WISCONSIN HOSPITAL ASSOCIATION

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December 30, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Service
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS–1720–P Proposed Rule—Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

On behalf of our more than 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Stark Law reforms to enable value-based arrangements and reduce other regulatory burdens.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid- and large-sized academic medical centers. We have hospitals in every part of the state – from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

Background

WHA appreciates the amount of attention CMS has been devoting to this very important issue. We have been actively advocating on Stark Law reform with both CMS and Congress for years. We are pleased to see that CMS agrees this is an issue that needs attention, and recognizes that these reforms could offer tremendous benefits to hospitals and the patients they serve by improving the quality of health care under Medicare.

WHA provided comments on CMS's 2018 request for information on Stark Law reform, and is again pleased to see that CMS took the comments it received under careful consideration when drafting this rule. In WHA's response to the RFI, we recommended CMS look at four key areas:

1. Clarifying confusing definitions.
2. Providing clearer exceptions from the law.
3. Prioritizing intentional, rather than unintentional violations.
4. Harmonizing the Stark Law with the Antikickback Statute (AKS).

We commend CMS for making significant strides under this proposed rule in three of those four areas: Clarifying confusing definitions, providing clearer exceptions, and syncing Stark Law with the AKS. While we understand CMS is constrained, to a large degree, by the existing federal statute on the issue of unintentional

violations, we nevertheless encourage CMS to do what might be in their power to make the Stark Law less heavy-handed or imposing against unintentional violations.

The Importance of Rewarding Value

Wisconsin has a national reputation as one of the best states in the country for health care. The federal Agency for Healthcare Research and Quality consistently ranks Wisconsin among the top states for health care quality. The Health Resources and Services Administration (HRSA) also ranks Wisconsin's Critical Access Hospitals among the top in the country. One might expect that the federal government would reward those it considers to provide high quality health care with higher Medicare reimbursements. Unfortunately, that is largely not the case. Wisconsin not only spends less per Medicare beneficiary than most states (it is in the bottom third of the 50 states according to the most recent data (2014) provided by the Kaiser Family Foundation), but it also receives well below the national average in its overall Medicare reimbursement. While Medicare reimburses hospitals at about 87% of their costs nationally, Wisconsin hospitals receive only about 75% of their costs under Medicare.

This is largely due to Medicare's antiquated fee-for-service payment model that pays providers based on the volume of services provided rather than the overall value of the care they provide. Alternative payment models that reward providers for high-value care are therefore one way for the federal government to begin rewarding states like Wisconsin that rank high, while also incentivizing other states to make gains as well. Unfortunately, violating the Stark Law is a high-risk gamble that providers take when they create alternative payment arrangements, and this has a chilling effect on the number of participants willing to explore such arrangements.

The Importance of Reducing Unnecessary and Burdensome Regulations

According to the American Hospital Association (AHA), an average size hospital already dedicates 59 full-time-equivalent positions to regulatory compliance, with over one-quarter of those individuals being physicians and nurses. Time spent on red tape and regulatory compliance results in less time with patients, frustration by providers, and burnout. The AHA estimates the annual cost of hospital regulatory compliance to equate to $1,200 per hospital admission.

Much of this burden is falling on practitioners by diverting their attention from direct patient care to other areas, such as record keeping. A 2017 study published in the Annals of Family Medicine noted that primary care physicians spend more than one-half of their workday, nearly six hours, interacting with EHR. The Stark Law likewise diverts resources away from patient-care and toward other areas, in this case, attorneys and compliance officers who must dig deep into the federal code to navigate the complex maze that is the Stark Law. WHA has heard from members who have missed out on hiring needed physicians due to delays in finalizing a contract that stem from confusion over the Stark Law. While this is a separate issue from value-based payments, it nevertheless is important for CMS to recognize and address.

Clarifying Confusing Definitions

We greatly appreciate CMS's recognition that current definitions are in need of clarification and **urge CMS to finalize its proposed updates to commercial reasonableness, fair market value, and the volume or value of referrals**. Specifically, we agree that arrangements need not generate a profit to be commercially reasonable and of value for the involved entities. We encourage CMS to strengthen this section by adding to the definition that commercial reasonableness is unrelated to the profitability of the arrangement. We also recommend clarifying that for the volume/value prohibition, compensation for personal productivity is permissible under the personal services, fair market value compensation and indirect compensation arrangements exceptions.

We also urge CMS to finalize its proposals reducing Stark Law liability for writing mistakes. Particularly, the "limited remuneration to a physician" exception for annual payments under $3,500 will help hospitals avoid liability for non-abusive conduct. Likewise, permitting writings to be executed within 90 days of when an arrangement begins will save hospitals and CMS resources that would otherwise be spent resolving self-disclosures for lapses that do not pose risks to Medicare program.

