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Joanne Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Attention: OIG-0936-AA10-P, Room 5521
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Acting Inspector General Chiedi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments to the Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty (CMP) Rules Regarding Beneficiary Inducements proposed rule (RIN 0936-AA10) about how the anti-kickback statute and the CMP law imposes undue burdens on physicians and serve as obstacles to coordinated care and efforts to deliver better value and care for patients. We commend the U.S. Department of Health and Human Services (HHS) and the Office of Inspector General (OIG) for focusing on removing unnecessary government obstacles to coordinated care, real or perceived, caused by the anti-kickback statute and CMPs. In updating the regulations, OIG should allow physicians to receive payment for the value of care provided and promote competition and choice by allowing physicians the same opportunities hospitals have in delivering care.

Overall, while supportive of the intent and direction of the proposed safe harbors, the AMA is concerned about the level of administrative burden required to comply with these proposed requirements especially on small, underserved, and rural practices. The increasing amount of administrative responsibility, reporting requirements, and monitoring forced upon physicians adds unnecessary costs not only to practices and the Medicare program but also negatively impacts patient care. Unnecessary administrative tasks undercut the patient-physician relationship. For example, studies have documented lower patient satisfaction when physicians spend more time looking at the computer and performing clerical tasks.¹ Moreover, for every hour of face-to-face time with patients, physicians spend nearly two additional hours on administrative tasks throughout the day. The increase in administrative tasks is unsustainable, diverts time and focus away from patient care, and leads to additional stress and burnout among physicians.²

¹ Street RL et al., *Provider Interaction with the Electronic Health Record: The Effects on Patient-Centered Communication in Medical Encounters*. Patient Educ. Couns., 2014; Kazmi Z, *Effects of Exam Room EHR Use on Doctor-Patient Communication: A Systematic Literature Review*. Inform Prim Care, 2013; Farber NJ et al., *EHR Use and Patient Satisfaction: What We Learned*. J Fam Pract 2015.

² Sinsky C et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*, Annals of Internal Medicine 2016.

By reducing or not creating new administrative burden, OIG can support the patient-physician relationship and let physicians focus on an individual patient's welfare and, more broadly, on protecting public health. Accordingly, throughout our comment letter, we make recommendations that will help reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care. For our detailed comments, please see below.

- a. Proposed Value-Based Terminology
 - i. Value-Based Enterprise (VBE)
 1. Two or More VBE Participants

The AMA appreciates the OIG providing for the ability of a value-based enterprise (VBE) to be informal and be between two individuals or entities. However, OIG needs to recognize the reality that while a VBE can be between two individuals, most circumstances will require legal consultation and drafting of an agreement. These costs—along with other requirements proposed for the value-based safe harbors—could be prohibitive for a small, underserved, and rural practice to enter into a VBE. To address this concern, the AMA recommends that CMS and OIG have an optional online portal for value-based enterprises to register their value-based arrangement. This concept is discussed further below.

2. Party to a Value-Based Arrangement

The AMA does not oppose the proposal that each VBE participant must be a party to a value-based arrangement. However, the AMA is concerned about the timing of including all participants prior to participating in the VBE. Individual physicians or other clinicians should not be prevented from providing value-based care to patients because they have not formally been added to a value-based arrangement. Thus, OIG should create a grace period of 90-days to allow for situations of technical non-compliance. In addition, OIG should permit VBEs to add participants throughout the duration of the value-based arrangement on an ongoing basis or, at a minimum, on an annual basis.

3. Accountable Body

The AMA does not object to the proposal that the VBE must have an accountable body or person responsible for financial and operational oversight of the VBE. However, we question the practicality and burden of such level of formality on a small VBE.

The AMA is opposed to requiring that a VBE have a compliance program, requiring that all VBE participants affirmatively recognize the oversight role, having more specific responsibilities on the accountable body or responsible person, implementing reporting requirements or mechanisms for obtaining access to participant data, and imposing a standard requiring either independence or a duty of loyalty. While the AMA appreciates the need for accountability and for compliance programs, the above proposals unnecessarily create additional burden without substantially reducing the risk of program fraud and abuse. The vast majority of clinicians are not looking to defraud the federal government; therefore, more paperwork requirements are not going to decrease the risk of harm. This additional layering of more burden will lead to further physician burnout and potentially decrease desire to participate in value-based arrangements. Moreover, OIG is already requiring a governing document that should address the majority of fraud and abuse concerns. With the independence or a duty of loyalty, the AMA doubts that a small VBE can ever have someone who is independent of the interests of individual VBE participants when that independent individual is one of few participating physicians.

4. Governing Document

The AMA believes that a governing document can provide transparency regarding the structure of the VBE, the VBE's value-based purposes, and the VBE participants' roadmap for achieving those purposes. We also appreciate the flexibility in having a governing document not being formal bylaws or in another specific format. However, as stated above, we have concerns about the additional burden and cost placed on small, underserved, and rural practices in forming VBEs. OIG could help these practices by providing a checklist and/or model terms for a governing document. Moreover, the AMA proposes that CMS and OIG have an optional online portal for value-based enterprises to register their value-based arrangement. This online portal could form the basis of a governing document by answering questions about how the parties intend to achieve the value-based purposes.

ii. Value-Based Arrangement

The AMA supports the definition of value-based arrangement and appreciates the proposed breadth to include commercial and private insurer arrangements. In the preamble, OIG mentions that the proposed definition is intended to capture arrangements for care coordination and certain other value-based activities among VBE participants within the same VBE. The AMA seeks clarification as to how this description that includes care coordination and other value-based activities corresponds with the requirements for proposed safe harbors regarding value-based arrangements, which all require the coordination and management of care and not other value-based activities.

iii. Target Patient Population

The AMA is generally supportive of the concept of target patient population being based on legitimate and verifiable criteria and including private and commercial insurer patients. The AMA strongly believes that a physician's or a VBE's entire patient population could be considered a target patient population as long as such determination is based on legitimate and verifiable criteria. This consideration would decrease administrative burden by not requiring a physician to first determine whether one patient receives value-based activities while another patient does not. Moreover, allowing the entire patient population to be included also further promotes population health management and all payer models operating outside of CMMI.

The AMA opposes limiting the definition of target patient population to patients with a chronic condition because it would defeat a major purpose of providing care: prevention. The health care system should not wait until someone develops a chronic disease to qualify for a target patient population and then receive value-based care protected from the anti-kickback statute. Instead, the target patient population should be focused on the prevention of chronic diseases to begin with and then on the proper treatment of a chronic disease once diagnosed. Moreover, such limitation would prevent VBE participants from providing better coordination of care for other categories of patients that are not disease specific like patients being discharged from hospitals following acute care or targeting a specific zip code or county with higher mortality. For similar reasons, we also oppose target patient population being limited to patients with a shared disease state that would benefit from care coordination.

The AMA prefers the OIG using "legitimate and verifiable" over the alternative "evidence-based" because evidence-based may be too restrictive or interpreted as being too restrictive. The VBE should not

have to go through a rigorous peer review or case study process to determine a target patient population. This type of requirement will have greater negative impact on small, underserved, and rural practices.

The AMA is not opposed to other parties being involved in selecting the target patient population including payers. We are concerned about payers potentially increasing program integrity risks or shaping target patient populations that are focused on stinting or delaying care under the auspices of “controlling costs.” Thus, any selecting by another party cannot use tools such as prior authorization or utilization management in a way to define to a target patient population.

iv. Value-Based Activity

The AMA supports the definition of value-based activity. We urge caution in OIG potentially further interpreting how an activity is “reasonably designed” to achieve a value-based purpose or requiring that VBE participants entering into the value-based arrangement engage in an evidence-based process to design value-based activities that they believe will reach such goal. As stated previously, evidence-based process may be too restrictive or interpreted as being too restrictive. The VBE should not have to go through a rigorous peer review or case study process to determine a target patient population. This type of requirement will have greater negative impact on small, underserved, and rural practices.

The AMA supports excluding from the definition of “value-based activity” any activity that results in information blocking. The AMA strongly supports the elimination of unjustified information blocking that prevents data exchange. HHS broadly needs to prohibit networks, exchanges, developers, and other health care providers from blocking the electronic availability of clinical data to health care providers who participate in shared patient care. Information blocking under these circumstances interferes with the provision of optimal, safe, and timely care. While we support the prohibition on information blocking, the AMA has concerns regarding the broad definition of terms and has sought clarification as to ONC’s interpretation in the proposed rulemaking “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.”³ Given the unknown impact and potential unintended consequences regarding the interpretation of information blocking, at this time, we recommend that OIG focus more on what is provided in statute regarding information blocking.

v. Value-Based Purpose

The AMA supports the proposed definition of value-based purpose and appreciates the inclusion of infrastructure investment and operations necessary to redesign care delivery. However, we are opposed to requiring the coordination and management of care for the target patient population for each of the proposed safe harbors at 1001.952(ee), (ff), and (gg). Instead, OIG should require only that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes. This proposal is designed to provide needed flexibility for parties participating in alternative payment models, especially rural practices where other VBE participants may be distant and not regularly involved to coordinate or manage care. While the health care system strives to provide better coordinated care, such care is not always practical and other types of care that provide value should also be rewarded. Value-based arrangements and care cover much more beyond care coordination with outcome measures that require achieving better care. Furthermore, by not requiring coordination and management of care, the safe harbors would be more closely aligned to the Stark exceptions.

³ [AMA Response](#) to the ONC Proposed Rule on Information Blocking.

The AMA also disagrees with the current definition of “coordinating and managing care” that requires patient care activities and sharing information to achieve safe and more effective care for the target patient population. While the goal of coordinating care should be to achieve more effective care, requiring constant achievement is not practical in the practice of medicine. The nature of medical practice is constantly evolving and responding to emergent infectious diseases and natural disasters that may negatively impact outcomes or necessarily increase costs. In these instances, physicians may not be able to achieve more effective care at no fault of the provider. OIG should recognize this reality and define “coordination and management of care” to mean “the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in an attempt to achieve safer and more effective care for the target patient population.”

