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December 31, 2019

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

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

Dear Ms. Verma:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 members, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Stark Law reforms to enable value-based arrangements and reduce other regulatory burdens.

As health care needs and experiences have grown increasingly complex over the past decade, New Jersey's hospitals, health systems and post-acute care providers are working to deliver more value-based care to patients, and to meet the demands of patients, other providers, the government, and other payers for accountability and affordability. However, the tools available to us have been limited and our development of innovative payment arrangements has been greatly stymied by the Stark Law.

We appreciate and echo CMS's view that the volume-based health care landscape at the time the physician self-referral law was enacted bears little resemblance to the increasingly value-based landscape of today. We applaud CMS's 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.

Our comments on the proposed rule follow. We focus first on the new value-based exceptions and then the reforms and clarifications to reduce current Stark Law burdens. We also note New Jersey's advances in implementing a successful commercial gainsharing program. Additionally, we wish to express our support for the American Hospital Association's (AHA) submitted recommendations.

NEW VALUE-BASED EXCEPTIONS

The creation of new exceptions designed specifically to foster and support efforts to achieve a system of value-based care is extremely significant. They are a major step in removing the impediments we currently face in implementing value-based payment arrangements that reward

our physicians for delivering high-quality, cost effective care with better outcomes. The proposed regulations establish a basic foundation and definitions that apply across all three of the new exceptions (full risk arrangements, value-based arrangements with meaningful downside financial risk for physicians, and value-based arrangements).

FRAMEWORK FOR THE NEW EXCEPTIONS

We support the basic foundation of the three proposed exceptions included in the regulations. We agree that the regulations should not require particular legal structures for carrying out value-based activities; nor should any particular type of payment model (such as a shared savings or capitation model) be a precondition to receiving protection under the new exceptions; and that 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. **We urge that the purposes be finalized as proposed with one modification**. "Appropriately reducing costs" also should include cost reductions for providers participating in the arrangement, the benefit of which will extend to the Medicare program and improve value overall. It should not be limited to reducing the costs of payers. **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. They are creatures of the volume-based, fee-for-service environment and represent some of the strongest barriers to the type of value-based innovation the agency desires to achieve.

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. Instead of requiring that the criteria for selection be "legitimate," an ambiguous term that is likely to result in legal disputes over its meaning, CMS should address the behaviors that it wants to preclude. The commentary indicates that CMS is specifically concerned about selecting only lucrative or adherent patients and avoiding costly or noncompliant patients. We agree that result would be inappropriate. **Instead of creating ambiguity, CMS should call out the types of specific behaviors that are unacceptable.** We agree with the requirement that selection criteria should be verifiable.

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 unreasonably limits the range of "at risk" arrangements that it protects. In the Medicare context, for example, the exception would not protect a hospital that provides care management analytics or pay-for-performance bonuses if they relate solely to reducing the costs of inpatient care. **Instead of requiring that an arrangement be at risk for every and all services that a payer'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.**

For the physician "meaningful financial risk" exception, the proposed 25% threshold will significantly limit its utility. **We recommend a more pragmatic 10% in the final rule**. The dual goals should be to assure that physicians are willing to participate in these important efforts while also protecting against any encouragement to overutilize. In a 2018 Deloitte survey of U.S. physicians, most said they were willing to link around 10% of total compensation to quality and cost measures. That threshold also would be higher than the average amount of physician compensation linked to performance goals today based on the Deloitte survey.

The proposed "Value-Based Arrangements" (no financial risk required) exception should be finalized as proposed. This is the only one of the three exceptions that does not require the acceptance of significant risk. Maintaining that option is essential to spur the shift to value-based payment models across the spectrum of hospitals and communities.

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% (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.

Any compliance monitoring obligations should be included in the regulations. In the commentary, CMS's mention of "implicit" compliance monitoring obligations is confusing and potentially concerning. 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 where 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.

EXPAND GAINSHARING PROGRAMS

NJHA is pleased that CMS has authorized the use of gainsharing in many Medicare programs. NJHA has long supported gainsharing and has been a leader in this area starting with the first Medicare gainsharing demonstration in 2004. Temporarily halted by a legal decision, the initial program led to modifications in the civil monetary penalties gainsharing provision in MACRA. The demonstration restarted in 2009 with 12 hospitals and 1,300 participating physicians, and covered 150,000 Medicare patients. It ran for three years and then expanded to 23 hospitals as part of the BPCI Model 1 initiative, concluding in 2016. Implementation was achieved with no reported problems. Gainsharing, whether focused on internal cost savings (i.e., the New Jersey demonstrations) and/or reductions in payments compared to a target price (i.e., shared savings) is an essential component to any effective physician engagement strategy, particularly as reimbursement to providers transitions from fee-for-service to value-based payments.

