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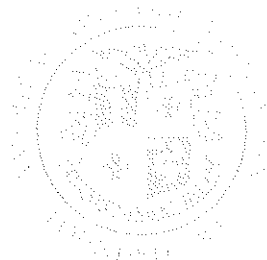
The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Self-Referral Disclosure Protocol, Patient Protection and Affordable Care Act (PPACA), Section 6409.

Dear Secretary Sebelius:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) wishes to express our strong support for the development of the self-referral disclosure protocol (SRDP) required under the *Patient Protection and Affordable Care Act* (PPACA) and to make recommendations for its implementation.

Section 6409 of the PPACA gives the Secretary of Health and Human Services authority to address an increasingly significant problem in the implementation of the self-referral law (Section 1877 of the *Social Security Act*). While originally intended to provide a “bright line” standard to assure hospitals and others clear guidance, the self-referral law has evolved into a series of increasingly complex, confusing and continually changing rules. Form and audit-type requirements are given the same weight as the core requirements of a legitimate arrangement for compliance purposes. As a result, hospitals are at risk for draconian compliance penalties that have no relationship to the harm, if any, to the Medicare program. But the problems stemming from the law’s current implementation go beyond individual compliance. Health reform initiatives that call for closer working relationships between hospitals and physicians only heighten the importance of fair and workable implementation of the self-referral law. The AHA urges the Secretary to make full use of the new authority granted by Congress in Section 6409 to address the unintended consequences of the current rules and assure fairness in enforcement of the self-referral law.



The SRDP will enable providers to disclose an actual or potential violation of the self-referral law and it will enable the Secretary to determine what, if any, repayment is due by a provider based on the individual facts and circumstances of the situation. Previously, the Centers for Medicare & Medicaid Services (CMS) had no mechanism for handling voluntarily disclosed, actual or potential violations and, significantly, all violations – whether it was a paperwork or form requirement that simply was not met or a payment that knowingly exceeded fair market value – were treated the same regardless of the nature of noncompliance. The SRDP creates a realistic mechanism for settling non-fraud violations of the self-referral law.

To be effective, the SRDP will need to offer providers a clear and understandable process for presenting and resolving disclosed issues – a framework that is fair; adjusts repayments to the harm, if any, to patients and the program; takes financial condition of the provider into account; and offers reasonable certainty or predictability of outcomes. The AHA makes the following recommendations to ensure that the SRDP achieves these objectives.

ESTABLISH A TWO-TRACK PROCESS

The process should allow for summary disposition after an expedited review or a negotiated resolution after more detailed review. Creating an expedited process recognizes that many actual or potential violations do not involve a complex set of facts, while detailed review would be used when the circumstances require a more involved description or analysis.

Expedited Review

Where a provider's disclosure of material facts and circumstances demonstrates that a matter can be resolved without significant additional evidence, it should be handled through an expedited process. This expedited process is particularly suited to situations where there is an inadequate or incomplete writing, but the disclosing party can present clear evidence of a financial relationship that is legally binding through contemporaneous records of the performance of the parties over time supplemented by testimonial declarations. Missing signatures, mistaken payments, mistaken non-collection of payment, and holdover leases are examples of situations that typically could be handled on an expedited basis.

Although it is likely that matters resolved through the expedited process will consist largely of those involving inadequate or incomplete writings, the SRDP should not be limited to those situations. The expedited process should be available for any disclosure where the provider can readily demonstrate the material facts and circumstances of an otherwise legitimate, compliant arrangement.

Triaging disclosures would be analogous to the process fiscal intermediaries undertake to complete a desk review. The SRDP should set forth the basic information required that, if accepted by the Secretary after appropriate verification, would move the provider quickly to the resolution phase of the SRDP.

Detailed Review

In the alternative, where the circumstances giving rise to an actual or potential violation necessitate a more involved description or analysis, the provider (on its own initiative or at the Secretary's request) would set forth additional information regarding the nature and extent of the violation. This might include situations involving complicated facts, such as those concerning arrangements with complex payment methodologies, or situations where the extent to which the self-referral law applies is unclear.

A two-track process would serve the interests of the agency and providers. Resources can be allocated most efficiently, reducing unnecessary burden for the agency and providers. An efficient and transparent process will enable providers to identify what will be needed to quickly resolve outstanding liabilities. The SRDP should not attempt to define the circumstances or categories of arrangements for which the protocol is available. To do so would limit its utility and the ability of the agency to appropriately address complex situations that must be evaluated on a case-by-case basis.

PROVIDE FOR ASSESSMENT OF MITIGATING FACTORS AND IDENTIFY THE RANGE OF POSSIBLE OUTCOMES FOR RESOLVING DISCLOSED MATTERS

Mitigating Factors

The PPACA explicitly provides three mitigating factors: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of such self-disclosure; and (3) the cooperation in providing additional information. In addition the SRDP should take into account other mitigating factors: whether the parties' failure to meet all the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; the corrective action taken by the parties; whether the services provided were reasonable and medically necessary; whether access to a physician's services was required in an emergency situation; whether the Medicare program suffered any harm beyond the statutory disallowance. Mitigating factors should be considered whether the disclosure proceeded through an expedited process or a detailed review.

Compromise

CMS compromises should, as a practical and policy matter, reasonably reflect the harm, if any, to the Medicare program. One resolution would be the imposition of *stipulated damages* for categories of violations posing the least risk of harm to the program or its beneficiaries. In those instances, the amount could range up to \$10,000. For example, arrangements involving missing signatures, or where a course of dealing demonstrates that parties had agreed to an economically compliant, but un- or improperly documented arrangement would be eligible. Stipulated damages should be available regardless of whether the disclosure proceeded through an expedited or detailed review process. The compromise should be based on the facts and circumstances of the noncompliance. The outcome should not turn on the profile of the referring physician or the level of business he or she refers to the hospital. When CMS is made aware, through the self-disclosure process, of what it considers to be a more substantive violation, it should still consider the mitigating factors in determining the amount of the assessment, the form

of settlement agreement, and nature of releases.

Relation to Other Laws

The SRDP should address how a provider's disclosure under this process relates to actions by other agencies and how it relates to other laws. A disclosure under the SRDP should satisfy the obligation to report an overpayment created under the PPACA (Section 6402(a)). The timeframe for returning an overpayment should be suspended until the Secretary determines the amount, if any, of an overpayment subject to return. Payment of the compromised amount should be deemed payment in full for purposes of the overpayment refund obligation under Section 6402. If CMS believes that a disclosed matter warrants referral to the Department of Justice (DOJ) or another investigative agency, it should give notice to the provider as soon as that determination is made. A provider should be able to request participation of a representative of DOJ or another investigative agency in order to resolve potential liability under other laws.

Hospitals take seriously their obligations under the Medicare program and devote significant resources to compliance programs and activities. For all the reasons we've described, implementation of the self-referral law has made compliance a virtual impossibility. The SRDP, which the AHA supported throughout the legislative process, is a means to address the unintended consequences of the current rules and restore fairness. We urge the Secretary to act promptly in establishing the SRDP and to make full use of the authority newly granted by Congress to assure fair enforcement of the self-referral law.

We would greatly appreciate an opportunity to meet to discuss these issues in greater detail. If you have any questions, please feel free to contact me or Maureen Mudron, deputy general counsel, at mmudron@aha.org or (202) 626-2301.

Sincerely,

Rick Pollack
Executive Vice President

cc: Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services