such as Stark, serve as an impediment to the delivery of integrated health care delivery.

Barrier to Integration
Integrated delivery of care requires collaborative relationships. Most notably is the physician-hospital relationship. In order to provide truly integrated health care, hospitals and physicians must have a shared vision. Moreover, hospitals need the ability to develop programmatic incentives to drive this alignment, a feat barred by Stark Law. Further clarification regarding "commercial reasonableness" and permissible variations of "volume and value" within compensation arrangements between hospitals and physicians is necessary.

Disproportionate Penalties
The regulatory complexity is aggravated by the lack of latitude for unintentional mistakes. Financial penalties include the refund of all payments received related to the prohibited financial arrangements. This can be financially devastating. This can include, for example, a hospital's failure to obtain a physician's signature on a lease. Consequently, the hospital is prohibited from billing Medicare for all services ordered by that physician. Other penalties include the potential liability of the False Claims Act (FCA). This can exponentially increase penalties. The liable risk associated with technical violations of Stark Law, and subsequent ties to FCA, must be made proportional to the offense.

Sincerely,

Richard E. Morrison
Vice President of Government and Public Affairs
Adventist Health System