



Maryland
Hospital Association

December 30, 2019

Submitted Electronically

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

Joanne Chiedi
Acting Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

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

OIG-0936-AA10-P Proposed Rule (Medicare and State Healthcare Programs: Fraud and Abuse)

Dear Ms. Verma and Ms. Chiedi:

On behalf of the 61 hospital and health system members of the Maryland Hospital Association (MHA), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule modernizing the physician self-referral law (commonly known as the “Stark Law”) and the Office of the Inspector General (OIG) proposed rule revising safe harbors under the Anti-Kickback Statute (AKS). Maryland’s hospitals welcome CMS’s and OIG’s recognition that the health care payment landscape has changed dramatically since the inception of the Stark Law and AKS; thus, the laws themselves require significant revisions to continue fostering the innovative, value-based programs currently driving health care quality improvements and appropriate cost reductions.

Under the Maryland Total Cost of Care Model (Maryland Model), hospitals, working with primary and post-acute care, state agencies, and other stakeholders, are responsible both for delivering high-value, better-coordinated care and for improving population health across the state. Innovations that include value-based models are integral to meeting the quality improvement, cost-savings, and population health goals of the Maryland Model. We therefore appreciate CMS’s and OIG’s efforts to remove the chilling effect that the Stark Law and AKS have had on the transition to value-oriented care. We welcome the many changes intended to remove regulatory obstacles to coordinated care and to eliminate unnecessary administrative burdens.

I. Newly proposed value-based exceptions.

A. Full financial risk exception proposed at 42 CFR § 411.357(aa)(1) and meaningful downside financial risk to the physician exception proposed at § 411.357(aa)(2).

Maryland hospitals are subject to fixed-revenue global budgets in addition to all-payer rate setting by the state's Health Services Cost Review Commission and under the Center for Medicare and Medicaid Innovation. As proposed, the full financial risk exception seems to contemplate capitated and global budget models. We therefore seek clarification on whether the Maryland Model may fit into this exception, such that programs developed under the auspices of the Maryland Model would not require individual waivers from the Stark Law.

We also echo the suggestions within the American Hospital Association (AHA)'s comment letter regarding a lower threshold for what constitutes meaningful financial risk in the meaningful downside financial risk exception. As a 2018 Deloitte survey showed, most physicians are willing to link approximately 10% of their total compensation to quality and cost measures. A higher threshold creates the inverse concern that, if physicians must pay more, then they may be incentivized to stint on care. As Maryland continues to innovate and create new programs to improve health, we believe that lowering the threshold will offer a more gradual pathway to downside financial risk. That would better equip providers to take on more risk as they become further adept at working within the system.

B. Value-based arrangements proposed at 42 CFR § 411.357(aa)(3).

Our previous comment letters on Stark Law revisions indicated that any regulatory approach to gainsharing¹ must include flexibility that allows hospitals and physicians to employ the model that best suits their circumstances. Since then, Maryland has received federal approval of and implemented the Hospital Care Improvement Program, Maryland's physician gainsharing program, and the Episode Care Improvement Program, Maryland's bundled care initiative. Both programs have proven integral to the success of the Maryland Model.

To this end, we echo AHA's suggestion to expand the proposed definition of value-based purpose to protect appropriate cost reductions for provider participants, and not just for purposes that result in cost-savings for payers. This expansion ensures that care redesign programs supporting the Maryland Model, such as the Hospital Care Improvement Program, can continue to flourish and create internal cost-savings for Maryland's hospitals. This ultimately results in lower costs to payers.

Furthermore, as we move ahead with the Maryland Model, both hospital and non-hospital providers have recognized that expansion of value-based arrangements is key to achieving its

¹ For purposes here, we define gainsharing as the direct payment from hospitals to physicians of incentives that are based on hospital care cost and quality.

goals. Therefore, we applaud CMS's proposal for a value-based arrangement exception. It permits value-based enterprise (VBE) participants that are part of the arrangement to set their own benchmarking, remuneration, and quality methodologies, regardless of the level of risk involved. This flexibility is the key to modernization.

Thus, we hope CMS finalizes the provision as-is, rather than adopting the proposed alternatives. Moreover, we echo the AHA's suggestion that any compliance monitoring obligations should be included explicitly within the regulations, with clear guidance from CMS on the specific monitoring that will be required of hospitals.

II. Decoupling required compliance with Anti-Kickback Statute (AKS) and other federal or state laws governing billing or claims submission from the Stark Law exceptions.

CMS's decoupling of the requirement that an arrangement which fits within a Stark Law exception must also fit within an AKS safe harbor is a welcomed streamlining of the regulations. However, CMS and OIG have noted that, under the proposal, an arrangement may fit within a Stark Law exception, but not entirely within an AKS safe harbor (and vice versa). We urge CMS and OIG to give additional guidance on the resulting interplay between the Stark exceptions and AKS safe harbors. Without more certainty on how CMS and OIG intend to monitor the program and reconcile concerns, the rule may have a daunting effect on innovation because parties are unclear as to their respective liability.

III. Request for comments regarding price transparency.

Along with AHA, we urge CMS not to move forward with a requirement related to price transparency in every exception for the newly proposed value-based arrangements. We are concerned that this provision overlaps with the recently finalized price transparency requirements that were issued in November, thus potentially inundating patients with duplicative and ineffective notices. It also runs counter to CMS's efforts to reduce unnecessary paperwork that benefits neither patients nor providers.

Given the continually evolving policy conversations around this issue, we welcome robust and focused stakeholder engagement processes led by CMS specifically on price transparency rather than through the lens of the proposed Stark Law revisions.

IV. Removing the monetary cap on aggregate retail value of patient engagement tools and supports for newly proposed safe harbor.

We appreciate OIG's recognition that health care is not limited to the provision of medical items and services. Social determinants of health, such as transportation burdens and housing issues ranging from access to safety, also must be addressed. As we focus not only on the care needs of patients we serve but also on improving the health of all people in our communities, Maryland's

hospitals expend effort and resources to meet social and other non-medical needs. Doing so entails an investment that is significantly more than \$500 per patient per year, the cap noted in the AKS proposal.

For example, our member hospitals have expressed interest in providing financial assistance for housing modifications to lessen chances of falls or other injuries that lead to hospitalization. Such modifications (e.g., installation of handrails) may easily run higher than the proposed limit, but the benefits from these investments—preventing future hospitalizations and allowing individuals to remain safely in their homes—far outweigh the expense. Although OIG indicates that some supports furnished may exceed the limit based on the patient’s financial need, the appropriateness of these instances would be determined on a case-by-case basis.

We seek additional details regarding the criteria upon which each case will be judged. Success of the Maryland Model will require scalable innovations around social needs and determinants; we are therefore concerned this low threshold will hinder providers’ ability to address non-medical needs in a manner that is meaningful for positive health outcomes. To that end, we urge OIG to remove the monetary cap, and to instead rely on other combinations of safeguards proposed in the rule to produce meaningful protections against fraud and abuse involving patients and programs. That way, hospitals are not penalized for doing right by patients and communities.

We also recommend that OIG expressly permit the VBE participant to delegate the furnishing of tools or supports through an entity acting on the VBE participant’s behalf and under the VBE participant’s direction.

Again, we thank CMS and OIG for your focus on these critical issues. Maryland’s hospitals greatly appreciate the strides that both agencies have taken to carve out spaces where hospitals and physicians may continue to innovate to enhance care coordination, improve quality, and appropriately reduce costs under the Maryland Model.

Sincerely,



Robert F. Atlas
President & CEO