The AMA is also opposed to precluding some or all protection under the proposed safe harbors for arrangements between entities that have common ownership. This type of restriction could preclude protection for care coordination arrangements within a group practice or among entities in integrated health systems that could otherwise qualify for proposed safe harbor protection. Churning patients through care settings to capitalize on a payment scheme or generate revenue is not a value-based purpose and would not receive any safe harbor protection under the anti-kickback statute. Furthermore, a fraudster could establish separate ownership structures for each care setting to get around any “common ownership” requirement.

The AMA believes that remuneration in the form of cybersecurity items or services could meet the definition of the coordination and management of care for a target patient population. For example, cybersecurity items or services may be needed to help share information between two or more VBE participants. Value-based arrangements may overlook potential opportunities to work with small community physicians if those practices cannot afford proper cybersecurity tools. Put simply, small practices may be priced out of participation in APMs if they cannot access affordable cybersecurity tools. Moreover, cybersecurity items or services could also improve the quality of care for a target patient population by ensuring that information is shared securely and without alterations. While we believe that a majority of cybersecurity items or services would receive protection under the proposed cybersecurity safe harbor at 1001.952(jj), hardware and other infrastructure investments for cybersecurity services are not covered under the cybersecurity safe harbor as currently proposed.

b. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor

The AMA supports the concept behind OIG’s value-based safe harbors. The health care system is moving to a world that pays health professionals to manage episodes of patient care in a more comprehensive and coordinated way. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all may run afoul of these laws. The proposed safe harbors help to reflect the changing realities of the practice of medicine and we appreciate OIG’s time and thoughtful effort put into the proposals.

However, the AMA is opposed to the proposed safe harbor regarding care coordination because of the additional administrative burden that physician practices need to comply with to receive protection and the limitation to in-kind remuneration only. Namely, the need to meet 11 requirements and 7 definitions. We appreciate that one of OIG’s guiding principles was to design proposed safe harbors useful for a range of individuals and entities in the coordination and management of patient care. Yet, small, rural, and

underserved practices may not have resources and capability to meet the proposed requirements, and therefore, may not be able to independently participate in a value-based arrangement.

Any proposed safe harbor or exception must be entity agnostic and not further promote consolidation of the health care system. This means that a rural, one physician practice should have the same capability to implement the exception as a large health system. Safe harbors—like the one proposed—that favor certain larger entities or increase burden may lead to further consolidation and increase costs. Physicians should not have to be employed by a hospital or sell their practice to a hospital or another corporate entity to participate in Medicare or in innovative delivery models. Moreover, any change should not unnecessarily increase administrative burden on practices. The mounting burdens of the modern health care delivery system are taking a toll on physicians by contributing to the growing problem of work-induced burnout and emotional fatigue. Ultimately, physicians should be able to maintain their independent practice while at the same time have access to the infrastructure and resources necessary to participate in APMs.

Alternatively, the AMA suggests a potential option that we believe appropriately balances allowing innovative value-based arrangements to flourish with protecting the programs and patients from harm and abuse. Under the monitoring and assessment portion of the proposed rule, OIG proposes potentially requiring VBEs to submit certain data to the HHS that would identify the VBE, VBE participants, and value-based arrangements. If structured correctly along with relief from some of the more burdensome requirements of the care coordination safe harbor, we believe that providing such data could be an appropriate solution that increases the likelihood that the VBE participants use care coordination items and services, ensures that any remuneration is well-tailored between VBE participants, and promotes the VBE participants' best interest in achieving the intended purpose of the value-based arrangement.

Our optional proposal would require the VBE to submit to the HHS the requirements of a written arrangement through a portal that prompts certain questions from the user (e.g., who is participating in the value-based enterprise?). The responsible party could also certify against the penalty of perjury that all information is true, accurate, and complete. At the end of providing all of the information, a downloadable copy of all of the questions and answers would be available and could be considered to meet the written agreement requirement of the proposed safe harbor and provide for a governing document. This result is extremely beneficial for small practices that cannot afford the costs of an attorney to draft up a written agreement and, by default, creates compliance with the technical, written agreement requirements. Moreover, it could serve as a bona fide determination that the value-based arrangement is directly connected to the value-based activities for the target patient population.

We encourage the HHS to utilize the Quality Payment Program (QPP) portal as the source for managing and documenting a VBE's written agreement. The QPP portal is a model for a user-friendly interface that physicians are familiar with as a result of their participation in the Merit-based Incentive Payment System (MIPS). It would also be beneficial to leverage already existing government resources. Moreover, having the capability to save as you go would be greatly appreciated.

The AMA believes that part of the HHS's reasoning behind having so many requirements and definitions is the unknown as it relates to value-based arrangements. The HHS is familiar with rooting out fraud, waste, and abuse in the fee-for-service world and, while CMMI has models promoting value-based care and arrangements, those models are subject to participation agreements and annual evaluations and may have fraud and abuse waivers. By having this option for the safe harbor, the federal government gains

valuable data and potential insights into how the health care system plans on providing value-based care. This data can help inform technical assistance, investigatory priorities, and future rulemaking as health care transitions to rewarding value.

By providing transparency and valuable data to the federal government regarding value-based arrangements, the anti-kickback safe harbor requirements should mirror the equivalent, proposed Stark exception requirements at §411.357(aa)(3). This would decrease administrative burden because any monitoring, assessment, or analysis for compliance with the proposed Stark exception would then mirror the anti-kickback safe harbor. It would also provide a positive incentive for VBEs to provide data to the HHS. Alternatively, if mirroring Stark is not appropriate, certain proposed requirements of the safe harbor should no longer apply or be limited. Specifically, the contribution amount and the limitation to only in-kind remuneration should be removed. The requiring of outcome measures should also be broadened to include process measures given process measures contribute to good outcomes. In addition, the monitoring and assessment requirement should provide more flexibility and opportunity for corrective action. For a more detailed explanation, please see below regarding our reply to the specific requirements.

We view our alternative as an option. Thus, if a VBE decides it does not want to disclose this information through a portal, the VBE must meet the more stringent requirements set out in the proposed anti-kickback safe harbor.

i. Outcome Measures

The AMA is opposed to requiring that parties to a value-based arrangement establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured, and which the parties reasonably anticipate 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. For example, OIG never defines “outcome measure,” which is a term of art in the quality measurement and reporting world.

Mandating an outcome measure as a requirement for safe harbor protection may disadvantage certain specialties as well as rural practices and practices that treat high risk patients. A number of methodological issues exist that must be addressed before requiring the use of outcome measures, such as the development of better risk-adjustment models at the measure level (not just the program level as proposed) and stratification by specialty. In addition, infrastructure challenges may prevent physicians from having the ability to be measured on outcome measures, such as not having appropriate data elements in the electronic health record (EHR). Practices may also experience interoperability issues that may interfere with the exchange of information needed to use outcome measures or may be unable to do longitudinal tracking due to the lack of uniform patient identifiers and patient attrition when tracking outcomes.

There are very few outcome measures in the Medicare program and it has proven difficult to measure through a quality measure. A specialty should not be penalized because they have good outcomes on a procedure or process because of the lack of a valid outcome measure. OIG should be incentivizing and encouraging good patient care and not the existence of outcome measures for the sake of having outcome measures. While we understand that outcome measures can come from internal sources, only sophisticated health systems with advanced data analytics have the capability to internally develop

outcome measures. Small, underserved, and rural practices do not have the resources to develop these measures internally, which could lead to further consolidation of the health care system.

OIG also needs to address issues regarding individual physician participant measurement compared to group measurement. OIG is assuming that individual physicians can wield sufficient influence on which measures are developed and available to meet the needs of their target patient population. Outcome measures at the physician level can also be particularly challenging to construct for two primary reasons—small sample sizes and the difficulty of identifying outcomes for which the physician can and should be held accountable (i.e., outcomes that are largely dependent on the quality of care received, not other factors). Thus, holding physicians accountable through the application of safe harbor protection for something that is not necessarily within their direct control would be imprudent.

The proposal requires that the parties reasonably anticipate that the outcome measure will advance the coordination and management of care of the target patient population. Care coordination is not an outcome. Instead, care coordination is a process that leads to an outcome. Thus, outcome measures do not measure or advance the coordination or management of care.

Given these concerns and the definition of “outcome” being vague, it appears that simply carrying out a planned activity successfully would count as a successful outcome. We believe it would be hard for OIG to be more restrictive than this result, since there are relatively few outcome measures being used in CMS models or anywhere else. While beneficial, this result also means that there would not necessarily be any benefit for those who actually are using real outcome measures, particularly given the requirement for continuous improvement. Thus, the AMA is concerned that the OIG will decide later to restrict what counts as an outcome measure, and any participant who relied on using something else would suddenly be out of compliance. One compromise might be to require improvements on process measures and maintenance or improvement on outcome measures that are already high.

Overall, valid and reliable outcome measures could potentially lead to more direct measures of quality and their development by medical specialties should be encouraged and funded. However, we also recognize that certain types of measures might be more appropriate for certain specialties and practice settings than for others. Furthermore, process measures that are evidence-based can be integral to improved outcomes and in some specialties, this foundational step must first be addressed before moving on to outcome measures.

Thus, alternatively, the AMA recommends that the outcome measure requirement be expanded to include process measures. Process measures, for which there is strong evidence that fulfillment of the measure intent, such as providing or not providing a specific treatment will improve patient outcomes or safety, should be included. Process measures continue to serve a purpose, especially when coupled with cost, because it is often the breakdown in a process that contributes to poor outcomes and increased resource use. If the Medicare program was structured to allow physicians to focus on a targeted clinical or disease area, such as preventing diabetes and the measures correlated with the clinical episode, process measures would be seen as more valuable.

The AMA generally agrees with OIG by not considering patient satisfaction or convenience to be valid outcomes measures for this proposed requirement because of the lack of evidence tying patient satisfaction to better clinical outcomes.

The AMA cautions OIG on requiring parties to rebase the outcome measures where rebasing is feasible because of the number of factors that go into rebasing and the flexibility in determining whether and when it is appropriate to rebase. Any time frame must be beyond one year and should be looking at a five-to-ten-year horizon. When value-based arrangements are created or when a patient is a new to a value-based arrangement, the patient will generally initially see increased costs because they are now receiving more preventative care to reduce the risk of a more serious health event. For example, Clinician A may take preventive care steps to prevent colon cancer or to identify cancer at an earlier stage (e.g., colonoscopies, blood work) in the first year that reduces the risk of cancer for five years. Clinician B may not take any preventive care steps for a patient and the patient later develops cancer four years later. If rebasing is done on a year basis, Clinician B would be rewarded for providing care at no cost and good outcomes, while the Clinician A would not be rewarded because the clinician provided high cost care with no discernible improvement of outcomes.

