American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

December 31, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-8013

CMS-1720-P

Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Proposed Rule

Dear Administrator Verma:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to respond to a proposed rule that modifies the physician self-referral law to help support value-based care.

Before we offer our specific comments on the proposed rule, we would like to reiterate our request for the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) to create more opportunities for emergency physicians to participate in alternative payment models (APMs). Emergency physicians play a vital role in their communities, serving as safety-net clinicians who care for people at their greatest time of need. As we treat each patient, we must make a critical decision about whether the patient should be kept for observation, admitted to the hospital, or discharged. Fundamentally, we act as a gateway to the hospital for many patients and are, therefore in a prime position to be meaningful participants in APMs that attempt to shift our health care system to one that rewards value over volume. However, while many emergency physicians are ready to take on downside risk and participate in Advanced APMs, there simply are not any opportunities to do so. ACEP has developed its own proposed physician-focused payment model that was submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), called the Acute Unscheduled Care Model (AUCM). The PTAC recommended the AUCM to the HHS Secretary for full implementation. On September 27, 2019, Secretary Azar responded to the PTAC's recommendation by stating that he believes that core concepts of the AUCM should be incorporated into APMs that CMS' Innovation Center (CMMI) is developing. We look forward to working with CMMI to advance emergency patient care through the implementation of this model.

With respect to the physician self-referral law, given all the consolidation in health care, especially with health systems purchasing provider practices, it is difficult for the average physician to know for sure whether some of the care coordination they are providing is legally permissible. Therefore, we appreciate the CMS' attempt to make modifications to the law that are necessary to remove unnecessary government obstacles to coordinated care. However, we also believe that it may be difficult for physicians, especially those practicing in rural areas or as part of small group practices, to comply with some of the new exceptions that CMS is proposing. Our comments

WASHINGTON, DC OFFICE
2121 K Street NW, Suite 325
Washington, DC 20037-1886

202-728-0610
800-320-0610
www.acep.org

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below focus on those proposed policies that could potentially impact emergency physicians and the patients we serve, as well as point out those proposals that we believe would create a significant administrative burden.

Facilitating the Transition to Value-Based Care and Fostering Care Coordination

Proposed Definitions

In general, ACEP supports the specific definitions CMS proposes in this section of the rule: value-based activity, value-based arrangement, value-based enterprise, value-based purpose, and target patient population. However, we do have a few comments on two of the definitions to ensure that emergency physicians (once we have more opportunities to participate in APMs) can take advantage of the newly created exemptions to the physician self-referral law.

Value-Based Enterprise

While ACEP appreciates that CMS is allowing two individuals or entities to join together to form a value-based enterprise (VBE), we are concerned that some of the requirements that are being proposed are overly burdensome and complicated—potentially requiring legal consultation before the VBE can actually be established. Specifically, CMS is proposing that two individuals must have a written agreement in place to form an VBE and that one individual or entity must be responsible for financial and operational oversight of the VBE. Although such requirements make sense for large VBEs, we believe that they could pose a barrier to the formation of VBEs between two small physician practices. With respect to the written agreement requirement, while we understand that CMS' intention is for the agreement to be informal and non-standardized, we still believe that many individuals or entities would still feel more comfortable consulting a lawyer to ensure that they met all regulatory requirements—thereby creating a potentially expensive additional cost. Further, requiring one individual or entity to be responsible for financial and operational oversight of the VBE could pose a major barrier to forming a VBE. There could be future instances where a small emergency physician practice wants to enter into a VBE with a primary care practice to better coordinate care for a subset of patients that are discharged from the ED. However, having to decide which of these two practices would have the oversight responsibility could create a significant amount of tension in the negotiation process. Granting one practice with this responsibility would inherently make that practice more powerful than the other, thereby eliminating the opportunity for the two practices to enter into an equal partnership. **ACEP, therefore, requests that CMS not finalize these requirements for smaller VBEs,** especially those between two individuals or small physician practices.

ACEP is also opposed to the proposed requirement that a VBE have a compliance program. While we appreciate the need for accountability and for compliance programs, this proposed requirement would create an additional burden without substantially reducing the risk of program fraud and abuse. It would also exacerbate the growing problem of physician burnout and potentially decrease the desire to participate in value-based arrangements.

Target Patient Population

ACEP generally agrees with the proposal to establish the target patient population based on legitimate and verifiable criteria. We also support allowing a VBE's entire patient population to be considered part of the target patient population. However, we oppose limiting the definition of the target patient population to patients with chronic conditions. Such a restrictive definition would make it difficult for emergency physicians to participate in VBEs, since much of the care we provide is for acute rather than chronic conditions, or (potentially complicating things further) for an acute exacerbation of an underlying chronic condition. Having the ability to coordinate care for patients with

acute conditions could also improve overall population health since we would be ensuring that they receive appropriate and timely care before they potentially get a chronic disease.

