acofp AMERICAN COLLEGE OF OSTEOPATHIC FAMILY PHYSICIANS
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December 31, 2019

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P

Dear Administrator Verma,

On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled *Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations* (CMS-1720-P).

ACOFP is the professional organization representing more than 20,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation's health care system by improving health care delivery and outcomes and ensuring that patients receive high-quality care.

As an organization with many osteopathic family physicians in solo, small and rural practices, we appreciate efforts to reduce physician administrative burden and policies that recognize and support primary care services. Family physicians play a critical role in improving the overall health of Americans and serve as the lynchpin in value-based care. We believe changes to the physician self-referral (Stark Law) regulations, in addition to changes to the Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) rules regarding beneficiary inducements, are critically necessary to supporting improved care delivery.

Our full comments are detailed on the following pages. Thank you for the opportunity to share our feedback with you. Should you need any additional information or if you have any questions, please feel free to contact ACOFP at advocacy@acofp.org or (847) 952-5100.

Sincerely,

Robert C. DeLuca, DO, FACOFP *dist.*
ACOFP President

1. Value-Based Compensation Arrangements

In general, ACOFP supports the transition from a fee-for-service payment model to one that supports value and improved outcomes. Specifically, we support efforts to focus on patient-centered, value-based care. We support this transition and believe that the proposed changes take steps in the correct direction. As we have previously commented to CMS, increased access to primary care is more likely to result in preventive services and treatment for medical conditions before they become chronic and costly to treat. Primary care: (1) increases access for underserved populations; (2) improves quality of care; and (3) leads to improved prevention, early management of health problems, and more appropriate care (i.e., reduces unnecessary or inappropriate specialty care), all of which reduce overall health care costs.

ACOFP supports the proposed new exceptions to Stark Law related to value-based compensation arrangements. Value-based care emphasizes wellness and prevention, which are at the core of our osteopathic philosophy and training. We believe **the proposed definition of "value-based purpose" aligns with and can support our osteopathic mission**. Our expectation is that this will incentivize value-based enterprises to partner with physicians delivering high quality primary care as this can reduce unnecessary or avoidable high-cost specialty care. In terms of how to determine quality and whether costs are reduced, we believe there is a straightforward way to monitor costs and services avoided that resulted from increased access to primary care.

With respect to the types of value-based compensation arrangements proposed, **we support the various levels of risk and corresponding requirements**. This is in alignment with CMS' consideration that value-based arrangements (VBAs) with higher levels of financial risk present fewer fraud and abuse risks, meaning there should be fewer restrictions that allow the greatest flexibility. However, we urge CMS not to limit the scope of these VBA exceptions to nonmonetary remuneration. The agency also should consider additional flexibility how these arrangements can be implemented. These arrangements have historically resulted in imbalances between physician practices and larger entities. We recognize the variability and options across the tiered VBAs, but remain concerned that these may be to the detriment of or exclude certain small and rural practices from fully participating in VBAs. For example, in our response to the Office of Inspector General proposed rule on the AKS and beneficiary inducements CMP, we recommend limiting the compliance program requirement such that the value-based enterprise is required to have an accountable body or person that is responsible for compliance. This onus should not be placed on solo, small, or rural VBA participants. The requirements and program integrity protections proposed as part of each VBA should be sufficient to ensure there are minimal fraud and abuse risks.

CMS also proposes a conforming change to the Group Practices rule to ensure consistency with the new VBA exceptions. While we appreciate the proposed consistency between this rule and the newly proposed exceptions, **we have concerns that this proposal may limit the flexibility available to operate within a VBA**. We therefore encourage CMS to ensure that this change does not unnecessarily limit financial arrangements to the detriment of VBAs with significant risk-sharing.

2. Other Proposed Changes to Existing Stark Law Regulations

Limited Remuneration to a Physician

ACOFP supports CMS' proposed exception that would permit remuneration to a physician for items and services not to exceed $3,500 per calendar year. We encourage the agency to finalize this exception as proposed.

Cybersecurity Technology and Related Services

ACOFP supports the proposal to protect nonmonetary remuneration of cybersecurity technology and related services. Many of our members are in small or solo practices and maintaining technological services, including related to cybersecurity, have been increasingly challenging. While we recognize CMS' concerns with regards to the provision of hardware, we encourage CMS to expand this protection to include hardware donations. As evidenced by recent data breaches and the increasing prevalence of malware and cyberattacks, both cybersecurity hardware *and* software are critical elements of ensuring patient information is protected.

In addition, there are many instances of ransomware putting essential functions at risk. As the health care system continues to move toward electronic health records (EHRs) and interoperability, such ransomware attacks can derail patient care and care coordination. Physician practices want to protect their patients and protecting their electronic systems is a key component of this. As such, we do not believe a 15 percent contribution is necessary to ensure donated hardware is used to improve cybersecurity and urge CMS to finalize its proposal to exempt small and rural providers from this contribution requirement. We believe any contribution requirement will inhibit the use of cybersecurity systems, leaving the more vulnerable points of the health care continuum at risk of cyberattacks.

Electronic Health Records Items and Services

ACOFP supports CMS' proposed updates to the EHR exception provisions. Specifically, we support:

- Modifications to the interoperability and information blocking definitions. We believe these changes will provide additional clarity for physicians and ensure consistency across various Federal efforts.
- Eliminating the sunset provision of the EHR exception. This exception will continue to be needed and is relevant absent a significant legislative change to the Stark Law. By ensuring there is no later sunset date, this will provide flexibility for practices to continually improve and advance EHR capabilities.
- Eliminating the 15 percent recipient contribution requirement. As noted above, physicians are inherently incentivized to use and deploy technological advancements to improve care and protect patients.

ACOFP also recommends that CMS eliminate any restrictions or limitations that would inhibit needed technology upgrades, updates, or replacement, both for EHR hardware and software. This flexibility is needed to ensure physicians are continuously mindful of and do not face barriers to ensuring their systems are up-to-date and interoperable with those of their health care partners.

3. Additional Flexibilities

In general, ACOFP supports proposed changes that offer more flexibility in health care delivery and eliminate the pitfalls of minor or benign errors. First, we strongly support the proposed protection that would create a 90-day grace period for the writing or signature requirement of any compensation exception. The writing or signature requirement has resulted in administrative errors and subsequent penalties for missteps that were not the intent of the Stark Law. This is much needed flexibility so that physician practices are not unduly punished for mere clerical errors. Second, we support the proposed modifications and clarifications related to designated health services (DHS), including with respect to compensation unrelated to DHS. We agree with CMS that the current

permissible exception is too restrictive, and we appreciate the clarity that establishes a brighter line between designated health services and non-patient care services that could be provided by non-licensed medical professionals.

We commend the agency for considering past comments and proposing much needed changes to the Stark Law to support coordinated care and to eliminate undue burden for physicians.