December 31, 2019

*Submitted Electronically Via Federal Rulemaking Portal: www.regulations.gov*

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

**Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations [CMS-1720-P]**

To Whom It May Concern:

The U.S. Chamber of Commerce (the "Chamber") submits these comments in response to the recently published proposed rule regarding revisions to the physician self-referral regulations (the "Proposed Rule").[1]

The Chamber applauds efforts by the U.S. Department of Health and Human Services ("HHS") Centers for Medicare & Medicaid Services ("CMS") to reduce regulatory burdens that can inhibit innovative arrangements to promote value-based care. We believe these proposed changes are a vital step in advancing the transition to value-based care and the coordination of care.

Furthermore, the Chamber supports the alignment between CMS and the HHS Office of Inspector General ("OIG") in proposing changes to regulations implementing the physician self-referral law (the "Stark Law") and the Anti-Kickback Statute. Consistency among the Stark Law exceptions and the Anti-Kickback Statute safe harbors will significantly reduce the regulatory burden for members of the health care industry. The Chamber encourages CMS and OIG to continue to look for ways to more closely align the Stark Law and Anti-Kickback Statute regulatory frameworks.

The Chamber strongly supports the establishment of Stark Law exceptions and Anti-Kickback Statute safe harbors that allow health care entities to work together to improve patient outcomes. Value-based arrangements developed under these new safe harbors have the potential to improve the quality and affordability of patient care across specialties, geographic areas, and disease types. Further, the Chamber appreciates CMS's efforts to impose safeguards to prevent these exceptions from limiting medically necessary care.

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[1] 84 Fed. Reg. 55,766 (Oct. 17, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22028.pdf.

In these comments, the Chamber urges CMS to continue to streamline and modernize the Stark Law regulations such that health care providers and payors, among others, can focus on delivering high-quality patient care in an efficient manner. Our comments provide support for aspects of the Proposed Rule that reduce unnecessary complexity and provide suggestions for how CMS can further refine its proposals.

## PROPOSED VALUE-BASED DEFINITIONS

### Quality and Cost Measures for "Value-Based Purpose"

The Proposed Rule sets forth a definition of "value-based purpose" that would include: "coordinating and managing the care of a target patient population; [ ] improving the quality of care for a target population; [ ] appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or [ ] transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population."[2] CMS seeks comment on whether, and how, to define these terms and whether the agency should adopt specific measures and methodologies "to determine whether quality of care has improved, [ ] whether costs are reduced or expenditure growth has stopped or what parties must do to show they are transitioning from health care delivery and payment mechanisms based on the volume or value of items and services provided to mechanisms based on the quality and costs of care."[3] To ensure that parties to a value-based arrangements have sufficient flexibility to design and implement innovative value-based arrangements, we request that CMS adopt an approach that gives parties to a value-based enterprise ("VBE") the discretion to determine quality and cost measures that are appropriately tailored the enterprise and its participants. Additionally, to the extent that CMS includes cost reduction as a permissible value-based purpose, we would encourage CMS to adopt sufficient safeguards to ensure that any cost-cutting measures do not reduce or limit medically necessary care.

As CMS acknowledges in the Proposed Rule, members of the health care industry are working to develop a variety of alternative payment initiatives that move toward value-based care.[4] These initiatives differ in a number of ways, including patient populations and providers, health technologies and data capabilities, and included items and services. Predetermined or narrowly defined quality measurements may not provide sufficient flexibility to protect innovation in this rapidly changing environment.

Similarly, to determine whether costs are reduced or expenditure growth has been stopped, the VBE should be permitted to analyze relevant cost data in a manner that aligns with participants' existing systems and processes, as well as the nature of the specific payment model, to determine savings. VBE participants should have the flexibility to determine among themselves the most appropriate way to measure savings for their specific value-based arrangements. Imposing prescriptive requirements as to how VBEs would be required to determine cost savings would introduce unnecessary complexity to this regulatory framework and increase compliance burdens.

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[2] *Id.* at 55,773.

[3] *Id.* at 55,775.

[4] *Id.* at 55,776.

Further, participants who have entered into a VBE to transition "from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population" should have flexibility in how they demonstrate this purpose to CMS. We agree with the agency's view that this category should include the integration of VBE participants in team-based coordinated care models, establishing infrastructure to provide patient-centered coordinated care, and accepting increased levels of financial risk from payors or other participants in value-based payment arrangements.[5] We do not believe that this category needs more precise boundaries. Rather, allowing participants to decide amongst themselves how to best demonstrate this goal is in line with the agency's objectives of promoting innovation and reducing regulatory obstacles.

Excluding Certain Entities from the Definition of "VBE Participant"

The Chamber urges CMS not to exclude drug companies, suppliers of durable medical equipment, prosthetics/orthotics, and supplies ("DMEPOS"), laboratories, medical device companies, pharmacy benefit managers, or any other entities from the definition of "VBE participant." We share CMS's concern regarding arrangements or behaviors that could give rise to a risk of program or patient abuse. However, to address this concern, CMS should focus on limiting or prohibiting the types of behavior or relationships that it finds to be abusive. It should not distinguish between health care entities based on product or service type.