Proposed Exceptions

CMS is proposing three exceptions for compensation arrangements: 1) full financial risk; 2) meaningful downside financial risk; and 3) general "value-based arrangements" (which could include zero risk arrangements). The Office of Inspector General (OIG) also proposes similar safe harbors to the anti-kickback statute in its companion proposed rule,[1] and we urge CMS and OIG to align their final policies to the extent possible. ACEP does not foresee many of our members taking advantage of the full financial risk exception, so our comments are limited to the other two proposed exceptions.

Value-Based Arrangements with Meaningful Downside Financial Risk

ACEP believes that this exception would most commonly apply in a case where a physician participates in an APM that requires downside financial risk. While "downside financial risk" in APMs typically means that the participant is liable for some or all financial losses compared to a pre-determined spending benchmark, we request that for the purposes of this exception, CMS expand the scope of the definition of downside financial risk to include infrastructure, health information technology, and other operational costs that the physician invests in to participate in an APM. By allowing these costs to count as "downside financial risk," CMS could expand the APMs that could fall under this exception to include "upside-only" APMs. Even in APMs where physicians are not liable for losses, they still have to put in significant resources to be successful and are at risk of losing that investment if they are unable to receive a shared savings payment or other types of payment bonuses under the APM.

Further, ACEP opposes CMS' proposal to define "meaningful downside financial risk" as requiring a physician to pay an entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. This percentage is too high (significantly higher than what most current downside risk APMs require) and would limit the ability of a physician to participate in a value-based arrangement and receive protection under this proposed value-based exception. ACEP, therefore, recommends that meaningful downside financial risk be defined at 5 percent to support physician participation in value-based arrangements.

General Value-Based Arrangements Exception

ACEP supports this exception as it would potentially allow emergency physicians and other physicians who do not have an opportunity to be in a traditional APM to participate in a value-based arrangement. We also support CMS' proposal that the exception permits both monetary and non-monetary remuneration between parties and are opposed to limiting the scope of the proposed exception to non-monetary remuneration. We do have concerns with potentially requiring a recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the nonmonetary remuneration. This potential contribution requirement would add unnecessary burden, complexity, and potentially be cost-prohibitive to small and rural physician practices. If CMS were to add a contribution requirement, the agency should at least exempt small and rural practices. Further, CMS

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[1] Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements Proposed Rule, 84 Fed. Reg. (October 17, 2019).

should create a flexible minimum amount that is based on the size of the participating physician practice, instead of finalizing an arbitrary threshold of 15 percent.

Price Transparency

CMS is seeking comment on how to promote price transparency in the context of the physician self-referral law and whether to potentially include any price transparency requirements in the physician self-referral regulations. Overall, we do not think that the physician self-referral regulations are the appropriate place to add new price transparency requirements. However, before discussing our rationale for why we would oppose such a proposal, we have some overarching comments about how price transparency should be applied to emergency care.

In general, ACEP applauds the Trump Administration's effort to improve price transparency in health care. However, as CMS considers imposing any new requirements, we urge you to keep in mind issues that are unique to emergency care. As emergency physicians, we are bound by the Emergency Medical Treatment and Labor Act (EMTALA). This law stipulates that a hospital may not place any signs in the ED regarding the prepayment of fees or payment of co-pays and deductibles, which can have the chilling effect of dissuading patients from "coming to the emergency department." To do so could lead patients to leave prior to receiving a medical screening examination and stabilizing treatment, which as a fundamental condition for satisfying EMTALA are provided without regard to financial means or insurance status. If we attempt to get pricing information to patients prior to stabilizing them, not only would that violate EMTALA (one of the most foundational principles of this important patient protection since it was enacted three decades ago) , but it could also potentially cause the patient's health to deteriorate since it could delay the patient from receiving critical care. The last thing we want to do is put our patients in a position of making life-or-death health care decisions based on costs.

During emergencies, a patient's concern should be focused on receiving the appropriate care, rather than choosing their emergency care based on cost. In the ED, minutes and seconds matter, and emergency physicians are often required to exercise their best clinical judgment quickly. Patients who have life-threatening illnesses and injuries obviously do not have the ability to shop around for the "lowest cost" clinician. Furthermore, in delivering acute care, knowing what patients' total out-of-pocket costs will be before they are diagnosed and stabilized is nearly impossible until a proper course of medical care and progression is followed. A large proportion of emergency care involves the acute diagnosis, treatment, and stabilization of diffuse and undifferentiated clinical conditions. For example, two of the most common patient presentations are "chest pain" and "abdominal pain." These initial symptoms have a large range of ultimate diagnoses and require a large variety of patient-specific lab tests, radiology exams, and other interventions. This is very different from being able to figure out total costs for an urgent care patient with a small, clean, superficial laceration or a sore throat. Further complicating the issue is the fact that emergency care is billed in two separate components, the facility fee, and the professional fee. Therefore, patients must sort through costs included in at least two different bills, each of which may have different cost-sharing obligations associated with it.

