

December 31, 2019

Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5521
330 Independence Avenue, SW
Washington, DC 20201

OIG-0936-AA10-P

Re: 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

Dear Acting Inspector General Chiedi,

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 anti-kickback statute and civil monetary penalty (CMP) rules to help promote 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) 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 Centers for Medicare & Medicaid Services (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 anti-kickback statute, 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 Office of the Inspector General's

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(OIG's) attempt to make modifications to the statute 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 safe harbors that OIG is proposing. Our comments 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.

Proposed Value-Based Terminology

In general, ACEP supports the specific definitions OIG proposes in this section of the rule: value-based enterprise (VBE), value-based arrangement, target patient population, value-based activity, VBE participant, and value-based purpose. We also appreciate OIG's attempt to align these definitions with those found in CMS' companion proposed rule that modifies the physician self-referral law.¹ However, we do have a few comments on three of the definitions to ensure that emergency physicians (once we have more opportunities to participate in APMs) can take advantage of the newly created safe harbors to the anti-kickback statute.

Value-Based Enterprise

While ACEP appreciates that OIG 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, OIG is proposing that two individuals must have a written agreement in place to form a VBE and that the VBE must have an accountable body that is 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 OIG's 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 the VBE to create an accountable body that is 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. For such a small VBE, the accountable body would likely be one of the physician practices. Having to decide which of the 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 OIG 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

¹ Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule, 84 Fed. Reg. (October 17, 2019).

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.

Value-Based Activity

ACEP supports excluding from the definition of “value-based activity” any activity that results in information blocking. Overall, ACEP appreciates and supports HHS’ 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 OIG’s repeated references in the preamble to the Office of the National Coordinator (ONC) for Health Information Technology Interoperability and Information Proposed Rule². 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 burdens some 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 OIG refrain from making references to the ONC proposed policies and only focus on definitions and requirements that are explicitly laid out in the statute.

“Care Coordination Arrangements” Safe Harbor

ACEP supports the intent of the Care Coordination Arrangements safe harbor as it would potentially allow emergency physicians and other physicians who do not have an opportunity to be in a traditional APM with downside financial risk to participate in a value-based arrangement. However, unfortunately, we believe that it would be extremely difficult for our members to comply with all of the safe harbor’s proposed requirements if finalized. OIG is imposing 11 requirements and seven definitions for this safe harbor, while at the same time, limiting it only to “in-kind remuneration.” For small and rural practices, it may not be worth implementing these requirements to get a safe harbor with such a limited scope.

We are specifically opposed to the requirement that the value-based arrangement must include one or more specific evidence-based, value outcome measures which carry a “reasonable expectation” that it will advance the coordination and management of care of the target patient population. The proposal is administratively burdensome, confusing, and does not reflect the lack of valid outcome measures for many specialty practices. Overall, there are not many outcome measures in the Medicare program, and emergency physicians and other specialists should not be penalized for something that is out of their control. OIG should be incentivizing and encouraging good patient care and not the existence of outcome measures for the sake of having outcome measures. Small, underserved, and rural practices do not have the resources to develop these measures internally, which could lead to the further consolidation of the health care system. Therefore, we encourage OIG not to finalize this requirement or, at minimum, create an exception for certain small and rural-based VBE participants. Alternatively, OIG could consider expanding the definition of an outcome measure to include some existing measures that are technically process-based but do include strong evidence that fulfillment of the measure, such as providing or not providing a specific treatment, will improve patient outcomes or safety.

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

In addition, we are opposed to OIG limiting the safe harbor to the protection of only in-kind, non-monetary remuneration. We believe the safe harbor should also protect monetary remuneration. To help physicians achieve the goals of value-based care, physicians should be able to receive monetary incentives for shared savings to facilitate coordinated care and promote well-designed alternative payment models. Further, limiting remuneration to “in-kind” remuneration would prevent physician practices in VBEs from hiring their own care managers or other staff. These care managers would have to rely on people employed by a central entity, who may or may not integrate effectively with the physician and the physician’s own team.

Finally, we strongly oppose OIG’s proposal that the recipient of the in-kind remuneration pay “at least 15 percent of the offeror’s cost.” The contribution requirement adds unnecessary burden, complexity, and can potentially be cost-prohibitive. If OIG were to add a contribution requirement, it should at least exempt small and rural practices. Further, OIG should create a flexible minimum amount that is based on the size of the participating VBE participant, instead of finalizing an arbitrary threshold of 15 percent.

Value-Based Arrangements with Substantial Downside Financial Risk

ACEP believes that this safe harbor 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 safe harbor, OIG 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,” OIG 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.

OIG also states that in the case of a VBE participant that is a physician, a payment that meets the requirements of the physician self-referral law’s regulatory exception for value-based arrangements with “meaningful downside financial risk.” As discussed in our comments on the CMS companion proposed rule, 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. We therefore recommend that meaningful downside financial risk be defined at 5 percent to support physician participation in value-based arrangements.

