

**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515**

August 13, 2013

Ms. Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Administrator Tavenner:

As the lead author of the Self-Referral Disclosure Protocol (the “Protocol”) found in Section 6409 of the Affordable Care Act, and as Ranking Member of the Ways and Means Subcommittee on Health, I am concerned about the implementation of this provision. While I am pleased that CMS implemented this provision quickly, and met the required date under the statute for delivering its *Report to Congress*, I continue to have concerns about how long it is taking the agency to resolve disclosures. It is my understanding that while CMS has received nearly 300 submissions under the Protocol since it was published in September 2010, the agency has settled fewer than 30. Some submissions have taken nearly a year to process, creating enormous uncertainty for those who have submitted disclosures under the Protocol.

Clearly, CMS is overwhelmed by the number of disclosures it has received through the Protocol. Accordingly, the process that CMS is using to resolve disclosures must be modified. As you know, providers and suppliers often utilize the Protocol when a violation of the Self-Referral law is discovered during the course of due diligence. While I commend CMS for expediting its review of this subset of submissions, it is important to me that all providers and suppliers that avail themselves of the Protocol receive prompt dispensation of their submissions.

I recognize that CMS is underfunded and understaffed. In particular, sequestration has done a great deal of harm to the agency and its ability to fulfill its mission. Notwithstanding that fact, CMS should consider promptly modifying the Protocol so that disclosures can be settled more promptly. As CMS considers how to revise the Protocol, it is important to ensure that CMS

continues to have the latitude to administer the Protocol as the agency sees fit. Furthermore, I recognize that as we move to alternative payment models, the following statements are true: (a) fee for service will be with us for some time until new payment models have evolved on a widespread basis; and (b) many of the alternative payment models contemplated, including accountable care organizations, for example, are built squarely on the foundation of fee for service. As such, it is important to ensure CMS retains flexibility in addressing noncompliance with the Self-Referral law to combat newly emerging fraud schemes, as we are still operating in a fee for service environment. Accordingly, I do not seek to prescribe any particular way that CMS must handle disclosures under the Protocol. I do, however, provide the following recommendations, which may help alleviate the backlog and improve timely processing of submissions going forward:

1. Consider revising the Protocol to include guidance on time parameters to ensure providers and suppliers have some certainty when making submissions under the Protocol.
2. Consider modifying the internal deliberative process that is used to make determinations about the amounts due and owing to more easily resolve disputes. This may involve, for example, requiring information back from each of the CMS components involved in the administration of the Protocol more quickly so that there is less turnaround time in processing disclosures.
3. Consider making certain, limited information related to CMS's internal deliberative process public. This would be akin to the recent modification to the OIG's Self Disclosure Protocol ("SDP") whereby OIG modified its SDP to make certain information related to its calculation of damages available to the public. Such a modification to the Protocol would allow providers and suppliers to better understand whether the Protocol is the appropriate avenue for resolving a particular violation, or whether another avenue is more appropriate, including, without limitation, refunding the overpayment to the Medicare Administrative Contractor ("MAC"), or working with the local U.S. Attorney's Office ("USAO") to resolve the actual or potential violation of the Self-Referral law. Some subset of disclosures would then likely be siphoned either to the MAC or to the USAO, thus alleviating some of the backlog and/or reducing the number of disclosures received under the Protocol going forward.
4. Consider more readily transferring some number of cases that may be more serious and involve potential violations of the Anti-Kickback Statute to the Office of the Inspector General. Once such cases are identified, they should be rapidly dispensed with in this manner. Perhaps some front end modifications can be made to the Protocol to ensure agency staff can promptly identify the universe of submissions that should be more immediately transferred to OIG.

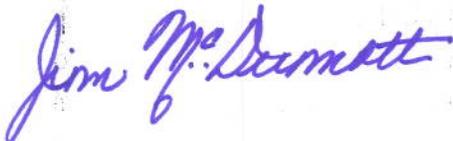
5. It is my understanding that providers and suppliers have done a better job with getting CMS the information it needs at the front end to allow CMS to make its determinations. This is in large part due to CMS's excellent education efforts in this regard. However, if the quality of the submissions is still problematic such that the agency continues to receive incomplete submissions and is spending time going back and forth with providers to obtain the information required under the Protocol, CMS may need to modify the Protocol to incent providers to supply an initial complete submission. This could be accomplished by moving providers and suppliers with repeat difficulties in submitting required information to the "back of the line." Or, the Protocol could be modified to state that a provider's obligation to report and return an overpayment under Section 6402 of the Affordable Care Act would no longer be tolled for incomplete submissions under the Protocol.

Again, I appreciate your efforts in faithfully administering the Protocol. However, it is important that providers and suppliers have some level of certainty that a submission made through the Protocol will be acted upon in a timely manner. It simply is not sustainable to continue as CMS is currently operating if there is a one year backlog in resolving submissions.

I will continue to monitor this situation to ensure that the backlog is remediated in a reasonable manner, and that CMS administers the Protocol in a manner that allows for some degree of certainty. I ask that you contact my staff no later than **October 15, 2013**, with a written, detailed plan for addressing the backlog of disclosures the agency has received under the Protocol, as well as your initial thoughts related to revising the Protocol to address submissions going forward.

Thank you in advance for your attention to this matter. Should you have any questions, please do not hesitate to contact Tiana Korley on my staff at (202) 225-3106 or [Tiana.Korley@mail.house.gov](mailto:Tiana.Korley@mail.house.gov).

Regards,



Jim McDermott  
Member of Congress

cc:

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