New Value-Based Exceptions

WHA commends CMS for deciding to fundamentally alter the framework for how value is perceived and exceptions are granted under the proposed rule. This is a significant positive development that we believe will help increase participation in more value-based payment arrangements and help move the needle in improving high-quality, high-value health care. We also believe that creating different types of arrangements that qualify for exceptions will encourage innovation and testing of new, varied payment models that will allow entities to see what works best for their unique patient population and provider structure. We appreciate that in addition to clarifying the definitions of fair market value, commercial reasonableness, and volume or value of referrals for prior exceptions, CMS is proposing to create entirely new exceptions that are free of that past framework.

We also support CMS's proposal to define value-based purposes as those which fall under four premises: coordinating care or managing a patient population, improving quality, reducing costs, and transitioning to payment and service based on quality and restraining costs. As part of this, we encourage CMS to ensure that cost reductions for providers participating a value-based arrangement should be included as one of the applicable cost reductions; it should not only be limited to cost reductions for payers.

Regarding arrangements that require entities to take on full or meaningful financial risk, we believe CMS should consider additional flexibility. First of all, we recommend the risk only be required to apply to the items and services to which the remuneration relates, rather than to all services. Additionally, for the meaningful financial risk exception, we recommend CMS lower the 25% threshold to a lower level. It is important to remember that the current level of participation in value-based arrangements is very low. In fact, a 2018 Moody's Investors Service analysis on not-for-profit hospitals found that less than 3% of net patient revenue came from capitation and risk-based contracting in 2017, a number that has stayed relatively consistent since 2013. WHA's Public Policy Council discussed this issue during its most recent meeting and concluded that it would be fairly intimidating to go from taking on no risk to taking on 25%. If CMS really wants this exception to move the needle, it should consider a lower threshold, perhaps 10%.

Due to the reason previously mentioned, WHA's Public Policy Council also surmised that the **value-based arrangements which require no financial risk are likely to be the ones most utilized by providers looking to venture into value-based payment models. We believe CMS should ensure that option is a viable option going forward, and not adopt any of the alternative proposals that could reduce their utility, such as limiting the exception to only nonmonetary remuneration, requiring cost-sharing, or requiring ambiguous performance or quality standards.** After all, the value in this type of exception is the new lens from which CMS is seeing this issue; in other words believing that it is inherently beneficial for the Medicare program to base payment arrangements on the quality and value of care provided. While it may be a bold leap for CMS, it is a necessary one to get rid of the current barriers in Stark Law which block more widespread adoption of meaningful value-based payment reforms.

Harmonizing the Stark Law with the Antikickback Statute

We appreciate the Department of Health and Human Services taking the initiative to coordinate attempts to align the Stark Law governed by CMS with the Antikickback Statute governed by the Office of Inspector General (OIG). One area it is not clear that is aligned is the new proposal under the proposed AKS rule to allow

patient engagement tools with a value of up to $500 per-patient per-year for value-based arrangements. We believe this is an area CMS should give further consideration.

WHA's members are increasingly looking to how telehealth can help improve the quality, ease, and value of care provided. In fact, Wisconsin recently passed legislation spurred by WHA to greatly improve how Medicaid covers telehealth services. WHA is looking to make similar gains in how Medicare views telehealth, but is concerned that the Stark Law and AKS may create barriers for certain telehealth services where hospitals furnish remote patient technology to patients. For instance, under Medicare, providers would not be able to give people with disabilities or neurologic conditions free remote technology for home medical monitoring and telehealth visits, despite these technologies having the potential to improve quality and convenience for the patient while reducing costs for the Medicare program. Likewise, smart pillboxes that let a care team know when a dose is missed would not be permissible to give to a patient free of charge.

This issue is not only limited to telehealth. It could also extend to testing value-based arrangements where patients could be given free or reduced-cost healthy meals or vouchers for groceries, reduced-cost medicines, or other non-telehealth devices to allow patients to self-monitor. While the AKS proposal to allow a safe-harbor of up to $500 per-patient per-year is a step in the right direction, we urge CMS to explore how to incorporate similar flexibility as it might apply to the Stark Law. There is no reason that regulations should be a barrier to allowing technology to improve care and reduce costs in the Medicare program.

In conclusion WHA greatly supports CMS's efforts to reduce the burden of the Stark Law under this proposed rule. We believe CMS is taking many positive steps here that will help encourage more widespread adoption of value-based payment models, something more providers Wisconsin would like to participate in if not for the risks that violations pose. WHA appreciates the opportunity to provide comment on this proposed rule and looks forward to working with CMS to continue advancing these shared goals.

Sincerely,

Eric Borgerding
President & CEO