December 20, 2019

By electronic submission via www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Washington, DC 20201
Attn: CMS-1720-NC

Re: Notice of Proposed Rulemaking for Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P)

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) thanks the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the October 17, 2019 Notice of Proposed Rulemaking (NPRM) regarding the Physician Self-Referral (Stark) regulations. HLC applauds CMS for proposing numerous changes to the Stark regulations that "address any undue impact and burden"[1] in order to "support the transition to value-based care and the coordination of care among providers in both the federal and commercial sectors."[2]

HLC is a coalition of chief executives from all disciplines within American healthcare and the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans. With the move toward a healthcare system based on providing better value, HLC has convened a broad group of organizations beyond its membership that recognize the transformational effect of this shift on the existing legal framework governing U.S. healthcare. In order to better coordinate and deliver patient care, the legal framework must allow appropriate patient-serving care delivery and payment models involving broader collaboration among stakeholders in order to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth. The Physician Self-Referral (Stark) Law and Federal Anti-Kickback Statute Workgroup of HLC (the "Workgroup") includes a wide array of hospital, patient/consumer, physician, health insurance, medical device, pharmaceutical, information technology vendor, and supplier organizations.

As the October 2019 NPRM details, the Stark Law was enacted in 1989 under traditional fee-for-service Medicare when the "vast majority of covered services were paid based on volume."[3] This payment model provided little incentive for providers or patients to improve health or care delivery or focus on outcomes and instead incentivized providers to order more services and increase reimbursements. The Stark Law was a necessary tool in this payment environment to "combat the potential that financial self-interest would affect a physician's medical decision

making . . . and prevent a patient from being referred for services that are not needed or steered to less convenient, lower quality, or more expensive health care providers because the patient's physician could improve his or her financial standing through those referrals."[4] As our healthcare system undergoes a sweeping transformation away from a volume-based reimbursement model into a value-based environment that incentivizes care coordination, care continuity, provider efficiency, and patient-centered care delivery, there is an associated need to revisit the Stark Law to ensure that it appropriately reflects current and emerging healthcare delivery and reimbursement models while still preventing fraud and abuse. Aligning the fraud and abuse framework with the modern healthcare system is critical to ensuring that the system functions as efficiently and effectively as possible and supports stakeholder innovation and investment in systemwide improvement. HLC appreciates CMS and HHS' shared commitment to these goals and willingness to make significant modifications to the Stark regulations to better reflect the changing healthcare payment and delivery environment.

HLC also appreciates CMS and HHS' commitment to eliminating obstacles to care coordination and accelerating the transition to a value-based system through the Regulatory Sprint to Coordinated Care ("Regulatory Sprint").[5] In conjunction with the Regulatory Sprint, the Requests for Information (RFIs) issued by the HHS Office of the Inspector General (OIG)[6] and CMS[7] in 2018 demonstrated a welcome and significant commitment not only to align the fraud and abuse legal framework with new care delivery and payment models, but to consider practical implications of the current framework from the perspective of multiple health industry stakeholders.

We have organized our comments below in two parts. The first part highlights the proposals that we believe are most supportive of the transition to a value-based healthcare system as they are currently drafted, provides comment in response to several questions CMS posed in the NPRM, and offers general recommendations for possible modifications to related proposals where relevant. The second part highlights key areas that remain unaddressed by this NPRM for consideration in making future and further changes to the Federal fraud and abuse framework.

PART 1: PROPOSAL HIGHLIGHTS AND CLARIFICATIONS

The most significant modifications proposed in this and the OIG NPRMs are those adding exceptions and safe harbors that protect value-based care and payment arrangements. While we discuss the specific and proposed provisions of these exceptions below, their overall significance to healthcare transformation cannot be understated. The need for these exceptions to be clear, comprehensive, and inclusive is critical if they are to have their desired impact of improving care coordination, quality, and patient outcomes while reducing costs. We recognize and support the effort that went in to crafting these new exceptions and believe that what has been proposed is an excellent start. However, as written, we believe the exceptions are too narrow to enable the healthcare transformation goals described in the NPRMs. Our primary concern is that the exceptions will exclude several key stakeholders from protection, thus hampering the ability of the covered stakeholders to provide meaningful value-based care. We detail these concerns below as they apply to specific proposed provisions, but wish to emphasize here our support for a more entity-agnostic approach that allows an array of stakeholders to participate in value-based arrangements. Such an approach would allow necessary flexibility for healthcare delivery and payment entities to create and implement innovative value-based arrangements while still maintaining existing protections against inappropriate financial relationships inherent to the Stark Law.

Modifying Exceptions

We offer our enthusiastic support for the proposals modifying the electronic health record (EHR) donation exception (411.357(w)), including:

- Eliminating the exception's sunsetting provision and making the exception permanent;
- Clarifying that the exception is available to protect the donation of software and services related to cybersecurity; and
- Creating a new exception protecting the donation of cybersecurity technology and related services (411.257(bb)).