The AMA supports incorporating the CMS Quality Payment Program measures as an option to demonstrate compliance with the requirement to establish outcome measures because it would help with aligning measures across different aspects of the HHS.

ii. Commercial Reasonableness

The AMA opposes the requirement that the value-based arrangement be commercially reasonable because it adds unnecessary complexity to demonstrate compliance with the safe harbor. While we appreciate the explanation in the preamble defining commercial reasonableness, we are concerned about whether small, rural, and underserved practices can demonstrate this term without consulting legal counsel or increasing costs.

Alternatively, if OIG goes forward with this requirement, a commercially reasonable arrangement should be defined as an arrangement that would make commercial sense if entered into by reasonable entities of a similar type and size, even without the potential for referrals. We also ask that OIG clarify that an entity may enter into a commercially reasonable arrangement even when the results of the arrangement are at a loss.

iii. Writing

The AMA is generally supportive that the value-based arrangement be set forth in writing. OIG should permit a collection of writings rather than a single writing signed by all parties because such a requirement may be burdensome.

iv. Limitations on Remuneration

1. In-Kind Remuneration

The AMA is opposed to protecting only in-kind, non-monetary remuneration. Instead, the safe harbor should also protect monetary remuneration. As initiatives advance to align payment and care coordination to improve the quality and value of care delivered, physician leadership is instrumental to optimizing care, improving population health, and reducing costs. Physicians provide the care and see the cost inefficiencies and overutilization. In helping physicians achieve the goals of value-based care, physicians and other individuals should be able to receive monetary incentives for shared savings to facilitate coordinated care and promote well-designed alternative payment models.

The AMA also believes that limiting remuneration to “in-kind” remuneration would prevent physician practices in VBEs from hiring their own care managers or other staff and receive remuneration based on outcomes. 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. Moreover, any other costs the practice would incur for data analysis and generally time physicians spend on non-FFS services could not be compensated. The AMA is concerned that these factors would be likely to force more consolidation into large entities, rather than supporting independent practices.

Although certain outcome-based payment arrangements may be protected by proposed modifications to the personal service and management contracts safe harbor, the proposed safe harbor does not cover all forms of monetary remuneration in a value-based arrangement and this creates more additional burden and risk in ensuring compliance with both this care coordination safe harbor and the personal service and management contracts safe harbor.

2. Primarily Engaged in Value-Based Activities

We are opposed to requiring the coordination and management of care for the target patient population in this safe harbor. Instead, OIG should require only that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes. This proposal is designed to provide needed flexibility for parties participating in alternative payment models especially rural practices where other VBE participants may be distant and not regularly involved to coordinate or manage care. While the health care system strives to provide better coordinated care, such care is not always practical and other types of care that provide value should also be rewarded. Value-based arrangements and care cover much more beyond care coordination with outcome measures that require achieving better care.

The AMA is opposed to requiring that the remuneration exchanged be limited to value-based activities that only benefit the target patient population. OIG should recognize that remuneration exchanged for value-based activities may indirectly benefit patients outside of the scope of the value-based arrangement. Moreover, parties may find it difficult to anticipate or project the scope of such “spillover” benefits. As OIG notes, it should be mindful of the need to provide parties with sufficient flexibility and not require stringent one-for-one compliance that would be difficult and costly to monitor and would take physicians away from focusing on providing care to patients.

3. No Remuneration from Individuals or Entities Outside the Applicable VBE

The AMA understands the reasoning behind not protecting any remuneration funded by or otherwise resulting from the contributions of an individual or entity outside of the applicable VBE. We agree that pharmaceutical manufacturers should not be able to circumvent this requirement by providing funds to a third-party entity and then directing or controlling any aspect of the third-party entity’s participation as a VBE or a VBE participant. However, health care is expanding beyond the four walls of a physician office or hospital to include third parties providing social services that may be part of a VBE. These VBE participants may receive donations from a variety of stakeholders including foundations. Although difficult, we ask OIG to try to allow for certain donations that may benefit a VBE’s patients and should consider whether to add a safeguard where the donating third party can have no direction or control over how the funds are spent.

Given the complicated and unknown nature of VBEs, we oppose a requirement that remuneration must be provided directly from the offeror to the recipient. This could create practical impediments where a VBE participant operates all of the administrative tasks, controls the in-kind remuneration on behalf of the offeror, and manages it on behalf of the recipient.

v. Contribution Requirement

The AMA is strongly opposed to any contribution requirement from the recipient to receive protection under the proposed safe harbor. The contribution requirement would add unnecessary burden, complexity, and potentially be cost prohibitive. The contribution requirement would add burden in requiring setting the contribution amount in writing and ongoing monitoring and tracking of contribution amounts to ensure compliance. The requirement would increase complexity in determining offeror and recipient. For example, if a small VBE is sharing the services of nursing care coordinator it may be difficult to determine who is the offeror and recipient and how to split up the “contribution” amount especially if each party is paying their portion independently. Moreover, the contribution requirement could introduce prohibitive costs where a practice may not be able to afford the contribution amount and not be able to engage in value-based arrangements. As stated above, we propose an optional framework where a VBE provides data to the HHS. In return, certain requirements—like this contribution one—would not apply to that value-based arrangement.

Alternatively, if OIG goes forward with a contribution amount, OIG **must** have an exception for small, underserved, and rural practices. While we oppose contributions generally, the contribution amount will impose a significant financial burden on small, underserved, and rural practices that could negatively impact patient care. OIG should take into account the ability of these practices to bear the burden of the increasing demands on staff in implementation of the proposed rule. Furthermore, OIG should consider the additional administrative burden and complexity in determining whether a practice meets a definition and whether not having any contribution amount regardless of practice type is more beneficial and clearer for the health care industry.

“Small practices” should be defined as how small businesses are defined by the Small Business Association for NAICS code 621111 (Offices of Physicians).⁴ This definition is the same that CMS and OIG use when analyzing the need for a Regulatory Impact Analysis or in examining the Regulatory Flexibility Act for all proposed and final rules coming from the HHS, including this proposed and forthcoming final rule related to the physician self-referral law/anti-kickback statute.⁵

Alternatively, OIG could define a small practice similarly to how it is defined under the Quality Payment Program (QPP) as a Tax Identification Number or virtual group with 15 or fewer eligible clinicians.⁶ A significant advantage of using the QPP definition of a small practice is that physicians and practice administrators can determine whether they qualify as a small practice via the qpp.cms.gov website simply by entering their NPI. By enabling practices to look up their small practice status via the QPP portal and use it as the basis for waiving the contribution amount, CMS and OIG would minimize burden on these practices. In addition, because the QPP and proposed exceptions and safe harbors share the same purpose to promote value-based care, we recommend keeping the definitions consistent.

⁴ 13 CFR § 121.201 (Sector 62, Subsector 621).

⁵ 84 Fed. Reg. 55766, 55836 (Oct. 17, 2019)(Stark); 84 Fed. Reg. 55694, 55756 (Oct. 17, 2019)(AKS).

⁶ See 42 CFR § 414.1305.

“Underserved practices” should be defined as those in (1) medically underserved areas, as designated by the Secretary under §330(b)(3) of the Public Health Service Act; (2) primary health care geographic health professions shortage areas, as designated by the Secretary under §332(a)(1)(A) of the Public Health Service Act; or (3) a Critical Access Hospital.

“Rural practices” should be defined as those located in rural areas, as defined in the safe harbor for local transportation at §1001.952(bb).

If an individual or entity qualifies for one of the definitions, the proposed contribution requirements should be excepted. Thus, if an urban, large practice is in a medically underserved area, the practice is excepted from any contribution requirements.

If OIG goes forward with the proposal, we believe that “15% of the offeror’s cost” is a simple, easy to demonstrate the requirement for determining value. OIG should not require a more specific methodology for determining value, such as either the fair market value of the remuneration to the recipient or the reasonable value of the remuneration to the recipient. Both options add unnecessary complexity and additional costs both to determine “fair market” or “reasonable” value (e.g., hiring a consultant) and to maintain compliance throughout the existence of the VBE.

We are also opposed to proposals of having amounts ranging from 5 to 35 percent contribution, with different contribution amounts for different types of remuneration because, as with the contribution requirement, these add further complexity and burden on the practice of medicine.

vi. Requirements of a Value-Based Arrangement

1. Direct Connection to the Coordination and Management of Care

We are opposed to requiring the coordination and management of care for the target patient population in this safe harbor. Instead, OIG should require only that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes. This proposal is designed to provide needed flexibility for parties participating in alternative payment models especially rural practices where other VBE participants may be distant and not regularly involved to coordinate or manage care. While the health care system strives to provide better coordinated care, such care is not always practical and other types of care that provide value should also be rewarded. Value-based arrangements and care cover much more beyond care coordination with outcome measures that require achieving better care.

2. No Limitation on Decision Making; Restrictions on Directing or Restricting Referrals

The AMA supports the proposal that the value-based arrangement must not limit parties’ ability to make decisions in the best interests of their patients. This provision helps preserve patient freedom of choice among health care providers and ensures that the independent medical or professional judgment of VBE participants is not unduly restricted.

3. No Marketing of Items or Services or Patient Recruitment Activities

The AMA supports the proposal to exclude safe harbor for value-based arrangements that include marketing items or services to patients or patient recruitment activities.

vii. Monitoring and Assessment

The AMA opposes OIG's proposal that the monitoring and assessment involve only the coordination and management of care for the target patient population in value-based arrangements. Instead, as previously mentioned, OIG should require monitoring and assessment of that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes.

The AMA also believes that OIG should provide flexibility in monitoring and assessing progress toward achieving the evidenced based, valid outcome measures. While progress is the intent of these measures, progress may not actually be achieved for a variety of reasons that may or may not be in the control of physicians and others providing care. The practice of medicine is constantly evolving with new emerging disease threats and flu strains and a growing need to respond to natural disasters. All of these factors may impact the progress towards achieving an outcome measure that a physician may have little control over. Health care providers should not lose anti-kickback protection for outcomes they cannot control.

