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Tony Maida
Attorney at Law
tmaida@mwe.com
+1 212 547 5492

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Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
[Regulations.gov](https://www.regulations.gov)

Re: OMB Control Number CMS-2022-0102-0001

To Whom It May Concern:

This comment letter responds to CMS' request for comments on the documentation requirements of the Self-Referral Disclosure Protocol (SRDP). The healthcare bar and industry appreciate CMS' solicitation of comments on improving, and reducing the burden and cost associated with, the SRDP. The SRDP serves an important role in enabling entities to disclose Physician Self-Referral Law compliance issues, which can be commonplace given the very technical and complex regulatory framework and the law's strict liability nature.

The documentation requirements of the SRDP are burdensome in two main ways. First, the SRDP requires a "physician information form" for every physician and for each non-compliant arrangement. This is true even when the facts of the non-compliance are exactly the same and the same physicians are involved in each arrangement. It is tremendously time-consuming, tedious, and costly for organizations to pay their lawyers or staff to create these individual pdf forms that contain duplicative information. It seems likely that having all of these duplicative forms creates unnecessary burden on the part of CMS as well. The proposal discusses eliminating this individual form in the context of disclosing group practice non-compliance and instead having a single form covering all of the physicians in the practice. This would be a helpful step forward. This new form could also capture any of the nuances we sometimes see (physicians not needing to be disclosed before becoming a shareholder, different issues at different times for different members, whether it is a noncompliant ownership or financial relationship with a particular physician, etc.) in the group practice context. It would also be helpful for CMS to consider a new line to disclose information about the issue in the context of the group practice's DHS (e.g., a 6-year self-disclosure because of \$7,000 attributed incorrectly out of \$55 million in Medicare DHS revenue).

However, the questionable utility and unnecessary burden of the individual physician form requirement extends beyond group practice non-compliance to any ownership or compensation arrangement that involves multiple physicians. It would be more efficient and reduce significant burden and cost by developing a single form to permit disclosing the ownership or compensation relationship non-compliance regardless of the number of physicians involved in the arrangement. Such a per-arrangement form would enable the parties to clearly, and in one place, outline the facts of the arrangement and the physicians

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involved. This streamlined process would benefit both the provider community and CMS in reducing burden, duplicative work, and time and expense involved in using the SRDP. CMS could consider permitting parties to submit a spreadsheet identifying the physician(s) involved in the disclosure, with the key information currently requested by the physician information form. For example, similar to the financial analysis worksheet, it would be significantly less burdensome for parties to create a spreadsheet summarizing the information requested by the physician information form (e.g., physician name and NPI, physician organization information if applicable). Similarly, the spreadsheet could capture the nature of the noncompliant relationships with the physician, such as whether it is a compensation arrangement, an ownership or investment interest, and whether the relationship is direct or indirect.

The second requirement that merits revision is the format of the certification requirement. The protocol document requires a hard copy of the signed certification to be mailed to CMS, even though the submission is submitted electronically to the email 1877SRDP@cms.hhs.gov. The reason for disconnecting the certification form from the submission is not apparent and creates unnecessary burden to comply. Also, the need to submit a hard copy of a signed certification appears to require a “wet” signature from the client representative, rather than an electronic signature. Especially with the increase in remote work due to the pandemic, and the commonplace use of electronic documents and signatures (including by federal agencies on official documents), revising this requirement to permit submission of the certification electronically and with an electronic signature would significantly reduce burden without jeopardizing CMS’ ability to obtain a certification.

Please let me know if you have any questions about these comments.

Best,



Tony Maida

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