The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

December 24, 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 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) proposed rule which makes important reforms to the physician self-referral law ("Stark Law") to enable value-based arrangements and reduce other regulatory burdens.

The Stark Law—which was designed to address overutilization in a fee-for-service environment—is antiquated and must be reformed to allow for innovating models of care that promote care coordination. During the past several years, HAP has actively encouraged Congress and CMS to modernize the Stark Law to address the rapidly evolving health care environment.

Given profound frustration in navigating the complex and burdensome law, many Pennsylvania hospitals have shared their belief that wholesale reform—eliminating the law and replacing it with an approach that reflects current realities—is the best course. Recognizing the difficulty of that undertaking, we appreciate the incredible effort and thought that went into crafting the new value-based exceptions and reforms, and clarifications to reduce current Stark Law burdens.

We applaud CMS' efforts to remove the chilling effect the Stark Law has on innovation and the transition to value-oriented care and the unnecessary burdens it has created both inside and outside the value-based context. We also welcome the many changes intended to eliminate regulatory obstacles to coordinated care and unnecessary regulatory burden.

The comments below reflect points of particular emphasis. HAP fully endorses, and incorporates by reference, the comprehensive response to the notice of proposed rulemaking submitted by the American Hospital Association (AHA), and wishes to express support for the AHA's recommendations.

New Value-Based Exceptions

HAP joins the AHA in supporting the creation of new exceptions designed specifically to foster and support efforts to achieve a system of value-based care.

We support the basic foundation of the three proposed exceptions included in the regulations. Key flexibilities include:

- The regulations should not require particular legal structures for carrying out value-based activities
- No particular type of payment model should be a precondition to receiving protection under the new exceptions
- There should be latitude for including government and/or commercial enrollees in the patient population that is the focus of the activity ("target patient population")

It is important that the regulations allow for the different forms in which innovation will take place as well as the ability to test new models.

We also support the four types of value-based purposes on which an arrangement may be based and the latitude to choose any one of the purposes to focus on: coordinating/managing care; improving quality; appropriately reducing costs; and transitioning to service delivery and payment based on quality and control of costs.

Key points of consideration:

- "Appropriately reducing costs" also should include cost reductions for providers participating in the arrangement; it should not be limited to reducing the costs of payors
- CMS should not require that care coordination or management be a condition for protection, an alternative discussed in the commentary
- We welcome the decision to keep the value-based exceptions free of the cumbersome and ambiguous fair market value, commercial reasonableness, and "volume or value of referrals" conditions
- We urge CMS to find a better way to address its concern that a broad definition of "target patient population" will lead to inappropriate exclusions. CMS should call out the types of specific behaviors that are unacceptable, rather than relying on an ambiguous term of requiring that the criteria for selection be "legitimate"
- We agree that none of the exceptions should limit the types of remuneration protected. Each would protect, for example, payment incentives, support tools, and infrastructure assistance

Requirements Specific to Each of the Exceptions

- The "full financial risk" exception—Instead of requiring that an arrangement be at risk for every and all services that a payor's enrollee may need to qualify for the exception,

the focus should be on whether the arrangement has full financial risk for the items and services to which the protected remuneration relates
- The physician "meaningful financial risk" exception—The proposed 25 percent threshold will significantly limit its utility. We recommend a more pragmatic 10 percent in the final rule
- The "value-based arrangements" (no financial risk required) exception—Should be finalized as proposed

We urge that CMS decline to adopt any of the alternative proposals discussed in the commentary, each of which would dramatically reduce the utility of the exception.

- The exception should **not** be limited to nonmonetary remuneration. It would preclude commonplace structures, such as financial incentives to adhere to care protocols and shared savings models.
- It should **not** require 15 percent (or other) cost sharing by valued-based arrangement participants. The requirement would preclude a host of innovative value-based arrangements and take a disproportionate toll on small and rural physician practices, which are a key component in successfully improving care across patient populations.
- It should **not** require that "performance or quality standards must be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery." This alternative presents too ambiguous a standard, not consistent with the bright line test for which the agency strives under the Regulatory Sprint.

Monitoring Requirements

- Any compliance monitoring obligations should be included in the regulations. It should be clear whether an enforceable duty is being created. If that is the intent, it should be explicitly stated and incorporated into the regulation text itself. In the context of a strict liability statute, ambiguity places a hospital at unacceptable risk.

- Any required monitoring related to performance of the value-based arrangement should recognize that the goals are *prospective.* The proposed rule recognizes that, in a value-based activity, participants will come together to engage in an action or refrain from an action in a manner *reasonably designed* to achieve a value-based purpose. The activity will be evaluated prospectively at the outset of the arrangement and when it is up for renewal. During the course of the arrangement, however, there will be an opportunity to observe, learn, adjust and improve. CMS should be clear that an arrangement is not subject to termination during the course of the activity simply because a goal or purpose proves difficult to achieve or needs adjusting.

- If any monitoring requirement is adopted, CMS must be clear about what exactly hospitals are being called upon to do. In the context of clinical protocols, in particular, the burdens on value-based arrangement participants could be tremendous. For value-based arrangements in which physicians are measured against hundreds of care protocols or quality metrics, layering-on documentation requirements beyond what is otherwise appropriate from a clinical perspective is adding paperwork, not enhancing patient care.

Reforms and Clarifications to Reduce Stark Law Burdens

CMS's proposed clarifications to clearly distinguish the three cornerstones of existing statutory exceptions—commercial reasonableness, taking into account volume or value of referrals, fair market value—are major breakthroughs.

- *Commercial reasonableness*—CMS should finalize the proposed definition of "commercially reasonable" with one important modification. Much of the litigation related to this concept has mistakenly focused on whether the arrangement generated a "profit." We urge that the second sentence, which attempts to address that problem, be revised by making absolutely clear that profit is irrelevant to commercial reasonableness by inserting "Commercial reasonableness is unrelated to the profitability of the arrangement to one or more of the parties."

- *Takes into account volume or value of referrals*—CMS should finalize the proposed definition. In addition, we request that CMS resolve any lingering questions about the use of personal productivity compensation and the volume/value prohibition. To do this, we recommend that CMS make clear in regulatory text that compensation for personal productivity is permissible under the personal services, fair market value compensation and indirect compensation arrangements exceptions.

- *Fair market value*—CMS should adopt the proposed clarification that fair market value does not turn in any way on whether compensation takes into account or anticipates referrals.

The proposals reducing Stark liability for writing mistakes should be finalized.

- The "limited remuneration to a physician" exception for annual payments under $3,500 will be extremely helpful to avoid liability for non-abusive conduct. It also will save hospital and CMS resources in resolving self-disclosures related to arrangements that do not pose risks to federal health care programs.
- Similarly, the special rule permitting writings to be executed within 90 days of when an arrangement begins will save hospital and CMS resources that would otherwise be spent resolving self-disclosures for lapses that do not pose risks to the Medicare program. To further address lapses that do not pose a risk to the Medicare program, we urge CMS to

deem that a writing requirement is satisfied if the arrangement constitutes an enforceable contract under applicable state law.

Again, we thank you for your focus on improving value for patients and providers and for your consideration of our comments, as well as the comprehensive comments submitted by the AHA. If you have any questions relating to this response, please contact me at (202) 863-9287, or Jeff Bechtel, HAP's senior vice president, health economics and policy, at (717) 561-5325.

Sincerely,

Laura Stevens Kent
Senior Vice President, Strategic Integration