We appreciate OIG's intent for monitoring to be tailored based on the complexity and sophistication of the VBE participants, the VBE, and the value-based arrangement and available resources. We are opposed to requiring that both the party offering the remuneration and its recipient jointly conduct monitoring and assessment responsibilities.

The AMA strongly opposes the current proposal for terminating agreements. Instead, AMA supports OIG's alternative that the safe harbor should instead allow for remediation—within a reasonable timeframe—before any required termination. The AMA has seen success in other areas of program integrity when physicians are given the opportunity to remedy deficiencies. For example, the CMS Targeted Probe and Educate program allows multiple rounds of education regarding improper claims prior to referral to a RAC. While we are not asking for OIG to operate a similar program, corrective action plans can be a way to identify issues, put parties on notice, and provide an opportunity to improve rather than the harsh punishment of termination based off of a determination by the responsible party. Accordingly, we recommend that OIG amend the beginning of §1001.952(ee)(9) to read that “The parties enter into a corrective action plan within 60 days if the VBE's accountable body or responsible person determine that the value-based arrangement.”

If, after a reasonable period, the corrective action plan does not change the determination of the responsible party, then the parties should terminate the arrangement. The reasonable time period should be no less than a year to allow for corrections to take place and enough time to provide adequate assessment.

Alternatively, if OIG goes forward with just termination, we would also propose a longer timeframe that a value-based arrangement terminate with 120 days after making such a determination. Winding up all value-based arrangements will take much longer than two months. While we understand the concerns of a value-based arrangement being non-compliant for a longer period of time may increase the chance of

program and patient abuse, we also believe that concluding proper care coordination activities will take time and generally should not disrupt patient care.

As described above, we support requiring VBEs to submit certain data to the HHS that would identify the VBE, VBE participants, and value-based arrangements. However, if OIG requires such data, the AMA would expect relief from multiple safe harbor requirements.

viii. No Diversion, Resell, or Use for Unlawful Purposes

The AMA supports the proposal that the exchange of remuneration would not be protected if the offeror knows or should know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

ix. Materials and Record

The AMA questions the need for the requirement that the VBE make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the safe harbor. Maintaining this type of material is already part of any compliance program. Furthermore, unless OIG can demonstrate situations where they could not conduct an anti-kickback investigation or could not get access to information, the AMA doubts that the OIG will bring an anti-kickback case based solely on the lack of materials and records. Instead, the AMA believes that any case would be based on failure to prove that a different requirement of the safe harbor is met (e.g., a physician could not demonstrate the value-based activities).

x. Possible Additional Safeguards

1. Bona Fide Determination

The AMA objects to requiring that the accountable body or responsible person make a bona fide determination that the value-based arrangement is connected to the coordination and management of care for the target patient population. Instead, the AMA supports a bona fide determination that the value-based arrangement is connected to the value-based purpose(s) for the target patient population.

We also object to a bona fide determination of commercial reasonableness because we oppose the requirement that the value-based arrangement be commercially reasonable because it adds unnecessary complexity to demonstrate compliance with the safe harbor.

2. Cost-Shifting Prohibition

AMA has no objections to the possible additional safeguard of prohibiting cost-shifting.

3. Fair Market Value Requirement and Restriction on Remuneration Tied to the Volume or Value of Referrals

The AMA is opposed to including a fair market value requirement on any remuneration exchanged pursuant to a value-based arrangement or prohibiting VBE participants from determining the amount or nature of the remuneration they offer in a manner that takes into account the volume or value of referrals or other business generated.

c. Value-Based Arrangements with Substantial Downside Financial Risk

Generally, the safe harbors involving financial risk do not capture any aspect of risk that does not involve activities or services that are reimbursable about a payer. Thus, no matter how much a physician practice incurs in unreimbursed costs to qualify for an “upside-only” bonus, the physician would not be viewed as being in a “meaningful downside financial risk” arrangement. Thus, the AMA believes that the focus on risk should not just be focused on downside financial risk. Instead, OIG needs to address other risks such as upside, clinical, operational, contractual, or investment.

Moreover, many current value-based arrangements withhold payment from physicians for not potentially meeting a benchmark and have the clinically integrated network or group practice assume the risk on behalf of the individual physicians. The proposed safe harbors do not match this reality. Instead, a physician must pay out of pocket for potentially missing a benchmark, and it appears that the network or group practice cannot assume risk on behalf of individual physicians. Accordingly, we ask OIG to provide that the safe harbor allows for physician withholds and for allowing the network or group to assume the risk to meet the requirements of substantial downside risk.

i. Substantial Downside Risk

Overall, the AMA believes that the four forms of substantial downside risk are arbitrary percentages that may or may not have significant impacts depending on the situation. Thus, situations may exist in which beneficial payment arrangements for desirable care changes cannot qualify, while problematic payment or care delivery arrangements could qualify. The AMA recommends tying the requirements to the costs that participants incur to participate in the model and the amount of resources they have available to pay any downside risk.

The AMA recommends that all four forms of substantial downside financial risk be modified to better capture the true assumption of substantial downside financial risk for items and services furnished to patients by including projected spending as a method to compare costs. Projected spending should be added because historical expenditures may not be an accurate benchmark because these new value-based arrangements involve providing new and different services that were not performed before (e.g., transforming care by providing care coordination management services). These services may never be a part of historical expenditures because they have not been historically used in the care delivery system. Moreover, historical expenditure data may not be appropriately risk adjusted. Using projected spending as the benchmark accounts for new expenditures and can be appropriately risk adjusted for the targeted patient population. Accordingly, the AMA recommends adding “projected spending” to all four forms of substantial downside financial risk as follows:

(A) Shared savings with a repayment obligation to the payer of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to either historical expenditures or projected spending, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(B) A repayment obligation to the payer under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to either historical expenditures or projected spending

expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;

(C) A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of either historical expenditures or projected spending, or to the extent such data is unavailable, evidence-based, comparable expenditures; or

(D) A partial capitated payment from the payer for a set of items and services for the target patient population, where such capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments based on either historical expenditures or projected spending, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangement.

The AMA questions the practicality of having repayment obligation be a form of substantial downside risk. We are unaware of any value-based arrangement that can provide quality care at 80 percent of episode costs. Also, in our experience, most models operate on a discount method rather than a repayment obligation. Accordingly, it may be better to rephrase this form of substantial downside risk as discount based.

The AMA seeks clarification on the partial capitated payment form of substantial downside risk because capitation itself places a physician at risk because the physician is estimating the costs through a per member per month payment. Thus, AMA is confused as to why any requirement exists regarding a discount in the definition of a partial capitated payment and seeks clarification as to the reasoning behind including discounts.

The AMA supports including advanced APMs and other payer advanced APMs, as both terms as defined at 42 C.F.R. §414.1305, in the definition of substantial downside financial risk. This would further advance value-based arrangements and help incentivize participation and development of advanced APMs and other payer advanced APMs.

ii. Meaningfully Shares (OIG)

The AMA is opposed to the definition of meaningfully shares in the VBE's substantial downside risk if for physicians, the payment meets the requirements of "meaningful downside financial risk" as proposed in Stark.

Our interpretation of the definition means that the value of the remuneration the physician receives under the value-based arrangement is all the compensation that a physician receives under the value-based arrangement for services and any additional incentives. Thus, the 25 percent does not just apply to the value of the incentive payments. If our interpretation is incorrect, CMS/OIG needs to explicitly clarify that the 25 percent of the value only relates to the incentive payment and not the entire value of compensation received.

Based off our interpretation, this definition is too high of a risk-percentage to enable any physician to participate in a value-based arrangement and receive protection under this proposed value-based exception/safe harbor. Twenty-five percent risk of payment would cut into the cost of delivering services.

For example, existing programs have financial risk percentages at 8 percent of the participant's Medicare revenues or 3 percent of expenditures under the model (Advanced APMs), 5 percent of revenues (medical homes), and 9 percent of payments for professional services under the Merit-based Incentive Payment System (MIPS). The proposed financial risk percentage is 3 to 5 times the amount that current value-based arrangements are subject to. Thus, AMA would recommend that meaningful downside financial risk be defined at 5 percent to support physician participation in value-based arrangements. This amount would help ensure that the VBE participant is meaningfully engaged with the VBE in delivering value through its ordering and referring decisions.

The AMA supports including a protection for preparation for the implementation of a meaningful downside/substantial downside risk exception/safe harbor. Similar to the Medicare Shared Savings Program pre-participation waiver, the AMA believes that a one-year period of protection would be a sufficient timeframe.

The AMA understands the proposal that the physician must be under financial risk for the entire term of the arrangement. We seek clarification as to whether a physician could join the value-based arrangement while the arrangement is already ongoing, assume financial risk for the duration of their participation, and still receive protection. We would support such protection because the alternative is untenable. The alternative would require that prior to the start of the value-based arrangement all VBE participants must be locked into participating and no additional participants could be added during the existences of the VBE.

We are opposed to requiring the coordination and management of care for the target patient population in this safe harbor. Instead, OIG should require only that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes. This proposal is designed to provide needed flexibility for parties participating in alternative payment models especially rural practices where other VBE participants may be distant and not regularly involved to coordinate or manage care. While the health care system strives to provide better coordinated care, such care is not always practical and other types of care that provide value should also be rewarded. Value-based arrangements and care cover much more beyond care coordination with outcome measures that require achieving better care.

The AMA is opposed to any requirement to submit information to the HHS about the VBE, VBE participants, and the value-based arrangements. Instead, as described in a previous section, a portal should exist to supply this type of information under a different, alternative safe harbor.

d. Value-Based Arrangements with Full Financial Risk

The AMA is concerned that the full financial risk safe harbor will lead to further consolidation of the health care industry because hospitals must be included in the VBE to account for all items and services covered by Medicare Parts A and B for a target patient population. As a practical matter, the AMA is unaware of many value-based arrangements that take on total financial risk. Even the current CMS total cost of care models, certain items or services are excluded, notably Part D expenses or the models have a maximum limit on the downside risk. Thus, most VBEs may opt for the "meaningful downside risk" safe harbor unless OIG allows exceptions in the full risk safe harbor for services like transplants.

The AMA appreciates that the proposed definition would not prohibit a VBE from entering into arrangements to protect against catastrophic losses (e.g., global risk adjustments, risk corridors,

reinsurance, or stop loss agreement). The AMA asks for more clarification about permitted risk mitigation terms including a threshold on the amount of allowed mitigation to be considered full risk.

