Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

Submitted electronically

August 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
RE: CMS-1720-NC

Re: CMS Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's or the Agency's) Request for Information on reducing burdens of the Physician Self-referral regulations, also known as the Stark regulations, 83 *Fed. Reg*. 29524 (June 25, 2018). The Association of American Medical Colleges is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates CMS's acknowledgment "of the effect the physician self-referral law may have on parties participating or considering participation in integrated delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost." (83 *Fed.Reg.* 29525*).* The Association supports health care delivery and payment reform models that use incentives for higher-value care for patients, foster greater coordination among providers, and generally improve overall population health. Academic medical centers (AMCs) have been leaders in testing new payment models, including Medicare Shared Savings Program (MSSP) ACO (Accountable Care Organizations), Next Generation, CPC +, and other models. AAMC is also a facilitator-convener for the Bundled Payments for Care Improvement (BPCI) initiative for 21 hospitals and 14 health systems.

General Comments

To achieve the goals of delivery system reform, there is a need for changes to federal laws and regulations affecting hospital-physician arrangements that were enacted many years ago, including the Physician Self-Referral Law (also known as "Stark"), the Anti-kickback law, and the Civil Monetary Penalties (CMP) Law. Since enactment of the physician self-referral law (referred to as the Stark law) over 25 years ago, there have been major changes in health care delivery and payment, including many initiatives to align payment with quality and to improve coordination of care. Our members report that provisions in these laws which were enacted to address issues in a fee-for-service system, present significant barriers to clinical and financial integration aimed at improving the quality of care, population health, and reducing costs.

The Department of Health and Human Service Office of Inspector General (OIG) and CMS have played critical roles in the development and growth of delivery and payment reforms by establishing waivers for the federal program integrity laws for specific alternative payment models, such as the shared savings Accountable Care Organization (ACO) model and the Comprehensive Care for Joint Replacement (CJR) model. However, these waivers only apply on a case-by-case basis to the specific models. Physician participation in new innovative payment and delivery models is critical for their success; however, physicians are reluctant to participate in these models because the self-referral and other federal laws prohibit the financial relationships necessary to achieve the clinical and financial integration necessary to be successful in reform.

Specific concerns relate to prohibitions under the compensation standards of the Stark law and regulations, including "fair market value," "volume or value," and "other business generated" standards. These provisions make it difficult to structure incentive payments that reward physicians for improvements in quality and efficiency. There are existing exceptions for compensation arrangements, such as the fair market value exception, bona fide employment exception, and personal services arrangement exception. However, gaps and ambiguities in these existing exceptions present challenges in designing systems that are highly efficient and avoid the negative incentives of a fee for service structure.

Congress took an important step toward recognizing the need for change in the fraud and abuse laws when it recently limited the application of gain-sharing to the failure to provide medically necessary services. The highly regulated nature of the alternative payment models guard against the possibility that patients will be denied care or will be given poor quality care. Therefore, we recommend that CMS continue to make changes and create new exceptions to enable financial arrangements that involve risk sharing and gain-sharing when appropriate safeguards are in place. It is critical that CMS, the OIG, and other associated agencies coordinate their efforts to allow waivers not only of the physician self-referral law, but also of the civil monetary penalties and anti-kickback laws, as appropriate to support the clinical and financial integration needed for the success of these new delivery and payment models.

Given the increasing prevalence of payment programs that focus on meeting well-defined quality standards combined with requiring participants to accept more risk, and the need to, at a minimum, allow for gain-sharing with physicians and others, it is time for Congress, CMS, and

the OIG to consider the many changes that should be made to various fraud and abuse laws. With the ample protections against program and patient abuse that are now, and increasingly will be, part of the Medicare program, the focus should be on simplifying the criteria for the waivers and exceptions and making them broadly available as an important tool to encourage wider participation.

Our recommendations for specific changes to the Stark law regulations, including establishing an exception for alternative payment models, refining the compensation exceptions, and revising the Academic Medical Center Exception are enumerated below.

Academic Medical Center Exception

The Stark law has an academic medical center exception that allows financial relationships involving flows of money in the academic medical center to support the missions of teaching, research, indigent care and community service. It requires the meeting of certain conditions related to: the referring physician, the compensation received by the referring physician, specific academic medical center requirements, organizations that qualify as academic medical centers, and terms of the overall relationship. While the AAMC is appreciative of the recognition that AMCs need an exception, in its current form the exception does not account for the many changes to academic medical centers that have occurred since the exception was first created. Therefore, we recommend several modifications described below.

The AAMC recommends that CMS make the following changes to modernize the AMC exception and provide clarification.