In addition, we offer our enthusiastic support for the following additional proposed modifications to the EHR exception:

- Eliminating the 15% contribution requirement in the EHR exception for all physician recipients;[8]
- Deleting the condition that prohibits the donation of equivalent items or services to allow donations of replacement EHR technology;[9] and
- Adding protection for donation of a broad range of cybersecurity technology, including hardware, provided certain conditions are met.[10]

We also support the alignment of these provisions to the parallel anti-kickback statute provisions proposed by the OIG.

New Exceptions

We offer our general support for exceptions that protect:

- Value-based arrangements that require the assumption of risk (411.357(aa)(1), (2));
- Value-based arrangements that are risk agnostic (411.357(aa)(3)); and
- Indirect compensation arrangements that qualify for value-based arrangement protections (411.354(c)(4)).

We believe there is a significant need for exceptions that protect activities and initiatives that involve the integration of care, items, services, and payment across stakeholders, including those participating in a Medicare-approved value-based payment program and those that are not. We appreciate CMS's recognition of the need for exceptions that protect a variety of such arrangements. We particularly appreciate and support CMS' intention that the proposed exceptions apply to the compensation arrangements between parties in a CMS-sponsored model, program, or other initiative and thus would eliminate the need for any new waivers connected to CMS-sponsored models.[11]

As a general matter, we believe that many of the definitions and frameworks proposed in the NPRM are too complex and depend on vague metrics that will be challenging for entities to navigate as they assess compliance. We are thus concerned that many entities will be unwilling to utilize the proposed exceptions for value-based arrangements. Given CMS' stated goal that changes to the Stark regulations will unlock innovation and enable HHS to realize its goal of transforming the healthcare system into one that pays for value,[12] we believe that some of the proposals in the NPRM should be further modified to assure that this goal can be achieved. We have highlighted some specific areas of concern below.

Allocating risk in value-based arrangements (411.357(aa)(1), (2))
We are concerned that a focus on full and meaningful financial risk may make these exceptions unworkable for all but the largest health systems, which in turn may drive further market consolidation and increased costs for the healthcare system. While we support the creation of exceptions protecting risk-based financial arrangements, we believe that lower thresholds of financial risk will make participation in value-based enterprises easier and thus ensure that these exceptions encourage improved coordination rather than provider consolidation.

We are concerned that the differing standards for assuming a threshold of downside risk – whether "substantial" or "meaningful" – will be confusing and pose a potential barrier to greater participation in value-based arrangements.

Irrespective of further modifications to the full and meaningful risk exceptions, we urge CMS to allow for a 1-year implementation period for these new exceptions at minimum rather than the 6-month period as proposed. Stakeholders already participating in value-based care arrangements will need sufficient time to modify those arrangements to fit within one of the proposed exceptions, while others will require more time to develop arrangements that meet the requirements of the proposed exceptions. Given the complexity of the requirements for these exceptions, it is imperative that stakeholders have sufficient time and resources to identify and implement arrangements that are beneficial to the patients they serve. Providing at least one year before the exceptions are implemented will give stakeholders more time to prepare and establish arrangements that can achieve the goals of value-based care in a meaningful way.

New or Modified Definitions and Terminology

Value-based enterprise (VBE) participants
As discussed above, we strongly believe that these definitions should be entity-agnostic and provide equal protection to all entities willing to bear risk for value-based arrangements within the context of the Stark law. We would urge CMS to allow for flexibility on who can be a VBE participant in order to ensure that non-traditional healthcare entities are eligible as appropriate under Stark. Further innovation in the design, structure, and implementation of value-based arrangements must include an array of healthcare stakeholders to support sponsor and plan learning and to determine the range of potential benefits to diverse health systems and beneficiaries. For example, the inclusion of pharmacy benefit managers (PBMs) in these arrangements could help promote value-based care, as PBMs support all of the value-based purposes laid out by CMS.

Value-based purpose
We seek clarification on how quality would be measured and applied and whether reductions in certain types of services might be considered reductions in quality. For example, would measures such as reducing admissions be seen as reducing quality? We appreciate the acknowledgement that there are challenges with measuring whether a value-based purpose is achieving one of the four identified core goals and that the definitions lack the precision often sought in the Stark Law regulations. However, we note that little guidance is provided on how the assessment should be made or how CMS would determine if an arrangement is reasonably considered to achieve one of these goals. We strongly encourage CMS to provide more clarity with respect to this definition and its application.

Value-based activity
We note that the proposed definition does not include referrals. We question whether there may be a need for some flexibility for referrals in limited instances, such as for Accountable Care Organizations (ACOs).