AMA supports including a protection for preparation for the implementation of this safe harbor. Similar to the Medicare Shared Savings Program pre-participation waiver, the AMA believes that a one-year period of protection would be a sufficient timeframe.

We are opposed to requiring the coordination and management of care for the target patient population in this safe harbor. Instead, OIG should require only that value-based activities be directly connected to, or be reasonably designed to achieve, any of the value-based purposes. This proposal is designed to provide needed flexibility for parties participating in alternative payment models especially rural practices where other VBE participants may be distant and not regularly involved to coordinate or manage care. While the health care system strives to provide better coordinated care, such care is not always practical and other types of care that provide value should also be rewarded. Value-based arrangements and care cover much more beyond care coordination with outcome measures that require achieving better care.

e. Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency

The AMA generally supports the proposal to establish a new safe harbor to protect certain arrangements for patient engagement tools and supports efforts to improve quality, health outcomes, and efficiency to specified patients.

i. Limitations on Offerors

The AMA believes that the proposed safe harbor should not be limited to tools and supports that are furnished by a VBE participant. Instead, the proposed safe harbor should apply to any arrangement involving patient engagement tools or supports. Outside of the context of only value-based arrangements, to prevent illness or disease or to manage a disease or condition effectively, patients must be involved in their health care and be empowered to make informed health care-related decisions. Appropriate patient engagement tools and supports can foster successful behavior modifications that improve health, ensure that patients receive medically necessary care and other nonclinical, but health-related, items and services they need, and improve adherence to an appropriate treatment regimen. Moreover, by requiring VBE participation, administrative burden is increased because physicians and staff would need to determine whether the arrangement and patient falls within the value-based arrangement to determine whether a certain patient gets a tool or support compared to another.

We understand the potential for improper patient engagement tools and supports could result in inappropriate utilization, the steering of patients to particular providers that might not be in the patient's best interests, increased costs to payers and patients, and ant-competitive effects. However, given the structure and safeguards already in place in the proposed safe harbor, the AMA believes that these risks of harm are diminished. To further alleviate harm, OIG may also consider a requirement that the financial arrangement involving the patient engagement tools and supports be for a targeted patient population. Granted, the definition would need to be different than the current definition at proposed §1001.952(ee)(12)(ii) because of the current references to VBE, value-based arrangement, and value-based purposes. For example, the definition could mean an identified patient population based on

legitimate and verifiable criteria that is set out in writing in advance of the commencement of the arrangement and furthers patient engagement.

The AMA is strongly opposed to requiring some financial risk to qualify for this proposed safe harbor. While requiring risk may better align protected remuneration with value-based purposes, such requirement would limit the application to large practices and health systems. Small, rural, and underserved practices that are already operating on slim margins cannot afford to take on any risk and thus, would not be allowed to provide patient engagement tools and supports to a population that may not have great access to care.

ii. Limitations on Recipients

We appreciate that the scope of this proposed safe harbor would not be limited to federal health care programs in recognition that that the VBE or VBE participant may define the target patient population without regard to payer type. We further support providing safe harbor protection to a broader universe of patients by protecting patient engagement tools and supports furnished by VBE participants to any patient as long as the as the tools and supports predominantly address needs of the target patient population.

OIG also solicits comments about tools and supports furnished to patients in the target patient population when the VBE's assigned beneficiaries are identified retrospectively or on a preliminary prospective basis. The AMA is concerned about this statement and seeks clarification as to the definition of target patient population. The AMA's understanding of the definition is that identification of the precise population of patients is not required in meeting the definition of target patient population. To meet the definition of a target patient population, a VBE must identify patient population is based off of legitimate and verifiable criteria. Thus, retrospective or prospective assignment of an individual identified patient should not matter in meeting the population-based definition of target patient population.

iii. Limitations on Type of Remuneration

The AMA supports OIG not proposing a specific definition for preventive care item or service because it provides flexibility for participants that seek to furnish preventive care items and service to improve patient outcomes and better overall patient health. We are supportive of the three categories of tools and supports that would receive protection and believe that are sufficiently flexible but also sufficiently targeted to protect against risks of fraud and abuse. We urge OIG to provide as many examples of what is and is not considered a patient engagement support or tool in the preamble based off of comments. This guidance will help stakeholders define the line between permissible tools and supports. We also seek clarification as to how telehealth supports, and tools fit within the category of health-related technology.

While we do not have any objection to requiring that the participant confirm that the tools and services provided to a patient are not duplicative of, or substantially the same as, tools and services the patient already has, such a requirement may be difficult to implement or enforce. OIG provides the example of providing a new cell phone or wireless service to a patient who needs an application for remote patient monitoring if the patient already has these products and only needs the application. It may prove difficult to determine when or how much wireless service may be needed for the monitoring and whether the patient's current service is adequate for the purposes of remote monitoring. Thus, it may add more burden and confusion than protection from program or patient abuse.

For clarification purposes, we ask OIG to clarify the regulatory language in §1001.952(hh)(3)(i) because it currently may be interpreted to mean that any in-kind item, good, or service must be designed to identify and address a patient's social determinants of health (e.g., that the health-related technology must be designed to identify and address a patient's social determinant of health). For example, OIG could split out each illustrative example as follows:

- (i) Is an in-kind preventive item, good, or service; or an in-kind item, good, or service such as:
 - (A) health-related technology,
 - (B) patient health-related monitoring tools and services, or
 - (C) supports and services designed to identify and address a patient's social determinants of health;

1. Social Determinants of Health

The AMA strongly supports the inclusion of supports and services designed to identify and address a patient's social determinants of health (SDOH). The AMA defines health equity as “optimal health for all” and recognizes the importance and urgency of advancing health equity and addressing SDOH to ensure that all people and communities reach their full health potential. The World Health Organization (WHO) defines health equity as the “absence of unfair and avoidable or remediable differences in health among social groups.” This definition clarifies that inequities and disparities do not have to exist, but that inequities are produced; they do not just happen; the people who are negatively impacted by experiencing the injustice are not to blame; and there is something that we can actually do to close the gap.

According to Healthy People 2020, the “social determinants of health are conditions in the environment in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality of life outcomes and risk.” These social determinants include education, housing, wealth, income, and employment. We all experience conditions that socially determine our health or the SDOH. However, we do not all experience them equally. The SDOH are impacted by larger and powerful systems that lead to discrimination, exploitation, marginalization, exclusion, and isolation. In this country, these historic and systemic realities are baked into structures, policies, and practices and produce, exacerbate, and perpetuate inequities among the SDOH, and therefore affect health itself. These larger, powerful systems of racism and gender oppression—also known as the root cause inequities—are upstream to the social determinants of health. They have shaped the social conditions in which individuals and families live, and they work to produce inequities across society in complex ways, especially for those marginalized at the intersection of race and gender, i.e., Black and Native American women.

A commitment to health equity means we must address the SDOH and we must elevate and name the root causes of why health inequities exist and how they came to be—both in society and at the institutional level. The AMA demonstrates its commitment through addressing the social conditions that impact health, increasing health workforce diversity, advocating for equity in health care access, promoting equity in care, and ensuring equitable practices and processes in research and data collection. Although the AMA and physicians cannot control all factors that need to change to achieve health equity, the AMA views as its role to identify their importance and to urge and educate those who can have a direct role to act. Accordingly, the AMA supports the protection of the provision of supports and services designed to identify and address SDOH to help achieve health equity.

The AMA believes that all social determinants have the potential to improve health outcomes. Some social determinants may be more specifically aligned with preventive care and the coordination and management of care for patient than others. For example, OIG highlights the difference between transportation to medical appointments compared to a more general need for income through employment. Thus, it may be difficult to identify the most crucial social determinants to improving care coordination because addressing one social determinant may impact an individual's health more than another. If OIG decides to make distinctions among the categories of social determinants, the AMA suggests providing a non-exhaustive list of the types of tools and supports that would be permissible. Alternatively, given the variability and impact on individuals, OIG should not further define permissible categories of tools or services. While OIG may be concerned about potential misuse, the AMA believes that the other safeguards provide sufficient protection.

2. Waiver or Reduction of Cost-Sharing Obligations

Cost-sharing obligations are particularly problematic when the costs associated with reasonable collection efforts exceed the cost-sharing amount that would be potentially collected. Thus, similar to the OIG Policy Statement regarding gifts of nominal value, OIG should also issue guidance allowing for the waiver of cost-sharing amounts when the cost-sharing amount is nominal. For example, through the physician fee schedule, CMS is proposing to expand Medicare coverage to include services like virtual care visits. CMS pays approximately \$15 for a virtual check-in service. With a 20 percent cost sharing amount, a beneficiary pays approximately \$3. As defined by CMS and OIG, the costs of any "reasonable collection effort" would far exceed the \$3 collected. Requiring such efforts creates waste, adds unnecessary administrative burdens, and inappropriately increases costs to physician practices. Thus, OIG should create a new safe harbor to allow for this specific waiver of cost sharing. Alternatively, OIG should amend its interpretation of "reasonable collection efforts" under § 1128A(i)(6)(A)(iii)(II) of the Social Security Act so that these collection efforts do not include situations where the costs of the collection efforts by the provider exceeds the cost-sharing amount that would be potentially collected.

Additionally, cost-sharing obligations are particularly problematic with chronic care management (CCM) services. Patients may be discouraged from taking advantage of this high-value service due to the cost sharing amounts. OIG should create a safe harbor to waive cost-sharing amounts for CCM and other high-value services that may save money through better care coordination, improved patient outcomes, and avoiding unnecessary hospitalizations. This safe harbor could be tied to value-based arrangements that are focused on managing chronic conditions of a target patient population where the cost-sharing amount may discourage a patient from seeking primary care. Removing this unnecessary impediment to the physician-patient relationship could return impressive results. Regular appointments allow providers to more closely monitor patients and identify complications before they require hospitalization and to establish a more regular, wellness-based relationship between physician and patient. This can encourage the patient to reach out to a physician before resorting to more costly options such as calling an ambulance.

iv. Additional Proposed Conditions

1. Furnished Directly to the Patient

The AMA is opposed to the requirement that the tool or support must be furnished directly to the patient by a VBE participant. This limitation could have a negative impact on access to tools or supports because a patient may not be able to directly receive the tool or support because of a medical condition (e.g., being homebound) or may be impractical to travel long distances to directly receive such tool or support. OIG

should expand who can be furnished the tool or support to include caregivers or through a third-party delivery service. Moreover, OIG must expressly permit the participant to furnish the tool or support through someone acting on the participant's behalf and under the participant's direction. Otherwise, situations exist when a group practice as an entity is the participant that should be directly furnishing the tool or support; however, the entity is not an actual person that is capable of furnishing anything. Therefore, the arrangement would need an individual to furnish the support or tool on behalf of the participant.

