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August 24, 2018

The Honorable Alex M. Azar II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, NW  
Washington, D.C., 20201

Dear Secretary Azar:

On behalf of the AMGA, we appreciate the opportunity to comment on the “Medicare Program; Request for Information Regarding the Physician Self-Referral Law” (RIN 0938-AT64).

Founded in 1950, AMGA represents more than 450 multi-specialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one-in-three Americans. Our member medical groups work diligently to provide innovative, high quality patient-centered medical care in a spending efficient manner. Many of our medical groups already participate in the Medicare Shared Savings Program (MSSP) as Accountable Care Organizations (ACOs), the Next Generation ACO and the Comprehensive Primary Care + demonstrations, and in other Pay For Performance (P4P) demonstrations. AMGA has a strong interest in seeing improvements made to the Physician Self-Referral law so that more providers can participate and participate successfully in P4P programs and demonstrations.

In the Request for Information (RFI) the Centers for Medicare & Medicaid Services (CMS) recognizes “care coordination is a key aspect of systems that deliver value.” As a result, the agency, as the RFI states, “is focused on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care.” Further, the RFI states that, “CMS has identified some aspects of the physician self-referral law as a potential barrier to coordinated care.” CMS therefore invites public comment via a list of 20 questions on regulatory changes to the Physician Self-Referral law.

#### Preliminary Comment

The so-called Physician Self-Referral law, initially enacted in 1989 and formally titled the Ethics in Patient Referral Act, but more commonly referred to as the Stark law after its chief sponsor, former Rep. Pete Stark (D-CA), prohibits physicians from referring patients for “designated health services” payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship unless one of 35 exceptions applies. These health services include, for example, imaging, laboratory, and home health services. The law was designed to eliminate a physician's financial self-interest and reduce unwarranted or excessive utilization. Over the past several years, as CMS recognizes, Stark law has become

increasingly viewed as an impediment to care coordination and to P4P models that are designed to financially incent higher value services and lower spending growth. For example, the 2010 Affordable Care Act (ACA) gave CMS broad authority to waive Stark and four related laws to allow ACOs and bundled payment providers under the Bundled Payments for Care Improvement (BPCI), BPCI Advanced, and the Comprehensive Care for Joint Replacement (CJR) demonstrations to improve care coordination and continuity of care. The Congress has been considering reforms to Stark over the past several years. For example, on July 17 the House Ways & Means Health subcommittee heard testimony from four experts on reforming or modernizing Stark law.

CMS and the Congress are well aware that complying with Stark law even at baseline, or as applied outside of P4P or in fee-for-service Medicare, has become increasingly difficult to navigate in large part because of the ambiguity surrounding several provisions of the law. Leaving aside the law's strict liability provision that does not allow for considerations of provider intent, how exceptions to the law are defined are complicated. For example, answers to what constitutes a "referral," a "financial relationship," or an "entity" are not clearly drawn. Concerning the roughly three dozen exceptions, there are multiple kinds generally categorized under investment and ownership, compensation, and designated health services (DHS) in 10 categories. For example, the in-office ancillary services exception requires meeting a definition of a "group practice" that has eight standards, all of which have to be met at any one time. We note these facts because in its current form the law does not represent Rep. Stark's intention, as his goal was to establish bright line rules so that physicians could police their own conduct.

We argue below CMS can and should attempt to better manage Stark in an increasingly P4P payment world. This RFI is a good indication of the agency's intent. We also are encouraged that the Department of Health and Human Services, via comments by Deputy Secretary Eric Hargan, expects to publish a Stark proposed rule before the end of this calendar year. That said, AMGA is not confident creating new or improved regulatory exceptions will be ultimately successful. The agency would have to be able to propagate Stark-related regulatory relief that address three standards relevant to P4P or Alternative Payment Models (APMs): fair market value; the volume or value of referrals; and, commercially reasonable while at the same time also satisfy payment abuse or patient harm standards. (As an aside, CMS is well aware not all APMs under the Medicare Access and CHIP Reauthorization Act (MACRA) enjoy Stark protection. APMs need more than modifications to Civil Monetary Penalties law.) Attempts to accomplish this likely will lead to additionally lengthy and ambiguous, but not practical, relief. As the Senate Finance Committee concluded in its 2016 report, "Why Stark, Why Now?," "some commenters were not enthusiastic about creating additional waivers or exceptions to the Stark law because they believe that regulatory environment is already overly complex." We largely agree. Congressional action is ultimately required.