For the industry-wide move to value-based care to be successful, all entities along the continuum of health care delivery should be eligible for protection under these rules so as to encourage their participation in value-based arrangements. We fear that excluding certain entities, such as pharmaceutical manufacturers, pharmacy benefit managers, or laboratories, based on the belief that they play a minimal role in patient care coordination or value-based arrangements would be short-sighted. Failing to grant all types of health care entities protection under these new rules could chill future innovation in the move to value-based care, which would undermine the agency's main objective in proposing these revisions to the Stark Law regulations.

Definition of "Target Patient Population"

CMS proposes to define "target patient population" as "an identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the VBE's value-based purpose(s)."[6] We support CMS's proposal that "legitimate and verifiable criteria" may include health characteristics, geographic characteristics, payor status, or other defining characteristics. This interpretation gives VBE participants appropriate flexibility in designing value-based arrangements.

The finalized Stark Law regulations should allow VBE participants sufficient discretion to determine the most appropriate target patient population for the specific goals of the enterprise and the degree of risk that parties agree to take on from the payor. We agree with the agency's approach of allowing enterprises to think creatively as to how to categorize the target patient

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[5] *Id.* at 55,775.

[6] *Id.* at 55,773.

populations, within the general parameters that the criteria for including patients in such populations be "legitimate and verifiable." Further, the Chamber requests that CMS avoid defining target patient population so narrowly or restrictively as to limit a VBE's ability to adjust target populations over time and during the lifespan of a value-based arrangement.

Additionally, we support CMS's suggestion that it provide in the regulations a non-exhaustive list of selection criteria that would or would not be "legitimate and verifiable," assuming that industry members would have an opportunity to comment on such criteria. As long as the list remains non-exhaustive, we believe that including this list in regulations would provide clarity to members of the health care industry seeking to enter into novel value-based arrangements while still allowing for innovation.

**PROPOSED VALUE-BASED EXCEPTIONS**

Full Financial Risk

CMS has proposed to add an exception to the Stark Law that would apply to "value-based arrangements between VBE participants in a VBE that has assumed 'full financial risk' for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time."[7] To truly incentivize innovation, we recommend that this exception be broadened to also include VBE participants at full financial risk for a certain defined set of patient care items and services (e.g., all costs associated with knee replacement surgery).

As proposed, the full financial risk exception is too narrow—it will likely apply to only a small number of arrangements. Although this exception will provide the appropriate protections for structures based on capitation payments or global budget payments, it will not offer protection for more limited arrangements in which VBE participants still take on full financial risk. Like broader arrangements, value-based payment models for a defined set of patient care services have the potential to improve the quality of patient care while reducing costs. They also carry a low risk of patient or program abuse by creating an incentive for providers to limit the volume of services provided. Accordingly, the full financial risk exception should be broadened to value-based payment arrangements for a defined set of items or services.

Additionally, this exception should only include minimum time periods that are appropriate for the defined set of patient care items and services that are at risk. For example, a value-based arrangement in which a provider takes on financial risk associated with all items and services required for a knee replacement could have a minimum time period of six months. Minimum time periods for a participant to take on full financial risk should be based on the target patient population and included items and services. Limiting the application of this exception to a single minimum period of time applied across the board would impose an unnecessary obstacle to potentially beneficial innovation.

The Chamber supports CMS's proposal to protect value-based arrangements entered into in preparation for the implementation of the VBE's full financial risk payor contract where such arrangements begin after the VBE is contractually obligated to assume full financial risk for the

[7] *Id.* at 55,779.

cost of patient care for the target patient population but prior to the date the provision of care under the contract begins.[8] The Chamber urges CMS to provide this protection for at least one year prior to the effective date of the full financial risk payor contract. Providing this protection for one year prior to the effective date will allow VBE participants needed time to prepare for the provision of patient care under the contract. The Chamber is concerned that a shorter period of time, such as six months, would be insufficient for participants to adequately prepare for the implementation of the arrangement and could hinder its success. The Chamber also requests a conforming change be made to the Meaningful Financial Risk exception.

We also request that, consistent with the OIG's proposed Anti-Kickback Statute rule, CMS clarify that the proposed definition of "full financial risk" would not prohibit a VBE from entering into arrangements to protect against catastrophic losses, like global risk adjustments, risk corridors, reinsurance, or stop loss agreements.[9] These arrangements are an important mechanism through which VBE participants can become comfortable taking on financial risk. Accordingly, CMS should clarify that such arrangements are not prohibited under the rules. Further, VBEs should be permitted to source any such reinsurance internally.

Value-Based Arrangements

The Chamber supports CMS's proposal to add an exception to the Stark Law for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the VBE or any of its VBE participants.[10] We agree with CMS that this exception is important to allow health care entities to participate in value-based arrangements and care coordination activities while they build toward models in which they take on more risk. Additionally, we believe that this exception is important given that smaller participants, such as physician groups, are not used to risk-sharing and allowing them to participate in value-based arrangements without requiring them to assume a specific amount of risk will encourage innovation.