The AMA is also opposed to any condition that would require the participant to provide any patient receiving a patient engagement tool or support a written document describing: (1) the VBE participant, (2) the remuneration, and (3) the purpose of the remuneration. This technical requirement increases administrative burden in both having to create the written document for each tool or support for each patient and having to monitor compliance with this requirement. We also question whether OIG would use investigative resources based off of the lack of written documentation to a patient when all other requirements are met.

2. Funding Limitations

The AMA understand the reasoning behind not protecting any remuneration funded by or otherwise resulting from the contributions of, an individual or entity outside of the applicable VBE. Health care is expanding beyond the four walls of a physician office or hospital to include third parties providing social services that may be part of a VBE. These VBE participants may receive donations from a variety of stakeholders including foundations. Although difficult, we ask OIG to try to allow for certain donations that may benefit a VBE and should consider whether to add a safeguard where the donating third party can have no direction or control over how the funds are spent.

3. Direct Connection

The AMA opposes the requirement that the tool or support furnished to the patient have a "direct connection" to the coordination and management of care. As above, we believe that the tools and supports should be allowed either for all value-based purposes and not just the coordination and management of care. The AMA supports OIG's alternative suggestion of having a "reasonable connection" because the use of the term "reasonable" is more closely aligned to OIG's interpretation that the VBE has a good faith expectation that the tool or support will further the care for the patient rather than "direct."

The AMA appreciates that OIG does not further describe specific tools or supports that would be considered to have a direct or reasonable connection to the care for the patient because it supports the goals of fostering flexibility, adaptability, and innovation.

Unless OIG removes other requirements, the OIG is opposed to requiring that the VBE make a bona fide determination that the participant's arrangement to provide tools and supports to patients is directly or reasonably connected to the care for the patient because of the additional burden in making the determination and monitoring compliance.

The AMA is in strong support of requiring that the tools and supports be reasonably connected to any of the four value-based purposes. This proposal is designed to provide needed flexibility for parties participating in alternative payment models especially rural practices where other VBE participants may

be distant and not regularly involved to coordinate or manage care. While the health care system strives to provide better coordinated care, such care is not always practical and other types of care that provide value should also be rewarded. Value-based arrangements and care cover much more beyond care coordination with outcome measures that require achieving better care.

4. Medical Necessity

The AMA supports the proposal to require that the tool or support furnished to the patient must not result in medically unnecessary or inappropriate items or services being reimbursed.

5. Nature of the Remuneration

The AMA supports the current proposal to require that the tool or support must be recommended by the patient's licensed health care provider. The AMA is opposed to all of the other considerations by the OIG because requiring certification to 18 U.S.C. §1001 and 1519; documenting the desired goals; and monitoring requirements are all administratively burdensome and take physicians away from providing patient care.

6. Advancement of Specified Goals

The AMA supports the requirement that the incentives and supports must advance one of the specifically enumerated goals. We appreciate that OIG does not specify which tools and supports would advance the named goals to provide flexibility for participants and promote innovation.

7. No Diversion or Resell

The AMA supports the proposed condition regarding no diversion or resell of the tool or support.

8. Monetary Cap

The AMA does not object to the concept of a monetary cap. The AMA appreciates that the proposed monetary cap could be exceeded for certain patients who lack financial resources based on a good faith, individualized determination of the patient's financial need. We support OIG's approach to follow existing guidance related determining financial need in the context of cost-sharing waivers.

9. Materials and Records

The AMA questions the need for the requirement that the arrangement make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the safe harbor. Maintaining this type of material is already part of any compliance program. Furthermore, unless OIG can demonstrate situations where they could not conduct an anti-kickback investigation or could not get access to information, the AMA doubts that the OIG will bring an anti-kickback case based solely on the lack of materials and records. Instead, the AMA believes that any case would be based on failure to prove that a different requirement of the safe harbor is met (e.g., a physician could not demonstrate the value-based activities).

v. Potential Safeguards

1. Consistent Provision of Patient Incentives

The AMA requests that if OIG goes forward with this provision, that it requires participants to offer the same patient engagement tools or supports to an entire target patient population rather than provide the tools or supports because some patients may refuse to use the tools and supports. We are also concerned about the impact this potential proposal would have on the ability of small practices to offer any patient tools or support because of financial constraints.

2. Monitoring Effectiveness

The AMA is opposed to adding a condition that requires participants to use reasonable efforts to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient and would require the participant to have policies and procedures in place to address and identify material deficiencies. The AMA anticipates that such requirements would add administrative burden and potentially negatively impact the ability of small, rural, and underserved practices from providing tools and supports.

f. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives (1001.952(ii))
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The AMA is generally supportive of the CMS-sponsored model arrangements and patient incentives safe harbor as proposed at 1001.952(ii). We believe that this proposed safe harbor is appropriate given the amount of compliance activities and requirements that model participants are subject to under the participation agreement. These requirements alleviate most fraud and abuse concerns. Moreover, by not introducing one-off fraud and abuse waivers, the federal government can better use staff resources and eliminate unnecessary differences between different models' fraud and abuse waivers. To promote economy and efficiency of the CMMI models, OIG should also urge CMS to provide a similar Stark exception for CMMI models.

The safe harbor should protect the last payment or exchange of value made by or received by a CMS-sponsored model party following the final performance period that the CMS-sponsored model participant that is a party to the arrangement participates in the CMS-sponsored model. This duration of protection should extend even if the model has otherwise terminated. While the other proposals for duration of protection provide more certainty and finality, model participants should not be subject to anti-kickback violations for continuing to provide the same coordinated care to a patient for a terminated model if the service was initiated before the model was terminated or expired. We imagine that most payments or exchanges would be completed within the first few months after termination and that a few payments or exchanges after that time period would not increase the opportunity to game the length of time. Patients should also be allowed to retain any incentives received prior to the termination or expiration of the participation documentation of the CMS-sponsored model participant.

OIG should also consider protection under this safe harbor for value-based arrangements that are established in the Medicare Physician Fee Schedule (MPFS) and MIPS. For example, in the 2020 MPFS final rule, CMS finalized new codes that would provide bundled payment under the PFS for an episode of care including development of a treatment plan, care coordination, individual and group therapy, and counseling for patients with opioid use disorder (OUD). The OUD treatment codes involve counseling,

therapy, and care coordination, including consultations with specialists. We believe these arrangements, which are governed by Medicare's conditions for billing the codes should qualify for safe harbor protection as they are bundled payments that create incentives to provide efficient care that are not tied to volume but rather patient needs. Similarly, we urge OIG to consider safe harbor protection for physicians who are at financial risk in MIPS for the costs of their patient population throughout the period of attribution and following a hospital admission. To reduce costs and improve patient care, physicians in MIPS have an incentive to coordinate care during transitions between care settings.

g. Cybersecurity Technology and Related Services

The AMA strongly supports the proposed cybersecurity technology and related services exception. We applaud OIG for helping to empower physicians to actively manage their security posture, not hinder them.

The AMA is deeply concerned that our nation's health care providers and patients have been insufficiently prepared to meet the cybersecurity challenges of an increasingly digital health care system. Cybersecurity is a national priority and physicians, other health care providers, and patients need tools to secure sensitive patient information in the digital sphere. As clinical adoption of digital medicine tools accelerates with new innovations, and in light of increased public and commercial insurer coverage of digital medicine tools and services, there is increased urgency to advance policies that remedy vulnerabilities in cybersecurity. We believe efforts like the proposed exception help address these challenges and develop a national strategy that improves the safety, resilience, and security of the health care industry.

1. Definitions

a. Cybersecurity

The AMA is generally supportive of the definition of cybersecurity. However, we believe that CMS should also include the process of protecting information by "identifying" and "recovering" from cyberattacks.

By adding "identifying" and "recovering," the definition of cybersecurity would include the entire lifecycle of a cyberattack and also mimic the NIST framework highlighted in the proposed rule preamble. The addition of identifying would include understanding the business context, the resources that support critical functions, and the related cybersecurity risks enabling an organization to focus and prioritize its efforts, consistent with its risk management strategy and business needs. The addition of recovering would allow for back-up services to be provided which support reestablishing cybersecurity based-on continuous backups, failover, and reduce the impact of ransomware extortion. The AMA already believes that these concepts are protected under the exception; however, explicitly referencing identifying and recovering in the definition of cybersecurity will help highlight the importance of these functions.

The AMA is opposed to a definition of cybersecurity that is tailored to the health care industry. A broader, industry-agnostic definition is more appropriate because cybersecurity is a fluid, ever-changing concept. Thus, a narrower definition would increase the likelihood of unintentionally limiting donations and of the definition becoming obsolete over time.

Accordingly, the AMA recommends that the definition of “cybersecurity” should be the “process of protecting information by identifying, preventing, detecting, and responding to, and recovering from cyberattacks.”

a. Technology

The AMA appreciates that the intent of the exception is to be agnostic to specific types of non-hardware cybersecurity technologies. We believe that non-monetary remuneration should be covered to include items in the form of software and hardware.

The scope of covered items and services would also include hardware security appliances because many cybersecurity software products require the use of a specific hardware device to operate. Security appliances are purpose-built hardware appliances that are designed to protect computer networks from unwanted traffic and bolster the network’s cybersecurity. For example, an intrusion detection system (IDS) is a device that monitors a network or systems for malicious activity. Some IDS products have the ability to respond to detected intrusions. Systems with response capabilities are typically referred to as an intrusion prevention system (IPS). Intrusion detection and prevention systems (IDPS) are primarily focused on identifying possible incidents, logging information about them, and reporting attempts. In addition, organizations use IDPS for other purposes, such as identifying problems with security policies, documenting existing threats and deterring individuals from violating security policies. IDPS are necessary additions to the security infrastructure and contribute to a network’s overall cybersecurity. Accordingly, non-monetary remuneration should include items in form of software and hardware.

