Via email

August 21, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-NC
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1720-NC, Request for Information on Physician Self-Referral Law

Dear Ms. Verma:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 members, thank you for the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on the physician self-referral law ("Stark law").

As health care needs and experiences have grown increasingly complex over the past decade, our member hospitals strive to deliver more value-based care to patients and meet the demands of patients, other providers, the government, and other payers for accountability and affordability. However, the tools available to them are limited and their development of innovative payment arrangements has been greatly stymied by the Stark law. Our hospitals are eager to work both within and outside their organizations with diverse partners to deliver comprehensive, coordinated care to their patients. We are hopeful that CMS's modifications to the Stark law will enable them to do so by allowing them to develop and implement innovative programs that align providers through financial incentives, among other tools. **We are confident that changes to the Stark law that support the adoption of value-based payment arrangements while removing obstacles to care coordination will result in improved patient outcomes and patient experience while increasing efficiency**.

NJHA's recommendations include: (1) accelerating the transformation to a system of value-based care and (2) removing regulatory obstacles to coordinated care. These recommendations reflect the problems with the Stark law related to compensation arrangements that hospitals encounter every day. We refer you to the American Hospital Association's (AHA) comprehensive response the RFI and wish to express our support for their recommendations. **We neither recommend nor support modifying the regulations implementing the Stark law's ownership ban. The ban is a carefully crafted policy that is working as Congress intended.**

ACCELERATE THE TRANSFORMATION TO A SYSTEM OF VALUE-BASED CARE

The Stark law is one of the main impediments hospitals face in their efforts to implement value-based payment arrangements that rewards physicians for delivering high-quality, cost-effective care with better outcomes. Specifically, the Stark law makes it nearly impossible for them to design flexible payment terms that could help their organizations reach these goals through the delivery of coordinated care. In order for innovative payment arrangements involving new relationships with physicians to succeed, hospitals need to be able to make significant investments in care coordination without running afoul of the Stark law. Current Stark exceptions do not cover many of the innovations they seek to implement and the waivers of Stark for certain programs or projects are too limited to enable them to make broad-scale changes.

Therefore, NJHA recommends that CMS create a new innovative payment exception for value-based payment arrangements. The creation of this exception would present hospitals with a new opportunity to implement incentives that drive physician decision-making toward high-value care for each and every patient they see. We recommend that an innovative payment exception protect value-based incentive programs that promote: (1) accountability for the quality, cost and overall care of patients; (2) care management and coordination; and/or (3) investment in infrastructure and redesigned care processes for high-quality and efficient care delivery. The proposed exception should protect any remuneration that is provided and received pursuant to a clinical integration arrangement involving providers or suppliers of services and physicians or a physician practice. The exception should also protect incentive payments, shared savings based on actual cost savings, and infrastructure payments or in-kind assistance reasonably related to and used in the implementation of the clinical integration arrangement, and should be subject to objective, measurable and transparent performance standards.

NJHA believes this proposed innovative payment exception is essential to our hospitals' ability to improve 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. But the RFI raises other important questions: "How the arrangement furthers the purpose of the alternative payment model or novel financial arrangement" and "Whether and, if so, how the arrangement mitigates the financial incentives for inappropriate self-referrals, and/or overutilization of items and services, and patient choice. RFI at 7. Use of a special rule, noted above, is one vehicle that would enable CMS to limit the qualifying arrangements to those that incorporate adequate safeguards. As to safeguards for patient protection and quality of care, NJHA believes that the experience from the large-scale gainsharing demonstrations conducted by CMS in New Jersey, mentioned above, can help inform a discussion of the issues raised when hospitals are permitted to pay physicians for performance – both cost and quality.

NJHA has included an **Addendum** to this comment letter with additional information and background regarding gainsharing.

REMOVE REGULATORY OBSTACLES TO CARE COORDINATION

NJHA greatly appreciates CMS's recognition of the need to remove regulatory obstacles to care coordination. We recommend the agency do so by providing clear, unambiguous definitions of critical requirements. Our hospitals are often uncertain about what is acceptable under several Stark requirements; that uncertainty decreases their ability to innovate and undercuts care transformation. By offering guidance and clarity around the requirements with which they need to comply to receive payment, CMS will enable them to invest in integrated care and innovative payment arrangements in a manner that is compliant with the Stark law.

