

PUBLICATION

Comments Due for New Expedited Review Process for CMS's Voluntary Self-Referral Disclosure Protocol (SRDP) [Ober|Kaler]

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The creation of the SRDP through the Affordable Care Act as a mechanism to resolve potential Stark violations was welcomed by the industry. However, since enactment of the regulations implementing the SRDP in 2010, the volume of voluntary disclosures made to CMS has been significant and resolution of the voluntary disclosures has been slow. In fact, at the time CMS implemented the SRDP, CMS conservatively estimated that it would receive approximately 50 disclosures per year. CMS has now administered the SRDP for over three and a half years, and currently estimates that it will receive approximately 100 disclosures per year – an estimate that may also be conservative.

On May 2, 2014, in response to the dramatic increase in disclosures and growing burden on the agency to review and resolve matters disclosed through the SRDP, CMS published a [request for comments \[PDF\]](#) regarding its intent to revise the currently approved collection of information for the SRDP. 79 Fed. Reg. 25,133 (May 2, 2014). CMS also submitted a [Supporting Statement](#), which provides detail on CMS's proposals. More specifically, CMS proposes to create an optional expedited SRDP review process (Expedited SRDP Review Process) for disclosures that meet certain eligibility requirements. It also proposes to continue its already established SRDP review process (Standard SRDP Review Process). Lastly, CMS revised its burden estimates to complete the SRDP review process. Comments are due **June 2, 2014**.

For both review processes, CMS will continue to collect information describing the actual or potential violations(s), financial analysis for the amount due and owing, supporting documentation, and certifications from disclosing parties. The review processes differ in how disclosing parties under the SRDP will present collected information to CMS.

Standard SRDP Review Process

CMS suggests disclosing parties continue to use the Standard SRDP Review Process for disclosures presenting complex questions of fact or law, relating to ownership arrangements, and relating to certain compensation arrangements. Under the Standard SRDP Review Process, CMS will continue to require a complete, detailed description and explanation of the actual or potential violation(s).

Expedited SRDP Review Process

When disclosures have no indicia of fraud and involve common relationships (e.g., leasing and personal service arrangements), CMS suggests using the Expedited SRDP Review Process. The disclosing party can provide CMS with a more “streamlined” submission that would consist of certified factual statements and brief narrative summaries. CMS will admit a disclosure into the Expedited SRDP Review Process if the disclosure meets all of CMS's eligibility criteria for this review, which includes submission of all supporting documentation and the disclosing party's specific request for expedited review. CMS emphasizes that disclosing parties are not obligated to elect the expedited review.

Revised Estimates of Burden for Providers and Suppliers

CMS also revised and increased its estimated burdens for disclosing parties and for CMS in reviewing and resolving the disclosures. With respect to the burden on disclosing parties, CMS provided the following estimates:

- For a small entity with a few personal services arrangements:
 - Legal review estimates: Total of 15 hours to complete a disclosure
 - 10 hours of reviewing, identifying, and producing documentation
 - 5 hours to draft the disclosure
 - Financial review estimates to determine the potential overpayment amount: Total of 5 hours to complete
- For a larger entity with a larger number of complex arrangements:
 - Legal review estimates: Total of 65 hours to complete a disclosure
 - 50 hours to track the complex arrangements and produce documentation
 - 15 hours to analyze the documents and draft the disclosure
 - Financial review estimates to determine the potential overpayment amount: Total of 15 hours to complete

CMS's Supporting Statement also provides estimates of providers' costs in preparing a disclosure. CMS calculated this amount for legal review by determining the average cost of the disclosing party's legal counsel who are responsible for reviewing the contracts and/or arrangements prior to disclosure. CMS estimated the average cost for these personnel is \$92 per hour, based on 2012 Bureau of Labor Statistics, resulting in the following estimates of costs for a disclosing party's legal review:

- Legal review for smaller entities: \$1,380 (\$92/hour x 15 hours)
- Legal review for larger entities: \$5,980 (\$92/hour x 65 hours)

CMS calculated cost estimates for financial review by determining the average cost of the disclosing party's accounting personnel who are responsible for gathering, reviewing, and submitting the financial data. Estimating an average cost of \$63 per hour for these personnel based on 2012 Bureau of Labor Statistics, CMS calculated the following estimated costs for a disclosing party's financial review:

- Financial review for smaller entities: \$315 (\$63/hour x 5 hours)
- Financial review for larger entities: \$945 (\$63/hour x 15 hours)

In sum, CMS estimates a smaller entity's disclosure costs at \$1,695, while larger entities will pay an estimated \$6,925 making a disclosure.

Ober|Kaler's Comments

CMS's Supporting Statement offers providers an opportunity to reduce their expenses by taking advantage of the Expedited Review Process for less complex disclosures. However, CMS's burden estimates for providers may be understated. The comment process is a powerful tool whereby providers and suppliers can provide CMS with information on the costs and burden associated with the SRDP process. Providers and suppliers are urged to take advantage of this opportunity and provide their comments to CMS.

Those interested should submit their comments no later than **June 2, 2014**. Comments should be submitted by mail to OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: OIRA_submission@omb.eop.gov. Comments are available for review at: http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201405-0938-004.