- Referrals to a faculty practice plan should be protected even if referring physicians include community physicians employed by, or affiliated with, the faculty practice plan or the teaching hospital that is a component of the academic medical center. As new delivery models emerge, there has been an increase in relationships with community physicians which enables more coordination and increased access to services for the community served by the academic medical center. The requirement that a certain percentage of time or hours per week be spent providing "academic services or clinical teaching services" could be replaced by a requirement that the physician fulfill the requirements of his/her employment contract/agreement with a component of the academic medical center. The contract will reflect the overall needs of the academic medical center and the community it serves, considering that some physicians will be involved in research, education and clinical care, while others will be heavily involved in clinical care.
- Support payments to a faculty practice plan that support the AMC's mission should be protected. Many academic faculty practices need support payments for a variety of reasons. For example, to make available the full range of services needed by the community, it may be necessary to support a particular department that is losing money, such as pediatric cardiology, burn surgery or specialist who treat diabetes. Were it not for the academic medical center's financial support, this service would be unavailable to the community. There also may be a need to support a department that is struggling financially to ensure that medical residents have available the sufficiently diverse

population that is needed for training, and the different sites of care needed for training. For example, many AMCs have maintained all of the medical and surgical subspecialties even though each of these services may not support their expenses.

- Language should be added that permits alternative payment arrangements that academic medical centers are participating in to come under this exception.
- The existing exception includes a test for compensation that must meet the "set in advance" requirement. CMS should delete this "set in advance requirement." Given the rapid changes in the needs of many academic medical centers, they should be provided with the flexibility to make changes during the year provided that any changes are not made retroactive. The exception does not contain a "set in advance requirement." AMCs should not be disadvantaged by being held to a higher standard. In effect, the AMC is the employer.

The AAMC also requests that CMS make clear that academic medical centers transfers of money for mission support are protected even if the AMC protects payments to physicians using another exception, such as indirect compensation or personal services. This would include a recognition that mission support includes providing the community with needed services that would otherwise be unavailable or for which access is extremely limited, for example, trauma services.

CMS Should Establish an Exception for Alternative Payment Models

The AAMC recommends that a new valued based "alternative payment model exception" be created to the Stark law to allow renumeration that is provided and received under such arrangements. These alternative payment models pose little risk of program or patient abuse and are intended to provide better quality care and greater efficiency.

The conditions set forth by the OIG and CMS that must be met to obtain a waiver from the self-referral and anti-kickback laws for providers participating in the Bundled Payment for Care Improvement (BPCI) Model, the shared savings ACO program, and the CJR model, could be used as guidance in creating this exception. This exception should be designed to protect models that: 1) promote accountability for quality, cost and care of patients; 2) require care management and coordination; and 3) involve investment in redesigning care processes to ensure high quality efficient care delivery.

Any renumeration that is provided and received under such a clinical integration arrangement between providers (e.g. hospitals) and physicians should be protected under this exception as long as the remuneration is reasonably related to and used to achieve the objectives of clinical integration. This exception should protect incentive payments, shared savings payments that are distributed from cost savings, and support provided to assist with implementation of the clinical integration arrangement (e.g. electronic health care records, data or clinical analysis tools).

This new exception would allow hospitals and health systems to take steps that will improve care coordination, lower costs, and improve quality. For example, hospitals, health systems and physicians work to coordinate care as a team to achieve lower costs and higher quality. These teams need to be able to share information about their patients to make appropriate decisions

about the patient's care. This requires maintaining systems that securely transmit information across sites of care. To achieve this coordination, hospitals may need to provide data analytic tools to physicians to assist them in treatment decisions. In its current form, the Stark laws make it difficult to provide such tools.

In addition, hospitals and health systems want to reward physicians who participate in the development and adhere to pathways to achieve the best outcomes in treating their patients. In the current system, linking incentive payments to such pathways could be prohibited under the Stark law. Also, hospitals would like to incentivize physicians to reduce unnecessary health care expenditures by selecting the most efficient and effective treatment options. Physicians can be motivated to achieve this goal by sharing in the cost-savings achieved while still maintaining high quality. It is unclear as to whether some of these cost-savings financial arrangements are allowed under the Stark law.

Compensation Arrangements

The Stark law was intended to prohibit compensation arrangements that would improperly encourage utilization of services. There are a number of exceptions for compensation arrangements, such as the fair market value exception, personal services arrangement, and bona fide employment relationship. However, the definitions of key terms used in most of the compensation exceptions are not clear and have resulted in different interpretations. Hospitals, health systems, and physicians spend an enormous amount of time and effort to determine whether they are complying with the compensations exceptions.