Since there are so many variations in coverage amongst patients (even within an insurer's own product), it is virtually impossible for a provider to know the nuances for a particular patient. Therefore ACEP strongly believes that insurers should be the entities responsible for clearly providing information to consumers about the potential costs of seeking care under their particular coverage. With respect to emergency care, insurers should clearly provide information to consumers prior to the emergency (potentially at the point when the consumer obtains the coverage) about potential costs of emergency treatment. Physicians and other health care practitioners can participate by helping patients interpret their cost-sharing responsibilities, but the onus should be on insurers to make these costs transparent to

patients since they know exactly what the patient's cost-sharing requirements are. Patients today truly do not understand their "high deductible" health plans, and there is a dearth of information on "co-insurance," "deductibles," and "co-pays." Many times, patients receive a covered service but are unexpectedly required to pay the whole cost out-of-pocket because they have a large deductible that has not been met. In all, while physicians and hospitals may be able to provide raw pricing information upfront to patients in non-emergency situations, without accompanying information from insurers concerning the manner and methodology the insurer has utilized to adjudicate the patient's benefits, little can actually be achieved in the form of true transparency. In fact, this information from insurers is an essential component of transparency.

Since insurers are not subject to the physician self-referral law, applying price transparency requirements to the physician self-referral regulations would be inappropriate and would hold the wrong party (physicians) accountable under a strict liability statute. **Therefore, we oppose adding any new price transparency requirements in any existing or proposed physician self-referral exceptions.**

Fundamental Terminology and Requirements

Commercial Reasonableness

ACEP supports the proposed clarification that an arrangement may be commercially reasonable even if it does not result in profit for one or more parties. For example, hospitals, to meet EMTALA and other community obligations, may need to hire physicians to provide services, even if it does not make a profit off of those physicians. However, to avoid confusion, ACEP recommends that the CMS definition of "commercially reasonable" be consistent with the definition included in OIG's proposed rule.

The use of the phrase "legitimate business purpose" may also not be sufficient to provide enough certainty regarding compliance. Requiring that an arrangement be "on similar terms and conditions as like arrangements" is ambigious as clinicians may not be able to discern which arrangements would truly be similar. There are a number of scenarios to consider that could prove problematic, including situations where the entity does not have knowledge of similar arrangements or where there is a new payment arrangement that has no similarities to existing models. One reason clinicans may be unaware of similar arrangements is because they are afraid of potentially violating antitrust or anticompetitive regulations. Thus, any additional guidance CMS could provide to help interpret "legitimate business purpose" would be appreciated.

Recalibrating the Scope and Application of the Regulations

Proposed Definitions

Designated Health Services

ACEP supports the proposal to revise the definition of "designated health services" (DHS) to clarify that a service provided by a hospital on an inpatient basis does not constitute a DHS if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Inpatient Prospective Payment System (IPPS). However, we seek clarification as to what constitutes an admission or a referral for admission to a hospital and whether that definition would impact whether the service is a DHS. Patients can come into a hospital in different ways, including a physician instructing a patient to go to the ED, an emergency physician indicating in the medical record that a

patient should be admitted (which causes the patient to be admitted), or the patient was sent to the hospital to receive hospital services.

Electronic Health Records Items and Services

Information Blocking

Currently, the physician self-referral law prohibits a donor (or any person on the donor's behalf) of electronic health records (EHRs) from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems. Overall, ACEP appreciates and supports CMS' efforts to update the definitions of information blocking to align with those included in the 21st Century Cures Act. However, we do have concerns with CMS' repeated references in the preamble to the Office of the National Coordinator (ONC) for Health Information Technology Interoperability and Information Proposed Rule[2]. While we believe that the ONC proposed rule is a step in the right direction to reduce information barriers and improve access to data, we are concerned about the additional burdensome of the proposals in that rule would place on physicians, from investing in and adopting new technology to understanding all of the new definitions and exceptions around information blocking. Therefore, we recommend that CMS refrain from making references to the ONC proposed policies and only focus on definitions and requirements that are explicitly laid out in the statute.

15 Percent Recipient Contribution

ACEP is opposed to the current 15 percent contribution requirement to receive protection under the EHR exception. The contribution requirement adds unnecessary burden, complexity, and can potentially be cost-prohibitive. If CMS were to continue with the contribution amount, CMS must have an exception for small, underserved, and rural practices. While we oppose contributions generally, the contribution amount imposes a significant financial burden on small, underserved, and rural practices that could negatively impact patient care.

Providing Flexibility for Nonabusive Business Practices

Cybersecurity Technology and Related Services

ACEP strongly supports the proposed cybersecurity technology and related services exception. We, along with the overall physician community, are concerned that our nation's physicians and patients have been insufficiently prepared to meet the cybersecurity challenges of an increasingly digital health care system. We believe efforts like the proposed exception can help address these challenges and will be an important element of an overall national strategy that improves the safety, resilience, and security of the health care industry.

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[2] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, 84 Fed. Reg. (March 4, 2019).

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

William P. Jaquis, MD, MSHQS, FACEP

ACEP President