

Congress of the United States
Washington, DC 20515

September 21, 2015

Mr. Andy Slavitt
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
201 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201-0001

Dear Administrator Slavitt:

Please allow this letter to serve as our comments on the Physician Self-Referral Updates contained in the CY 2016 Physician Fee Schedule Proposed Rule ("Proposed Rule"), which was published in the *Federal Register* on July 15, 2015.

As authors of the *Stark Administrative Simplification Act* (H.R. 776), we are concerned about the disproportionate nature of the penalties providers face when disclosing technical violations of the Physician Self-Referral Law ("Stark Law") and the amount of time it takes for CMS to resolve a disclosure under the Self-Referral Disclosure Protocol ("SRDP"). These technical violations create very little or no risk of program or patient abuse. To correct these problems, our legislation creates a fixed penalty structure for "technical noncompliance," which is defined as an unwritten, unsigned or lapsed agreement that is otherwise compliant. Our bill creates an expedited process for resolution of these violations under the SRDP.

We appreciate that CMS has attempted to address the concerns set forth in our legislation. However, we believe the Proposed Rule, if finalized, will not cure the disproportionate nature of the penalties health care providers now face for technical violations of the Stark Law and will not cure the lack of predictability and certainty that occurs when resolving a technical violation that is disclosed through the SRDP. Therefore, we suggest the following revisions that we hope will be reflected in the Final Rule.

Writing Requirement

The Proposed Rule states that there is no requirement under the Stark Law that an agreement be documented in a single formal contract. Depending on the facts and circumstances, the Proposed Rule allows for a collection of documents, including contemporaneous documents showing the

parties' course of conduct, to satisfy the writing requirement of the leasing exceptions and other exceptions that require that an agreement be set out in writing.

The Proposed Rule goes on to replace several terms, such as: "agreement" with "arrangement," "contract" with "arrangement," "contracted for" with "covered by the arrangement," and "written contract" with "writing." While we applaud this attempt at clarification, we believe the Proposed Rule should go further and state that if an arrangement meets the state law requirements for an enforceable contract in the state where the contracting health care provider is located, then it satisfies the "set out in writing" requirement for the purposes of the Stark Law.

Many health care providers already rely on state law contract principles to determine what constitutes a valid and enforceable written agreement, and compliance with the Stark Law should be no exception. Additionally, because there is no federal contract law that would apply to arrangements that fall under the Stark Law, federal courts interpreting these arrangements are likely to turn to state law contract principles. This would be especially helpful since the Proposed Rule is silent on the signature requirement, which indicates that even though a collection of documents can be used to meet the writing requirement, the "collection of documents" would still have to be "signed by the parties."

Again, we applaud CMS for its attempt to reduce the burden on providers by clarifying that a collection of documents may satisfy the writing requirement contained in certain exceptions to the Stark Law. However, we believe the solution set forth in H.R. 776, which looks to state law contract principles, is a more practical approach that would give health care providers more reliable and consistent guidance on what constitutes a valid written arrangement under the Stark Law.

Holdover Arrangements

The Proposed Rule would also revise provisions in the Stark Law to permit indefinite holdovers under certain conditions or extend the holdover for a specific period of time provided additional safeguards are met. We approve of these revision and are very pleased CMS has recognized a lapsed contract or arrangement that is otherwise compliant does not pose a risk of program or patient abuse.

However, we believe that, in addition to a space lease, equipment lease, and a personal services contract, the indefinite holdover revision should also apply to an arrangement that is entered into pursuant to the fair market value exception because the logic of allowing an indefinite holdover for the first three arrangements also applies to the later.

As a final comment, we want to confirm that during a holdover period the parties would comply with the terms of the written agreement.

Temporary Noncompliance with Signature Requirements

The last provision in legislation that is addressed by the Proposed Rule is the Stark Law's signature requirement. In H.R. 776, we permit a health care provider to pay a fixed penalty for an otherwise compliant agreement that was not signed by one or more of the parties, regardless when the missing signature is discovered. We did so because an agreement that is a violation only because one or more of the parties failed to sign a written document causes no harm to the program no matter how much time has passed since the violation occurred.

In the Proposed Rule, CMS recognizes that it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures. While this recognition is admirable and long overdue, it fails to address those situations where the parties are *unaware* that an otherwise compliant agreement is missing one or more signatures. In that instance, much like an agreement that meets the Proposed Rule's criteria for an indefinite holdover, there is little risk of program or patient abuse.

While we understand that CMS wants to incentivize parties to exercise diligence with its rules and procure signatures in a reasonable amount of time, we believe this is another instance where state contract law principles would give health care providers more reliable and consistent guidance. As other commentators have said in the past, a legally enforceable agreement can exist under state law even in the absence of every required signature. We see no reason why the reasoning for this legal principle should not apply to those instances where an agreement violates the Stark Law only because the parties were unaware it was missing one or more signatures.

Stark Administrative Simplification Act

Despite the changes we have proposed above, we still believe the solutions found in H.R. 776 are a more appropriate way to ease some of the burden the Stark Law places health care providers. The bill would allow a health care provider to pay a fixed penalty when disclosing a technical violation, which is defined as an unwritten, unsigned or lapsed agreement that is otherwise compliant. CMS would have 90 days to determine whether the disclosure qualifies for the fixed penalty using criteria set forth in the legislation. If the agency fails to act within 90 days, the disclosure would be deemed to be accepted.

This fixed penalty structure and expedited resolution process would give health care providers more certainty and predictability regarding the outcome of a technical violation of the Stark Law than what is provided in the Proposed Rule. H.R. 776 would retroactively apply to any eligible

disclosure that is pending before CMS at the time the bill is signed into law, it would also help clear out the current backlog of over 400 disclosures, some of which have been waiting to be resolved for more than four years. While we believe the updates in the Proposed Rule are a good first step, they fall short of the congressional intent behind this important legislation.

Thank you for your consideration of these comments. We look forward to your responses to these comments when the Final Rule is issued.

Sincerely,



CHARLES W. BOUSTANY JR., M.D.
Member of Congress



RON KIND
Member of Congress