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Health Headlines

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Secretary of DHHS Issues Report to Congress Regarding Details of the Agency's Implementation of Self-Referral Disclosure Protocol

The Centers – Implementation of the Self-Referral Disclosure Protocol (SRDP) and its status after the first several months of operation are described in a report submitted to Congress on March 23, 2012 by the Secretary of the Department of Health and Human Services (DHHS). Section 6409 of the Affordable Care Act directed the Secretary to establish the SRDP, authorized the agency to reduce amounts due and owing for actual or potential violations of the Stark law disclosed under the SRDP, and required the Secretary to submit a report to Congress on the implementation of the SRDP no later than 18 months after the date on which it was established. The report provides some additional insight as to the workings of this disclosure and settlement process, although the final publicized settlements remain sparse.

The SRDP was established on September 23, 2011, and the report covers the period from that date through early March 2012. The report indicates that during that period, a total of 150 disclosures were submitted to CMS, with most of those submitted during the year 2011. Hospitals accounted for 125 of these submissions, with the other disclosures filed by clinical labs, group practices, community mental health centers, DME suppliers, and one ambulance company.

The most common types of violations disclosed involve a failure to comply with various exceptions in the Stark law rules for compensation arrangements (42 C.F.R. § 411.357), including the exceptions for personal services arrangements, rental of office space, recruitment, and nonmonetary compensation. The report also indicates that many disclosures involved multiple parties (including hospitals and physicians) and multiple complex financial arrangements. CMS analyzes each arrangement separately to determine whether it is appropriate to reduce amounts due and owing for violations of the Stark law.

At the time of the report, six of the 150 filed disclosures had been settled; and in the short period since the report was finalized, one additional settlement has been posted on the CMS website. As broken out in the report, for most of the remaining disclosures (61), CMS is awaiting additional information from the disclosing party. Many (51) of the remaining disclosures are under CMS review; a significant number (20) were placed on "administrative hold" for various reasons (such as bankruptcy proceedings or ongoing law enforcement activities); some (9) had been withdrawn by the disclosing entity; and a few (3) were referred by CMS to law enforcement.

The six settlements finalized at the time of the report represent an aggregate settlement amount of $783,060, representing the reduced amount due and owing collected from the disclosing providers. The dollar amount associated with the published settlements, however, varies widely:

- Two low-dollar settlements (one for $6,700 and another for $4,500) involve disclosures that a hospital had exceeded the calendar year non-monetary compensation limit for one or two physicians;

- A hospital paid $22,000 to settle the disclosure of a violation of the personal services arrangements exception in connection with an arrangement with a locum tenens physician for hospitalist services (this March 2012 settlement is reported on the CMS website but not included in the report);
- A group practice that failed to satisfy certain requirements of the employment relationship exception for a number of employed physicians settled for $74,000;
- A critical access hospital that disclosed several violations of the personal services arrangements exception in relationships with hospital and emergency room physicians settled for $130,000; and
- A hospital that failed to meet the terms of the personal services arrangements exception for compensation relationships with hospital department chiefs, medical staff leadership, and other physicians for onsite overnight coverage of patients at the hospital paid $579,000. This is the most significant settlement to date.

The report and the summaries of the settlements do not indicate the total "tainted" Medicare billings involved for the period in issue, the extent to which that amount was reduced to arrive at the settlement figure, or the formula for arriving at the settlement amount. The general factors set out in the statute and the protocol to determine whether a reduction in the amount owed is appropriate include the nature and extent of the improper practice, the timeliness of the disclosure, cooperation in providing additional information to CMS relating to the disclosure, and other factors CMS deems appropriate. The report explains that after receiving notice of the agency's determination as to the appropriate settlement amount, a disclosing party that is in financial distress may discuss with CMS alternative arrangements to reach a financial resolution. Such alternatives may include a long-term payment plan or, in limited circumstances, a further reduction in the settlement amount based on an analysis by CMS of the disclosing party's ability to pay.

The high number of disclosures for which CMS is awaiting additional information from the disclosing party underscores the relative complexity of the disclosure process, particularly if multiple arrangements, multiple parties, and long periods of time are involved in the matters at issue. The report highlights the fact that many of the initial disclosure submissions did not provide all relevant information and documents required by CMS, thereby slowing the resolution process. The CMS protocol requires a legal analysis of which elements of a relevant exception the arrangement satisfied and did not satisfy, a financial analysis that includes the total amount of remuneration involved, the amount of the tainted Medicare billings, a description of estimates made to arrive at these figures and the audit activity conducted, as well as relevant documents (*e.g.,* contracts). Given these standards, disclosure submissions can run to hundreds of pages, as noted in the report.

CMS states that it has conducted and is continuing its education efforts in the industry regarding the SRDP, and that the quality of the submissions is improving. CMS characterizes the implementation of the SRDP as a success, and reinforces its commitment to improving the process.

The "Report to Congress: Implementation of the Medicare Self-Referral Disclosure Protocol" is available on the CMS website and is attached here.

CMS settlements under the SRDP are published on the CMS website.

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