NJHA agrees that aspects of the Stark law have hindered the wide-spread implementation of coordinated care strategies by providers. We believe that gainsharing arrangements, properly structured, currently can qualify under any of several Stark law exceptions including risk-sharing, personal services, fair market value, and employment. As to this, we note that the federal Anti-kickback statute and the Civil Monetary Penalties law both remain in place to protect against sham gainsharing awards and incentives to stint on patient care. **NJHA would encourage CMS to extend the exceptions to make gainsharing available for use in more contexts.** Our suggestions include:

Risk-sharing exception. The current risk-sharing exceptions protects arrangements, including between hospitals and their physicians, who assist hospitals in managing their risk in accepting prospective payment DRG type reimbursement and similar payment methodologies. The risk-sharing exception is limited, however, to enrollees of commercial or self-insured plans, which are defined in such a way as to likely not cover Medicare Part A and B enrollees. It would be helpful if CMS would expand the definition to clarify its application to Medicare fee-for-service.

Personal services exception. Gainsharing arrangements can also qualify under the physician incentive plan provision at 42 CFR 411.357(d)(2). Again, this exception is limited to enrollees of health plans and it is unclear how it applies to Medicare fee-for-service. In addition, CMS should clarify that similar incentive plans with a hospital's employed physicians would be similarly protected.

Other exceptions. Several other exceptions potentially can protect properly structured gainsharing arrangements including the fair market value and employment exceptions. The only issue is compliance with those exceptions. One question that should be clarified pertains to compensation, which is typically interpreted to "not take into account the volume or value of referrals." But since the determination of savings will at least require consideration of a physician's admissions, arguably the methodology takes into account referrals, even if the award is determined independently and based on achievement of quality measures. If CMS were to deem such compensation to not take into account the volume or value of referrals, such as it did with 42 CFR 411.354(d), gainsharing could qualify under a number of exceptions. Use of a special rule would also permit CMS to limit qualifying arrangements to those that incorporate safeguards, much as it has done with arrangements that restrict referrals in network at 42 CFR 411.354(d)(4).

Clarifying these exceptions will produce a stable regulatory environment that encourages the use of gainsharing as a tool to support patient care coordination. NJHA has included an **Addendum** to this comment letter with additional information and background regarding gainsharing.

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. They have long been the source of controversy and litigation. We believe these provisions will make an important difference practically and legally.

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. Specifically:

- 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 hospitals and CMS resources that would otherwise be spent resolving self-disclosures for lapses that do not pose risks to 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.

Sincerely,

Jonathan Chebra
Senior Director, Federal Affairs

NEW JERSEY HOSPITAL ASSOCIATION ADDENDUM ON GAINSHARING

Background

Beginning in January, 1980, Medicare demonstrated payment by the case for hospital inpatient care in New Jersey. Successfully implemented statewide, the DRG model provided the prototype for the Medicare Inpatient Prospective Payment System (IPPS). With the implementation of IPPS, Medicare began shifting risk to the providers: Beginning with payment by the case, these strategies have evolved into more aggregate forms of payment including bundled payment, accountable care and, eventually, value-based payment, as well as more targeted initiatives that include specific groups of DRGs such as Comprehensive Joint Replacement (CJR). But, payment and provider strategies must be complementary: if providers are able to realize sufficient savings, they can better tolerate reductions in payment; if not, a payer strategy that down streams more risk will not work.

Following the DRG demonstration, discussions in the New Jersey provider community naturally began to focus on ways to foster effective provider collaboration; engaging physicians to help drive and maintain performance. The New Jersey Hospital Association organized a committee of physicians and hospital administration to develop a demonstration that could test a model that would maximize the effectiveness of gainsharing while, at the same time, directly addressing the concerns raised by the Stark law. (RFI at 4, 5). Above we noted that in 2004 Medicare awarded New Jersey a waiver to test whether or not a large scale, comprehensive physician incentive system (all DRGs, all inpatient costs, all physicians involved in the provision of inpatient care), based on performance, could be implemented without incurring the problems that are enumerated in the RFI. The demonstration was tailored to address Stark law-related patient protection concerns including: (a) stinting on care, early patient discharge and limiting medically necessary care, sometimes identified as “cherry picking,” “steering” and “phantom savings.” Specific safeguards were built in to maintain program integrity.

Basic Elements

The foundation for the demonstration methodology is an improved tool to measure provider performance: DRGs adjusted for severity of illness (“SOI”). This component also addresses concerns within the physician community, particularly related to fairness and objectivity. Severity adjusted systems of patient classification are able to recognize the more significant patient care challenges seen by certain physicians. Because of the relatively small number of patients seen by an individual physician, the objectivity offered by SOI provided the framework required to establish credibility within the physician community, reducing friction and promoting physician engagement. But the same methodology enabled the NJHA committee to directly address the Stark law-related concerns. Once the basic model was developed, input from CMS was solicited and the model revised to incorporate CMS suggestions prior to submission**.** We believe that beginning with the adjustment for SOI, the safeguards discussed below can work for the inpatient component of all gainsharing programs.