Target patient population
We believe that the current definition in the NPRM should allow greater flexibility for changes in the target patient population over time. For example, the current definition does not appear to allow for expanding the patient population over the course of the value-based arrangement.

We also believe that limiting this definition to patients with chronic conditions and/or shared disease states is unnecessary and may hinder innovation in healthcare delivery. We suggest that CMS maintain flexibility to allow providers to develop value-based arrangements that are in the best interest of the patient based on provider's clinical expertise. Furthermore, we recommend that CMS not limit these arrangements to specific disease states, but instead permit the greatest degree of flexibility when identifying targeted populations. Health and wellness are predicated on much more than just clinical circumstances surrounding a person's care; allowing for a wide variety of target populations types could help address the many factors that influence a person's health and a community's overall well-being. We note that there are several other safeguards proposed in this NPRM that will help ensure providers utilize this flexibility to support arrangements that are high-value and beneficial to beneficiaries.

Commercial reasonableness
We appreciate that this term is defined to differentiate it from fair market value. The NPRM includes two definitions of commercial reasonableness, and we would strongly recommend that CMS finalize the definition by requiring that the arrangement meet either one of the two. However, we believe that both proposed definitions are vague and as such would likely lead to greater confusion. We recommend providing further clarity in the given definitions.

Fair market value (FMV)
We applaud CMS for eliminating the connection between fair market value and the volume or value standard. While we appreciate further clarity differentiating general market value and fair market value, we are concerned that these revised definitions may still be confusing and require additional guidance, including information about how to document and establish FMV in a value-based context.

Alignment with Anti-Kickback Statute

We also recognize and appreciate CMS' efforts to align the proposed Stark Law regulation changes with the OIG's contemporaneous modifications to the anti-kickback statute regulations. However, we are concerned that the proposals are not sufficiently aligned. We believe that the differing standards that can be applied under each proposal would, if finalized, continue to pose a barrier to value-based care and care transformation. For example, both regulations utilize different metrics for determining downside financial risk and may require different conditions or standards for the corresponding exceptions and safe harbors. For example, the proposed exception for value-based arrangements would protect both in-kind and monetary remuneration, while the OIG's safe harbor for care coordination would only protect in-kind remuneration. We encourage CMS to maintain its broader proposed exception in this instance, but also offer it as an illustrative example of the differing standards for the same conduct proposed in both NPRMs.

We believe that the proposals would continue a dual regulatory environment where, for

example, an arrangement could meet the requirements of the Stark Law but violate the anti-kickback statute. While not all arrangements will implicate both the Stark Law and anti-kickback statute, there will be some arrangements that require compliance with both. Lack of consistency will make it even more challenging for entities to navigate this already complex regulatory framework as they design value-based arrangements. We strongly urge HHS to continue seeking opportunities to align the proposed changes to the federal fraud and abuse framework so that value-based entities do not face two regulatory constructs with different standards for compliance.

PART 2: OUTSTANDING ISSUES

We would strongly encourage CMS to consider using this rulemaking opportunity to address a number of other issues and items, including:

- Consider expanding the scope of covered technology within the EHR exception even further, to include:
    - Technology related to information sharing including mobile applications, clearinghouse services, and other solutions enabling the sharing of healthcare information among patients, providers, and payers;
    - Cloud-based items and services, practice management and revenue cycle systems and services, EHR storage, and subscription fees related to the use and exchange of health information; and
    - Industry-supported data collection, analytics, and other related technology services
- A plan for or recognition of the need to issue more sub-regulatory guidance, such as is in the form of FAQs, examples of allowable practices protected by the exceptions, and other clarifying information on how the exceptions apply. Issues for which sub-regulatory guidance would be most useful include how to apply the volume or value of referrals standard across exceptions (existing and proposed) and how to establish and document fair market value.

Thank you in advance for your consideration of the above proposals. Please contact Tina Grande at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

Mary R. Grealy
President

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[1] U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations ("NPRM"), 84 Fed. Reg. 55766, 55771 (October 17, 2019).
[2] NPRM at 55767 (2019).
[3] NPRM at 55768 (2019).
[4] NPRM at 55768 (2019).
[5] *See, e.g.*, NPRM at 55768 (2019); CMS RFI at 29524 (2018).

[6] U.S. Department of Health and Human Services Office of Inspector General. Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP ("OIG RFI"), 83 Fed. Reg. 43607 (August 27, 2018).
[7] U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services. Medicare Program; Request for Information Regarding the Physician Self-Referral Law (CMS "RFI"), 83 Fed. Reg. 29524 (June 25, 2018).
[8] NPRM at 55825 (2019).
[9] NPRM at 55826 (2019).
[10] NPRM at 55834-55835 (2019).
[11] NPRM at 55778 (2019).
[12] NPRM at 55772 (2019).