2. Conditions on Donation and Protected Donors

The AMA supports the concept of a safe harbor limiting the exception to donated technology and services to implement and maintain cybersecurity. However, we suggest that OIG also add that the donated technology and services are also meant to help reestablish cybersecurity. Adding the reestablishing language to the regulatory safe harbor would match the regulatory exception under Stark and highlight the importance of recovering in responding to a cyberattack. Thus, §1001.952(jj)(1) should read “The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.”

The proposed types of technology protected are appropriate in their breadth. While we understand that the technology types included are not meant to be exhaustive, OIG should also expressly include continuous monitoring and log management software. Additional services include e-mail protection, endpoint protection, access management, data protection and loss prevention, asset management, network management, vulnerability management, incident response, medical device security, and cybersecurity policy development. These types of tools can help identify and detect cyberattacks.

The proposed services protected are also appropriate in their breadth. The AMA is in strong support of and thanks OIG for including cybersecurity education services and services associated with performing a cybersecurity risk assessment or analysis as being protected under the proposed exception. These services are essential in preventing future cyberattacks.

The AMA opposes the potential addition of a deeming provision that would allow donors or recipients to demonstrate that donations are necessary and predominantly used to implement, maintain, or reestablish effective cybersecurity. The deeming provision would add unnecessary burden, would bring confusion to

a straightforward proposal, and does not provide any additional meaningful protection against fraud or illegal remuneration. While we appreciate that any such provision would not require compliance with a particular framework or set of standards, the AMA is concerned about how a donor and recipient could practically demonstrate “deeming” compliance and the additional burden associated with trying to demonstrate reasonable conformance to a widely recognized cybersecurity framework or set of standards. Physicians will struggle with answering questions like what “reasonable conformance” looks like and when is a framework or standard “widely recognized.”

Moreover, the proposed exception already requires that the technology and services be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. Thus, donors and recipients are already subject to this requirement and are essentially making such a declaration by providing and accepting the technology and services. The OIG may always bring an action against a physician who fails to use the technology and services predominantly to implement, maintain, or reestablish cybersecurity. Accordingly, a separate deeming provision is an unnecessary technical requirement.

We agree with OIG that the cybersecurity donation does not need a similar list of selection criteria found in the EHR safe harbor to ensure that parties can meet the volume or value condition for the cybersecurity safe harbor.

The AMA supports a broad scope of protected donors to significantly further the important public policy goal of promoting cybersecurity. Donors of cybersecurity should be individuals or entities that provide patients with health care items or services covered by a federal health care program and submit claims or request for payment for those items or services (directly or pursuant to reassignment) to Medicare, Medicaid, or other federal health care programs. Donors should also be health plans, EHR vendors, and ancillary service providers because they can play a central role in the adoption and use of cybersecurity. Furthermore, while the AMA understands that OIG enforcement experience raises questions about unscrupulous manufacturers, OIG should consider manufacturers as potential donors because they can play a direct and central patient care role that justifies protection for the provision of cybersecurity items and services and in protecting the security of devices in the health care ecosystem.

3. Conditions for Recipients

The AMA is supportive of allowing donation to patients of cybersecurity technology, as cybersecurity is a patient safety issue. OIG also recognizes that HHS “must protect its beneficiaries by fostering a culture of cybersecurity among its partners and stakeholders.”⁷ Physicians may be in a good position to teach patients about the safe use of personal health information technologies in ways that contribute to the practice’s cybersecurity posture. For example, helping patients understand the risks of unsecure communication and the need to communicate only through encrypted patient portals can further improve cyber hygiene of the practice. Furthermore, with the expected increase of patient-generated health data (PGHD), there will be an increased need to ensure all data sources and endpoints (e.g., consumer-facing remote monitoring systems) enlist good cyber hygiene practices.

⁷ OIG, Top Management #10: Protecting HHS Data, Systems, and Beneficiaries from Cybersecurity Threats (2017), available at <https://oig.hhs.gov/reports-and-publications/top-challenges/2017/2017-tmc.pdf#page=45>.

4. Written Documentation

We appreciate the OIG recognizing that the written documentation requirement does not require every item of cybersecurity technology and every potential service to be specified in the agreement. Instead, the written agreement must include a general description of the cybersecurity technology and services to be provided over the term of the agreement. Thus, we recommend that the proposed regulatory text reflects this approach by including the word “general” or “generally,” so that donors and recipients who do not engulf themselves in safe harbor preamble text are not unnecessarily including every item or potential service. Proposed §1001.952(jj)(4)(ii) should read “generally describes the technology and services being provided...”

The AMA seeks clarification on what the written requirements are surrounding value. The proposed regulatory language includes the amount of the recipient’s contribution (if any), while the preamble states that the written agreement requires a reasonable estimate of the value of the donation. AMA would be supportive of only including the recipient’s contribution (if any). However, if OIG decides to include the value of the donation in a written agreement requirement in regulatory text, we recommend that OIG use similar terminology of “a reasonable estimate of the value of the donation,” so as to not introduce any concept of fair market value or the need to hire a valuation consultant to determine the reasonable estimate.

5. Alternative Proposal for Inclusion of Cybersecurity Hardware Donations

The AMA is in strong support of the alternative proposal for inclusion of cybersecurity hardware donations. After seeing countless requirements placed on the practice of medicine without any positive incentives, the AMA appreciates a proposal where if a risk assessment is performed of a donor’s own organization and that of a potential recipient, the cybersecurity hardware donation is protected.

The AMA believes that defining “risk assessment” based on NIST Special Publication 800-30 is sufficient for the cybersecurity donation exception. We do not, however, believe that the proposal should incorporate specific standards or requirements because NIST’s definitions and structures are outside the capabilities of small and medium practices. Instead, OIG should provide potential examples of specific standards or requirements in preamble language as instructional and not mandate any specific standard or requirement to provide necessary flexibility.

The AMA is opposed to limiting the additional cybersecurity hardware permitted under the alternative proposal to certain kinds of hardware. While we understand the concerns about multiuse technology, some small practices may need basic hardware upgrades for donors to feel comfortable connecting to the small practice. For example, a practice may need a new server because the practice is currently operating on a Windows Server 2003 R2 where Microsoft’s extended support ended in July 2015. We note that such hardware donation would still need to be necessary and used predominantly to implement, maintain, or reestablish cybersecurity to receive protection. The scope of covered hardware items should also include hardware security appliances because many cybersecurity software products require the use of a specific hardware device to operate. Security appliances are purpose-built hardware appliances that are designed to protect computer networks from unwanted traffic and bolster the network’s cybersecurity.⁸

⁸ As stated previously, an intrusion detection system (IDS) is a device that monitors a network or systems for malicious activity. Some IDS products have the ability to respond to detected intrusions. Systems with response

The AMA supports exempting contributions for the upgrades, updates, or patches of remuneration that were previously donated. However, we oppose any limit on the amount or type of donated hardware by establishing a cap on the value of donated hardware.

The AMA is strongly opposed to any contribution requirement from the recipient to receive protection under the proposed exception. The contribution requirement would add unnecessary burden in requiring tracking of amounts, spending additional valuation costs to ensure that value is a “reasonable estimate,” and potentially prohibitive costs where a practice may not be able to afford the contribution amount.

Alternatively, if OIG goes forward with a contribution amount, OIG **must** have an exception for small, underserved, and rural practices. While we oppose contributions generally, the contribution amount on small, underserved, and rural practices will impose a significant financial burden that could negatively impact patient care. Furthermore, OIG should consider the additional administrative burden and complexity in determining whether a practice meets a definition and whether not having any contribution amount regardless of practice type is more beneficial and clearer for the health care industry.

Small practices should be defined how a small business is defined by the Small Business Association for NAICS code 621111 (Offices of Physicians).⁹ This definition is the same that CMS and OIG use when analyzing the need for a Regulatory Impact Analysis or in examining the Regulatory Flexibility Act for all proposed and final rules coming from the HHS, including this proposed and forthcoming final rule related the physician self-referral law/anti-kickback statute.¹⁰

Alternatively, OIG could define a small practice similarly to how it is defined under the Quality Payment Program (QPP) as a Tax Identification Number or virtual group with 15 or fewer eligible clinicians. A significant advantage of using the QPP definition of a small practice consistently is that physicians and practice administrators can determine whether they qualify as a small practice via the qpp.cms.gov website simply by entering their NPI. By enabling practices to look up their small practice status via the QPP portal and use it as the basis for waiving the contribution amount, CMS and OIG would minimize burden on these practices. This is also how the AMA defined small practice for its 2017 Physician Cybersecurity Survey.¹¹

Underserved practices should be defined as those in (1) medically underserved areas, as designated by the Secretary under section 330(b)(3) of the Public Health Service Act; (2) primary health care geographic health professions shortage areas, as designated by the Secretary under §332(a)(1)(A) of the Public Health Service Act; or (3) a Critical Access Hospital.

Rural practices should be defined as those located in rural areas, as defined in the safe harbor for local transportation at §1001.952(bb).

capabilities are typically referred to as an intrusion prevention system (IPS). Intrusion detection and prevention systems (IDPS) are primarily focused on identifying possible incidents, logging information about them, and reporting attempts. In addition, organizations use IDPS for other purposes, such as identifying problems with security policies, documenting existing threats and deterring individuals from violating security policies. IDPS are necessary additions to the security infrastructure and contribute to a network’s overall cybersecurity.

⁹ 13 CFR §121.201 (Sector 62, Subsector 621).

¹⁰ 84 Fed. Reg. 55766, 55836 (Oct. 17, 2019)(Stark); 84 Fed. Reg. 55694, 55756 (Oct. 17, 2019)(AKS).