Compensation that does not take into account the volume or value of referrals. The volume/value element of the Stark law has created immense confusion in the field and reduced the drive of hospitals and health systems to create innovative payment arrangements. To combat this chilling effect, **NJHA recommends CMS clarify that, for a fixed payment, the amount of compensation does not vary or take into account the volume or value of referrals if the amount is initially determined by a methodology that does not take into account referrals and is not subsequently adjusted during the term of the agreement based on referrals**. The volume/value element requires that the methodology used to formulate the amount of compensation paid must not take into account referrals. The parties' state of mind in arriving at the amount of compensation is not relevant; rather, the central question is whether the methodology actually utilizes a physician's referrals in determining the amount of compensation paid to a physician or an immediate family member. This clarification is essential to hospitals' and health systems' ability to align the goals of their organizations and physicians and to incentivize physicians to make value-based modifications on a patient-by-patient basis.

NJHA also urges CMS to clarify and reaffirm that the volume/value requirement is not implicated where the payment is based on physicians' personally performed services, even when those services incidentally increase or decrease the delivery of designated health services (DHS) by a hospital or other DHS entity. This clarification will reduce concerns that arise when hospitals engage in efforts to improve quality and efficiency through greater cooperation with their physicians (such as quality bonus programs, shared savings arrangements, and provision of infrastructure or other assistance at no charge).

Fair market value. **NJHA strongly recommends that CMS restore the definition of fair market value to the original language of the statute**. Doing so would rightfully de-couple FMV from the volume/value element of the Stark law, giving our hospitals a chance to design incentives that may impact referrals but that do not drive overutilization nor undercut medically necessary utilization. **To that end, NJHA recommends CMS define *fair market value* as "the value in arms-length transactions consistent with general market value" and define *general market value* as "the price of an asset or compensation for a service that would result from bona fide bargaining between well-informed parties to the agreement**." Whether or not the parties are in a position to generate business for each other is irrelevant (and the agency's addition of that language to the regulation has created needless confusion).

Commercial reasonableness. Despite guidance over the years on the definition of commercial reasonableness, there is still confusion on what is needed to satisfy that prong of various Stark

law exceptions. **NJHA urges CMS to clarify that commercial reasonableness is a question of whether the items or services being purchased are useful in the purchaser's business and purchased on terms and conditions typical of similar arrangements between similarly situated parties.** As described above, asking whether the amount of the purchase is reasonable is the subject of fair market value determinations, not commercial reasonableness. This change will enable hospitals to clinically integrate with physicians for improved care coordination even when the purchase of a physician practice, for example, is a net loss to their system.

Referral. Because care coordination requires some degree of care management, our hospitals need the ability to work together across their organizations and even outside of it, to ensure patients receive the right care at the right time. However, some of their physicians' efforts to do so are considered "referrals" under the current Stark law, even if the referral presents no risk for increased payment to their organizations. **Therefore, NJHA urges CMS to clarify that a referral only implicates the Stark law when it results in an additional or increased payment from CMS to the DHS entity**.

In addition to implementing fixes to the Stark law that will enable and protect value-based payment arrangements and expand hospitals' ability to provide coordinated care, NJHA requests that you also provide relief from certain technicalities of the Stark law that inhibit hospitals' ability to focus on patient care. Specifically, we recommend that you address needlessly confusing and burdensome documentation requirements that expose hospitals to potentially catastrophic payment denials without protecting against problematic arrangements. To do so, we urge you to provide an alternative method of compliance with documentation requirements that focuses on whether there is a legally binding agreement between the parties. **This method should provide that an agreement enforceable under applicable state law will be sufficient to satisfy the requirement in any Stark exception that an arrangement be set out in writing and signed by the parties**.

Finally, to give effect to any modifications you make to the Stark law, **NJHA urges you to separate the Stark law from the Anti-Kickback statute by eliminating from regulatory exceptions to the Stark law the requirement that financial arrangements must not violate the federal Anti-Kickback statute**. This requirement is unnecessary and will be an impediment to comprehensive, coordinated care by, for example, placing an unreasonable burden of proof on entities seeking payment with no offsetting benefit or protection to the Medicare program.

Thank you for your focus on improving value for patients and providers and consideration of the New Jersey Hospital Association's comments.

Sincerely,

Karen S. Ali, Esq.

General Counsel

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.