### Specific Comments

Our comments are limited to five of the 20 questions.

#1: Question one asks, in part, what "time frame of the arrangement (for example, ongoing or for a duration that aligns with a payer-specific initiative)" should be considered. We identify this question in context of the MSSP or ACOs. Over the past several years, AMGA members desirous of, or participating in, the MSSP have expressed concern their shared savings, patient incentive, and related waivers are dependent on program participation. While these waivers enable physician groups to alter their practice patterns to achieve improved care delivery and program

success, providers are de facto required to unwind these changes in practice patterns should they exit the MSSP. CMS is well aware of this issue. At a minimum, the agency should afford provider groups time to make adjustments such that going forward they are not in violation of Stark and accompanying waivers. CMS also should consider allowing provider groups to retain these waivers should they meaningfully participate in “other” or non-Medicare APMs via Medicaid and commercial plans. In addition, CMS should allow for Stark relief for a period of time for physicians who exit an ACO but continue to use the ACO's Electronic Health Record (EHR).

#2 and #3: Question two asks, in part, “what, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements,” and “what additional exceptions are necessary to protect accountable care organization models.” Question three asks, in part, “what exceptions are necessary to protect financial arrangements “that involve integrating and coordinated care outside of an alternative payment model?” In an effort to enhance care coordination among Medicare and non-Medicare payers, further leverage the agency's interest in bundled payment arrangements, and help level the playing field between MSSP and Medicare Advantage (MA), CMS could allow for anti-Stark behavior by comparatively decreasing reimbursement for ancillary services, bundle office and ancillary services, adopt a bundled payment plan that promotes shared risk among providers in an episode of care, And/or create a waiver once a risk revenue reaches a certain majority percent of the entity's total revenue.

#6: The RFI asks commenters to identify “possible approaches to address the application of the physician self-referral law to financial arrangements among participants in alternative payment models.” Generally, APMs, particularly if they share comparable financial risk thresholds, should enjoy the same Stark and other waivers as the MSSP under the ACA and/or under Medicare prepaid plans.

#16: Stakeholders are asked to comment on the role of transparency or whether “transparency about physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing . . . reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address.” In general, AMGA supports increasing program transparency. For example, we are encouraged by the transparency provisions noted in the current Physician Fee Schedule proposed rule, as well as CMS' efforts to develop Blue Button applications to increase beneficiary use of claims data, and the decision earlier this year to publicize Medicare Advantage encounter data. While we neither believe providing beneficiaries greater transparency is sufficient, nor do we believe CMS could adequately “design a model to test whether transparency safeguards . . . could effectively address the impact of financial self-interest on physician medical decision-making,” it would likely prove to have intrinsic worth. While AMGA supports increased transparency, we are well aware beneficiaries or patients largely do not shop when healthcare is “shoppable.” For example, as [a recent working paper by the National Bureau of Economic Research](#) demonstrated, when Magnetic Resonance Imaging (MRI) prices varied by 700%, patients largely chose to ignore the potential savings.

We thank CMS for consideration of our comments. Should you have questions please do not hesitate to contact AMGA's David Introcaso, Ph.D., Senior Director of Public Policy at (703) 842.0774 or at [dintrocaso@amga.org](mailto:dintrocaso@amga.org).

Sincerely,

A handwritten signature in cursive script that reads "Jerry Penso". The signature is written in a dark grey or black ink on a white background.

Jerry Penso, M.D., M.B.A.  
President and Chief Executive Officer  
AMGA