Patient Engagement and Support Safe Harbor

ACEP overall supports OIG’s proposed safe harbor to protect certain arrangements for patient engagement tools and supports to improve quality, health outcomes, and efficiency furnished by VBE participants to specified patients. However, we encourage OIG to broaden the scope of the safe harbor to include any arrangement involving patient engagement tools or supports, not only those that include some element of downside financial risk. This proposed limitation would make it difficult or impossible for many of our members who do not have the opportunity to participate in downside risk arrangements to take advantage of this safe harbor. It would also disadvantage small and rural practices that would serve patient populations that would greatly benefit from providing patient engagement tools and supports.

Further, we strongly support OIG’s proposal to include supports and services that are designed to identify and address patients’ social determinants of health. We appreciate that OIG and HHS recognize the importance of social determinants of health to a patient's overall health. In both the public and private sectors, many interventions have been developed in recent years to help identify barriers to health, such as transportation and access to food and housing. One such tool that ACEP supports to help manage care for patients with complex needs is the Collective Medical Technologies’ (CMT) Edie™ (a.k.a. PreManage ED) software. Edie™ is an information exchange that provides critical information on patients, such as how many ED visits patients have had in the last year, where they presented, their drug history, other providers who are involved with the patients, and finally, whether there is a patient-specific care management plan that could guide treatment. The platform improves patient care by allowing emergency physicians to make more informed clinical decisions and better direct a patient’s follow-up care. It also lowers health care costs through a reduction in redundant tests and through better case management that reduces hospital readmissions. Through an alliance with CMT, ACEP has seen this system mature in approximately 17 states. Washington state, in its first year alone, experienced a 24 percent decrease in opioid prescriptions written from emergency departments, a 14 percent reduction of “super-utilizer” ED visits, and state Medicaid savings of more than \$32 million.³

Care Delivery and Payment Arrangements & Beneficiary Incentives Safe Harbor

ACEP strongly supports the proposed safe harbor that would uniformly cover all CMS-sponsored APMs, including CMMI models. Currently, OIG undergoes an extensive review process to provide a fraud and abuse waiver for every individual CMMI model, thereby impeding the ability for CMMI to implement new APMs in a timely manner. As discussed above, ACEP has developed our own APM, the Acute Unscheduled Care Model (AUCM), that Secretary Azar has asked CMMI to explore incorporating into other APMs that are being developed. We hope that this new safe harbor will help speed up the process for which models like ours are actually implemented and can start improving patient care. We also request that OIG urge CMS to provide a similar physician self-referral exception for CMMI models.

Cybersecurity Technology & Related Services

ACEP supports the proposed cybersecurity technology and related services safe harbor. 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.

Electronic Health Records Safe Harbor

OIG proposes several changes to the existing electronic health record (EHR) safe harbor to align with the provisions of the 21st Century Cures Act. While we appreciate OIG and HHS’ commitment to addressing information blocking, we would like to reiterate our “Value-Based Activity” comments above regarding ONC’s proposed rule and request

³ <https://www.acepnow.com/article/emergency-department-information-exchange-can-help-coordinate-care-highest-utilizers/2/>

that OIG focuses more on what is provided in the statute regarding information blocking rather than what is in the ONC proposed rule.

ACEP also opposes the current 15 percent contribution requirement to receive protection under the EHR safe harbor. The contribution requirement adds unnecessary burden, complexity, and can potentially be cost-prohibitive. OIG is seeking comment on whether to eliminate the requirement or exclude certain individuals or entities, such as small and rural practices. While we encourage OIG to eliminate the requirement entirely, if OIG were to continue with the contribution amount, there must be an exception for small, underserved, and rural practices.

Local Transportation Safe Harbor

ACEP supports OIG's proposals related to the local transportation safe harbor. It is critical that patients have access to a full range of health care services, and helping individuals with their transportation needs is essential to achieving that goal. People who do not have access to care are more likely to defer seeking more routine care or visiting a primary care physician or specialist for more minor conditions or symptoms. Such deferral or delay will often result in their condition or symptoms becoming exacerbated and eventually, result in a trip to the ED. At this point, due to the progression of their condition, their care in the ED will be much costlier and more complex than if they had earlier access to more routine care in a physician's office.

OIG is specifically proposing to expand the distance in which residents of rural areas may be transported from 50 to 75 miles, and to remove any mileage limit on transportation of a patient from a health care facility from which the patient discharged to the patient's residence. With respect to the latter proposal, we encourage OIG to expand such transportation beyond inpatient discharges to include a patient that has been seen in the ED or under observation status at a hospital but not admitted.

ACEP is also supportive of the concept of expanding the local transportation safe harbor to include transportation for health-related, non-medical purposes that improve or maintain health. This transportation would potentially include going to food stores, food banks, or social services facilities. As stated above in our comments on the "Patient Engagement and Support Safe Harbor," we believe that addressing a patient's social determinants of health is essential to improving their overall health. Therefore we encourage OIG to consider finalizing such an expansion to the local transportation safe harbor.

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