To allow for flexibility in the transition to a value-based health care delivery and payment system, we recommend that CMS not limit the scope of this proposed exception to nonmonetary remuneration. We worry that limiting the scope of the exception to nonmonetary remuneration will discourage participation in innovative value-based arrangements.

Clarify Protection for Tools to Monitor Quality and Outcomes

The Chamber urges CMS to clarify that the proposed Stark Law exceptions for value-based arrangements would include protections that would allow VBE participants to provide the enterprise or one another, at free or reduced cost, tools and infrastructure necessary to monitor and measure quality and costs. These tools could include collection and analysis of data, software, equipment, information and services reasonably necessary or appropriate for measuring quality or cost and/or operationalizing the value-based arrangement.

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[8] *Id.* at 55,782.

[9] 84 Fed. Reg. 55,694 at 55,720 (Oct. 17, 2019) *available at* https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf.

[10] *Id.* at 55,783.

Significantly, the HHS press release announcing the CMS and OIG proposed rules provided a number of examples of arrangements that could potentially be protected by the proposed value-based exceptions and safe harbors including "a specialty physician practice [ ] shar[ing] data analytics services with a primary care practice;" hospital-provided care coordinators and data analytics systems "to help physicians ensure that their patients are achieving better health outcomes;" hospital-provided remote monitoring technology to alert physicians when a patient needs healthcare intervention; dialysis facility-provided data analytics software to nephrologists "to help them monitor patients' health outcomes."[11] Unfortunately, these examples were not included in the Proposed Rule. The Chamber requests that CMS clarify that such tools and services may be eligible for protection under the finalized rule.

Price Transparency

The agency requested comment on how to pursue its price transparency objectives in the context of the Stark Law and whether it should include price transparency requirements in each proposed exception for value-based arrangements.[12] The Chamber supports the goal of ensuring patients have access to useful and meaningful information on the cost and quality of health care items and services. However, we do not believe that the Stark Law regulations are the proper vehicle for this effort. Rather, we worry that requiring price transparency in the context of the Stark Law would increase the administrative burden on health care professionals and organizations and subvert the agency's intent to reduce that burden through this Proposed Rule.

**PROPOSED REVISIONS TO ELECTRONIC HEALTH RECORDS EXCEPTION**

CMS proposes to revise the existing Stark Law exception for certain arrangements involving the donation of interoperable electronic health records ("EHR") software or information technology and training services.[13] Specifically, among other things, the agency proposes to eliminate the exception's sunset provision, which is currently set for December 31, 2021.[14] The Chamber supports this proposal.

We agree with the agency's conclusion that the continued availability of this exception plays a significant part in achieving the agency's goal of promoting EHR technology adoption. Furthermore, we agree with CMS's reasoning that the EHR exception encourages EHR adoption by new physicians concerned about the cost of EHR technology and preserves the gains already made in the adoption of interoperable EHR technology.[15]

CMS also solicited comment on eliminating or reducing the 15 percent cost sharing requirement for small and rural physician organizations or, alternatively, for all physician recipients.[16] We do not believe that CMS should eliminate this cost sharing requirement for all physician

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[11] HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care (Oct. 9, 2019) *available at* https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html.

[12] *Id.* at 55,788-89.

[13] *Id.* at 55,822.

[14] *Id.* at 55,824.

[15] *Id.*

[16] *Id.* at 55,825.

recipients—it serves as a reasonable safeguard to ensure recipients will use the EHR technology and thus reduces wasteful spending. However, the Chamber supports relieving this cost sharing requirement for small and rural physician organizations and other providers with demonstrable financial need.

**PROPOSED EXCEPTION FOR CYBERSECURITY**

We support the agency's proposal to create a new Stark Law exception to protect arrangements involving the donation of certain cybersecurity technology and related services, including the proposal to exclude hardware from the definition of "technology."[17] The Chamber also agrees that the types of entities that can make cybersecurity donations under this exception should not be restricted.[18] Such a restriction could stifle advances in patient care coordination or health information security in the future.

However, we encourage CMS to require that there be a clear nexus between the cybersecurity donation and the business relationship. In other words, the cybersecurity technology should relate to the services or products that are the subject of the parties' relationship. For example, a hospital could be permitted to donate cybersecurity technology to a physician if such technology would secure the transfer of personal health information between the two entities and thus improve care coordination for shared patients. This exception should not allow cybersecurity technology to be used as a way to entice new business for entities providing unrelated services.

**CONCLUSION**

The Chamber commends CMS's efforts to revise the Stark Law regulations to promote a transition to value-based care across the health care industry. With the modifications described herein, we believe the agency's proposals will foster innovative value-based arrangements that both improve patient outcomes and reduce costs.

Sincerely,

Katie Mahoney
Vice President, Health Policy
U.S. Chamber of Commerce

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[17] *Id.* at 55,830–31.

[18] *Id.* at 55,833.