The three key elements that are included in the compensation exceptions, which are ambiguous, are: 1) the compensation must be fair market value; 2) the compensation must not be determined in a manner that takes into account the value or volume of Medicare referrals; and 3) the arrangement must be commercially reasonable. Our recommendations for modifications to each of these terms are included below:

Fair Market Value

Under the current definition, fair market value (FMV) must be established by reference to other prices for the same services in the community and agreed upon by both parties in an arm's-length transaction. The value must also be consistent with "general market" value, which is a price an asset would bring as a result of a bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business or compensate the other party. The requirement that parties may *not otherwise be in a position to generate business* was added by CMS in 2001 and has created considerable confusion. We recommend that CMS remove this requirement and define FMV as the value in arms-length transactions consistent with general market value. The definition of general market value should be modified to be the price of an asset or compensation for services that would result from bona fide bargaining between well-informed parties to the agreement. The reference in the current definition to the "volume or value of anticipated or actual referrals" should also be removed as it has resulted in significant confusion.

In addition, we recommend that CMS presume that compensation is fair market value if the hospital, health system, or physician received a valuation from someone with appropriate qualifications prior to entering into the arrangement. The burden of proof should be on the person challenging the valuation.

CMS should also ensure that the fair market value requirement allows incentive payment arrangements. There should be a recognition that it is difficult to determine whether a gain-sharing payment meets fair market value because payment under these arrangements is dependent on the total savings generated by participants in the APM. Concerns about fair market value in these situations should be addressed in other ways such as, for example, through setting safeguards related to quality, capping payments to physicians, and other criteria CMS identifies.

It is unclear if care management fees paid by a hospital to physicians need to satisfy the "fair market value" or "personal services" exception. Assessing fair market value can be challenging when hospitals seek to tie fees to the effect of care management on medical costs rather than time spent by physicians on the relevant activities.

Volume or Value of Referrals

Many of the Stark exceptions require that any compensation involved be calculated in a manner that does not take into account the volume or value of referrals between the parties. The meaning of "takes into account" has caused significant confusion and has been a barrier to innovative payment arrangements.

To address this barrier, we recommend that the main question that should be considered is whether the methodology used to set physician compensation was based on the volume or value of the physician's referrals. CMS should conclude that a fixed payment per service is deemed not to vary or take into account the volume or value of referrals if the amount is determined initially by a methodology that does not take into account referrals, and adjustments are not made based on referrals. While a payment might be made each time the service is provided, this is appropriate if the amount of the payment does not change.

In addition, CMS should affirm that when payment is based on a physician's personally performed services, the volume or value requirement is not implicated (even if those services result in an increase or decrease of delivery of services). Physicians are held accountable for ensuring that they provide only medically necessary services to their patients. Hospitals and physicians should be able to collaborate on efforts to improve quality and efficiency through bonus programs for quality, and shared savings arrangements.

Commercial Reasonableness

There is significant confusion over the definition of commercial reasonableness. It should not focus on determining whether the **amount** of the purchase is reasonable as that determination should fall under the category of "fair market value." We recommend CMS clarify that it means items or services purchased are useful and needed as part of the purchaser's business. It is possible that the purchase of a physician practice would result in a loss of money to the system;

however, it could still be commercially reasonable as it will help with improving care coordination and clinical integration.

Eliminate Requirement of Compliance with Antikickback Statute in Exceptions

The AAMC recommends that the requirement throughout the Stark exceptions that a compensation arrangement not violate the federal antikickback statute be eliminated. The self-referral law and the antikickback statutes are independent of each other and therefore this language should not be included in the Stark regulations. It creates another barrier to providers that are trying to comply with the exception as they then would have to go through the steps of proving they are complying with the antikickback statute, which is intent based.

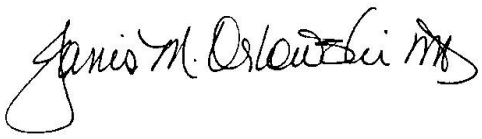
Advisory Opinions

We recommend that CMS take steps to improve the current advisory opinion process. Over the last 20 years, CMS has issued approximately 15 opinions regarding compensation issues. The small number of opinions is due to the fact that there are a limited type of questions that may be raised in the request and it takes a very long time to get a response to the questions that are accepted for review. As part of the advisory opinion process, CMS will not address general questions of interpretation and hypotheticals, which are the types of questions a hospital or physicians would find most useful to ask. We recommend that CMS expand the types of questions that would be accepted for an advisory opinion to allow those related to interpretation and hypotheticals. In addition, providers should be able to presume that the response to their question if favorable if they do not receive a response within 90 days of the completed request.

Conclusion

Thank you for the opportunity to present our views. If you have any questions, please feel free to contact Gayle Lee at 202-741-6429 or at galee@aamc.org or Ivy Baer, J.D., M.P.H., Senior Director and Regulatory Counsel, at 202-828-0499 or at ibaer@aamc.org.

Sincerely,



Janis M. Orlowski, MD, MACP
Chief Health Care Officer

cc: Ivy Baer, Gayle Lee