Over the term of the demonstration, the committees continued to function under the overall direction of a demonstration steering committee. Through feedback from the participants and deliberation at the NJHA committee level, the model was constantly revised and refined. The components of the methodology and program can be organized into five groups.

A. Basic Elements: The basic elements of the demonstration methodology are as follows: (1) The framework covers all DRGs, all inpatient costs, and all physicians that contribute to inpatient care. (2) Best Practice Norms are determined for each severity adjusted DRG based on costs developed using industry standard cost accounting. This is similar to the concept of target prices but is based on inpatient cost, not payments. Like IPPS, this approach was designed to operate utilizing routinely collected data – costs and cases reported to Medicare. This requirement greatly reduced implementation costs, eliminated arguments about the source and integrity of the data and insured that the program was auditable, replicable and scalable. (3) The methodology is applied uniformly to evaluate overall hospital resource utilization by each participating physician. Taken together, these methodological components eliminate opportunities for "sham" or "phantom savings."

B. Oversight: (1) The program is overseen by a hospital steering committee which establishes institutional and specialty-specific goals related to patient safety, quality of care and operational performance. (2) Subject to conditions set by the steering committee, incentive payments are made based on individual physician performance. (See below) In particular, conditioning the payment of performance incentives based on the achievement of specific quality related objectives created a direct linkage between efficiency and quality. This process is similar to other bundled payment initiatives.

C. Program Flexibility: Each set of providers – hospitals, physicians and systems – faces a unique set of challenges. The program can be applied hospital-wide, or targeted to specific specialties, specific DRGs, and/or limited to specific kinds of physicians – e.g., attending physicians, specialists, surgeons, etc. To respond to differing priorities, the methodology was designed to reward both (1) **Performance** – each physician's resource utilization compared to his/her peers (i.e., the Best Practice Norm), and (2) **Improvement** – each physician's resource utilization compared to his/her own performance, over time. The demonstration methodology was constructed as part of a continuing process of patient care improvement and maintenance. To enable the program to operate over time, hospital steering committees periodically rebalanced these components to address evolving priorities. Finally, both physician and hospital participation were voluntary.

D. Patient Safety and Quality of Care: (1) **Medically necessary care:** The methodological components set forth in "**Basic Elements**" (paragraph A above), particularly the adjustment for severity of illness, eliminate incentives to reduce or limit medically necessary care, "stinting" and "early patient discharge," or avoiding difficult or complex medical cases – "cherry picking." (2) **Limits on physician incentive payments:** Incentive payments must be reasonable – consistent with Medicare guidelines. There is a maximum incentive amount for each severity adjusted APR DRG so there is no additional incentive for exceeding Best Practice Norms. Taken together, these guard rails discourage overutilization, as well a "race to the bottom."

E. Program Integrity and Administration: (1) **No payment for referrals:** To be eligible to participate, the physician must have been on the medical staff for at least one year. (Exceptions were made for physicians new to the area, hospitalists, or other physicians that do not refer or admit such as emergency room physicians or intensivists.) Also, a one-year time lag was placed on new volume from physicians with multiple admitting privileges. (2) **Organization:** Where multiple hospitals were involved, providers could utilize a facilitator/convener to administer the program. This entity facilitated dissemination of Best Practices, liaison with CMS and provided for the independent application of the gainsharing methodology. This structure proved helpful to maintain program integrity and promote efficient implementation and administration. (3) **Notice and reporting:** Patients were notified of the program prior to admission and a standard data set was provided to CMS annually.

A more extensive set of comments, together with sample regulatory language, can be found in the comment submitted by NJHA in response to RE: CMS-1631-P – Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation (80 Fed. Reg. 41680, No.135/July 15, 2015/ Proposed Rules at 41926-41930).

Conclusion

At the heart of care coordination is the relationship between hospitals and physicians. The CMS demonstrations in New Jersey have shown that large scale gainsharing can be implemented successfully: hospitals and physicians came to the table and the process of change advanced, without jeopardizing patient care. Gainsharing can provide the financial engine that supports change. Gainsharing is a tool that must be made widely available because the industry is being asked to implement care coordination across all providers. We agree that clarifying existing regulation will provide the foundation for care coordination and we believe that the CMS/New Jersey demonstration can inform your deliberations concerning the basic elements for inpatient gainsharing and provide a critical part to current and future shared savings programs and bundled payments.