The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

August 23, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: Request for Information: Centers for Medicare & Medicaid Services, Physician Self-Referral Law

Dear Ms. Verma:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 240 member institutions, we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) regarding the physician self-referral law ("Stark Law").

During the past several years, HAP has actively encouraged Congress and CMS to revise the Stark Law to address the rapidly evolving health care environment. As CMS recognizes, the health care field is moving from a fee-for-service methodology toward new payment and delivery system models that emphasize value over volume. Public and private payors are holding hospitals accountable for reducing costs and improving quality in ways that can be accomplished only through teamwork with physicians and other health care professionals within and across sites of care, including the alignment of financial incentives. The Stark Law—which was designed to address overutilization in a fee-for-service environment—is antiquated and must be modernized.

Below, this response will: 1) endorse the comments of the American Hospital Association (AHA); 2) provide general feedback about the Stark Law from HAP members who must navigate the complex and burdensome law as they attempt to implement innovative payment arrangements; and 3) provide Pennsylvania-specific comments relating to aspects of the RFI.

1) Response of the American Hospital Association

HAP fully endorses, and incorporates by reference, the RFI response submitted by the American Hospital Association (AHA). In its comprehensive response, the AHA recommends, among other things, that CMS create a new innovative payment exception for value-based payment arrangements and remove regulatory obstacles to care coordination by providing clear, unambiguous definitions of critical requirements.

As noted by the AHA, the Stark Law makes it nearly impossible for hospitals to design flexible payment terms to promote coordinated care. In order for innovative payment arrangements involving new relationships with physicians to succeed, hospitals and health systems need the

ability to make significant investments in care coordination without running afoul of the Stark Law. Current Stark exceptions do not cover many of the innovations hospitals seek to implement and the waivers of Stark for certain programs or projects are too limited to enable hospitals to make broad-scale changes.

It is worth noting that many HAP members believe that recommendations to address problems with the Stark Law by creating a broad exception or addressing regulatory obstacles may actually be too timid, and that the proper course is to eliminate the law and replace it with an approach that reflects current realities. It is recognized, however, that this approach may only serve to delay much needed regulatory relief.

In making changes to the Stark Law, however, Congress and CMS must be mindful of the unintended consequence of the potential loss of consumer protections embedded in the law. It is important that future changes to the law do not negatively impact program spending or beneficiary care.

2) Comments From the Field

As part of its advocacy efforts, HAP has solicited feedback relating to the Stark Law from Chief Counsel and Compliance Officers employed by member hospitals. Below are comments from the field that HAP recently solicited from members. These comments provide insight into the frustration of the Pennsylvania hospital community with the current state of the Stark Law.

- Recent changes to the Stark Law are “just chipping away” at pieces of the law, and are “not tackling the big issues that would really make significant improvements in today’s environment.”

- My hospital does “all kinds of cartwheels” to fit current arrangements into the Stark Exceptions, and this work is “very time consuming and administratively difficult.”

- Currently, if you “do everything right—ninety nine fully compliant things—but the government can find one potentially bad intention and prove it, you are in trouble.”

- “Unfortunately the [Stark Laws] are so complex that they can be very difficult even for an experienced health attorney to understand and apply. There are many technical requirements that make it almost inevitable that unintentional violations will be made, with potentially serious financial consequences.”

- “The regulations seem to have strayed very far from the original concern about physicians being motivated by ownership/profit to over-utilize certain types of items or services.”

- Our hospital "has formed an ACO, and fortunately for purposes of the Medicare Shared Savings Program, certain waivers permit certain types of incentives to be paid to physicians for achieving quality and performance measures. However, it is not clear that Stark Law exceptions exist that would allow similar incentives to be paid under our contracts with commercial payors."

- "We have formed risk pools and seek to distribute any cost-savings in comparison to budget to ACO participating providers on a pro rata basis based upon attributed lives, subject to satisfactorily meeting certain quality measures. Unfortunately, the Stark Law leaves us somewhat uncertain as to whether such distributions would fall within the Stark Law exception for Risk Sharing Arrangements."

3) Pennsylvania-specific Comments

During 2016, the U.S. Senate Finance Committee and U.S. House Ways and Means Committee held hearings and solicited feedback from stakeholders regarding possible reforms to the Stark Law. In response to this request for feedback, HAP worked with member hospitals and its legal counsel to prepare the attached concept paper. This concept paper includes a number of technical recommendations that are consistent with the AHA's proposal to remove regulatory obstacles to care coordination. More fundamentally, however, the paper proposes the creation of a broad exception to the Stark Law to permit the implementation of alternative payment models. HAP hopes that the recommendations included in the paper are helpful to CMS as it evaluates changes to the Stark Law.

In addition to the information included above and outlined in the attached concept paper, HAP offers the following additional feedback:

- ***Provider Reporting***—HAP members have encountered Stark limitations in value-based program design, particularly as it relates to referral-based agreements and helping to empower providers to be successful in their value-based reimbursement relationships. As an example, payors want to provide reporting to primary care practitioners (PCP) to indicate the most efficient specialists in a network from a cost perspective. However, this reporting could be interpreted as paying for referrals, particularly if the PCP and specialists are employed by the same system. From a policy perspective, this reporting should not be prohibited, as value-based reimbursement inherently incents physicians to eliminate unnecessary or inefficient delivery of services, rather than drive over-utilization for economic gain.

- ***Quality Metrics***—HAP members also have encountered Stark limitations relating to quality metrics. Specifically, payors would like to begin offering incentives to follow a standard hospital care pathway that includes ordering specific services or tests from a specific location. While these provider incentives are in a patient's best interests, such metrics may conceivably violate the Stark Law.

Thank you for your focus about improving value for patients and providers and for your consideration of our comments. If you have any questions relating to this response, please contact me at (717) 561-5325 or Laura Stevens-Kent, HAP's vice president, federal legislative advocacy at (202) 863-9287.

Sincerely,

Jeffrey W. Bechtel, JD
Senior Vice President, Health Economics and Policy
The Hospital and Healthsystem Association of Pennsylvania