¹¹ Medical Cybersecurity: A patient safety issue, available at <https://www.ama-assn.org/delivering-care/patient-support-advocacy/medical-cybersecurity-patient-safety-issue>.

h. Electronic Health Records
i. Deeming

The AMA supports OIG's modifications to: (1) clarify that, on the date the software is provided, it "is" certified; and (2) remove reference to "editions" of certification criteria to align with proposed changes to the certification program. These two technical changes do not change the current interpretation of the safe harbor but provide additional clarity by removing awkward language.

ii. Information Blocking

The AMA supports the concept of updating §1001.952(y)(3) to recognize the significant updates regarding information blocking since the 2013 Final EHR Safe Harbor rule. The AMA strongly supports the elimination of unjustified information blocking that prevents data exchange. HHS broadly needs to prohibit networks, exchanges, developers, and other health care providers from blocking the electronic availability of clinical data to health care providers who participate in the care of shared patients. Information blocking under these circumstances interferes with the provision of optimal, safe, and timely care. While we support the prohibition on information blocking, the AMA has concerns regarding the broad definition of terms and has sought clarification as to ONC's interpretation in the proposed rulemaking "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program." Given the unknown impact and potential unintended consequences regarding the interpretation of information blocking, at this time, we recommend that OIG focus more on what is provided in statute regarding information blocking.

Moreover, while the reasoning behind alignment is not to change the purpose of the safe harbor condition, the AMA notes that OIG is incorporating an intent-based element into a safe harbor condition. This can make determination about whether all of the conditions are met more complex and increase regulatory and compliance costs.

The AMA opposes applying the knowledge standard to health plans for purposes of the EHR safe harbor. Instead, health plans should be subject to the "knows" or "should know" standard that is applicable to health information networks, exchanges, and developers. Health plans are not health care providers. Physicians have direct patient care responsibilities and an ethical duty to patients. Health plans do not have direct patient care responsibilities and may not have the same patient safety considerations that physicians and providers with direct patient care responsibilities have.

Moreover, health plans should be subject to the "knows" or "should know" standards because of the current dynamics between physicians and health plans, including the trend towards health plan offering or demanding access to EHRs. Historically, health plans have only had access to clinical information when necessary for payment. Physicians have acted as stewards to determine what information is necessary for each individual to be covered and for the physician to be paid. However, automated access to the EHR would potentially remove that barrier, potentially jeopardizing the physician's stewardship, and grant the health plan access to information in the EHR beyond what it needs for a particular transaction. This could have negative downstream consequences for patients and physicians. For example, a health plan could determine that the patient had already received imaging or another service from another plan and automatically deny coverage of that imaging service or require unnecessary prior authorization requirements that delay needed care. Even when patients already have coverage, there are examples of

payers making coverage decisions based on patient information that neither the patient nor the patient's physician knew the payer was receiving. Accordingly, given the potential consequences of health plan access to data, health plans should be held to a "knows" or "should know" standard for purposes of the EHR safe harbor.

Alternatively, OIG should decline applying any knowledge standard to health plans at this time for the EHR safe harbor. While we understand that it may be reasonable to have one condition that applies the same information blocking knowledge standard to all parties who voluntarily use the safe harbor to protect donations of EHR items and services, Congress did not include health plans as part of the information blocking provisions or discuss the EHR safe harbor. Therefore, Congress did not apply any intent standard to health plans and OIG should respect Congress's intent.

iii. Cybersecurity

The AMA supports the proposal to expand the EHR safe harbor to expressly include cybersecurity software and services. This expansion would make it clear that an entity donating EHR software and providing training and other related services may also donate related cybersecurity software and services to protect the EHR.

iv. The Sunset Provision

The AMA strongly supports the elimination of the sunset provision at §1001.952(y)(13). New entrants into medical practice, coupled with aging EHR technology at existing practices and the emergence of new and better technology, necessitate the availability of this safe harbor to achieve the HHS's objectives of widespread adoption of EHR technology. Thus, we support the elimination and oppose any further extension.

v. Definitions

1. Interoperable

The AMA supports the concept to update the definition of the term "interoperable" to align with the statutory definition of "interoperability" added by the Cures Act to §3000(9) of the Public Health Services Act. We support matching the statutory definition; however, as described above, we are opposed to specifically referencing proposed regulatory sections. Given the unknown impact and potential unintended consequences regarding the interpretation of interoperability and information blocking, at this time, we recommend that OIG focus more on what is provided in statute regarding the ONC proposed rule. Relatedly, we are opposed to linking the definition of "interoperable" with the proposed definition of "interoperability" at 45 CFR 170.102 in the ONC NPRM.

2. Electronic Health Record

The AMA is opposed to the new definition of electronic health records because of its potential breadth. We appreciate OIG's intention to not substantively change the scope of protection but by removing "used for clinical diagnosis and treatment for a broad array of clinical conditions," we believe the proposed definition expands protection well beyond what is prototypically considered an "electronic health record." For example, if a patient maintains a copy of their health information on their personal computer, such health information is: (1) transmitted by or maintained in electronic media; and (2) relates to the past,

present, or future health or condition of an individual or the provision of health care to an individual. Thus, this personal health record would be an “electronic health record” under the new proposed definition. The new proposed definition would also apply to health information on a smartphone or similar device, health information that is housed by a clearinghouse or a health plan, or health information gathered by a wellness app. Accordingly, we recommend including language like “used for clinical diagnosis and treatment” into the new definition. While the donation of EHRs is limited to certified EHRs, we believe that adding this language would provide the proper scope for “electronic health record” for purposes of the EHR safe harbor.

For example, electronic health record shall “mean a repository of electronic health information used for clinical diagnosis and treatment for a broad array of clinical conditions that: (A) Is transmitted by or maintained in electronic media; and (B) Relates to the past, present, or future health or condition of an individual or the provision of healthcare to an individual.”

vi. Additional Proposals and Considerations
1. 15 Percent Recipient Contribution

The AMA is opposed to the contribution requirement from the recipient to receive protection under the current EHR safe harbor. The contribution requirement adds unnecessary burden, complexity, and potentially could be cost-prohibitive. The contribution requirement adds burden in requiring setting the contribution amount in writing and ongoing monitoring and tracking of contribution amounts to ensure compliance.

Alternatively, if OIG continues with the contribution amount, OIG 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. OIG should take into account the ability of these practices to bear the burden of the increasing demands on staff in implementation of the proposed rule. Furthermore, OIG should consider the additional administrative burden and complexity in determining whether a practice meets a definition and whether not having any contribution amount regardless of practice type is more beneficial and clearer for the health care industry.

“Small practices” should be defined as how small businesses are defined by the Small Business Association for NAICS code 621111 (Offices of Physicians). This definition is the same that CMS and OIG use when analyzing the need for a Regulatory Impact Analysis or in examining the Regulatory Flexibility Act for all proposed and final rules coming from the HHS, including this proposed and forthcoming final rule related to the physician self-referral law/anti-kickback statute.

Another option is that OIG could define a small practice similarly to how it is defined under the Quality Payment Program (QPP) as a Tax Identification Number or virtual group with 15 or fewer eligible clinicians. A significant advantage of using the QPP definition of a small practice is that physicians and practice administrators can determine whether they qualify as a small practice via the qpp.cms.gov website simply by entering their NPI. By enabling practices to look up their small practice status via the QPP portal and use it as the basis for waiving the contribution amount, CMS and OIG would minimize burden on these practices. In addition, because the QPP and proposed exceptions and safe harbors share the same purpose to promote value-based care, we recommend keeping the definitions consistent across safe harbors and exceptions.

“Underserved practices” should be defined as those in: (1) medically underserved areas, as designated by the Secretary under §330(b)(3) of the Public Health Service Act; (2) primary health care geographic health professions shortage areas, as designated by the Secretary under §332(a)(1)(A) of the Public Health Service Act; or (3) a Critical Access Hospital.

“Rural practices” should be defined as those located in rural areas, as defined in the safe harbor for local transportation at §1001.952(bb).

If an individual or entity qualifies for one of the definitions, the proposed contribution requirements should be excepted. Thus, if an urban, large practice is in a medically underserved area, the practice is excepted from any contribution requirements.

The AMA also supports modifying or eliminating the contribution requirements for updates to previously donated EHR software and technology. OIG could potentially require a contribution for the initial investment only but not require a contribution for any update of the software already purchased. Similarly, as above, OIG should consider the additional administrative burden and complexity in determining whether the update is “new” and whether not having any contribution amount regardless of practice type is more beneficial and clearer for the health care industry.

2. Replacement Technology

The AMA supports the deletion of the condition that prohibits the donation of equivalent items or services to allow donations of replacement EHR technology. This current prohibition can lock physician practices into a vendor, even if they are dissatisfied with the technology, because the recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system. This cost difference between these two options is too high and effectively locks physician practices into EHR technology vendors. Accordingly, the AMA supports the deletion of this safe harbor requirement regarding replacement technology.

- i. Personal Services and Management Contracts and Outcomes-Based Payment Arrangements
 - i. Elimination of Requirement to Set Aggregate Compensation in Advance

The AMA strongly supports changing the requirement that aggregate compensation under these agreements be set in advance to a requirement that the methodology for determining compensation be set in advance. This proposal will provide the health care industry enhanced flexibility to undertake innovative arrangements and remove legal risk from many existing financial arrangements that meet all of the requirements of the current personal service and management contract except for the compensation being set in advance requirement.

- ii. Elimination of Requirement to Specify Schedule of Part-Time Arrangements

The AMA supports the proposal to eliminate requirements relating to agreements for services provided on a periodic, sporadic, or part-time basis. Existing safeguards provide sufficient safeguards against the manipulation of these arrangements to reward referrals.

iii. Proposal to Protect Outcomes-Based Payments
1. Outcome-Based Payments

The AMA opposes requiring satisfaction of an outcome measure in order to receive an outcomes-based payment. While the goal of outcome measures should be to achieve more effective care, requiring constant achievement is not practical in the practice of medicine. The nature of medical practice is constantly evolving and responding to emergent infectious diseases and natural disasters that may negatively impact outcomes or necessarily increase costs. In these instances, physicians may not be able to achieve more effective care at no fault of the provider. OIG should recognize this reality and allow for outcome-based payments when attempting to achieve or satisfy an outcome measure.

The AMA appreciates the proposal that there be one or more outcome measures because in many cases it would be impossible to have compliance with this requirement with only one outcome measure given the lack of proper outcome measures.

The AMA recommends keeping the examples of outcomes-based payment arrangements in preamble language and not to formally define the terms in regulatory text. Value-based care is constantly changing, and the proposed safe harbor needs to be flexible to allow for innovative and new payment arrangements that may not explicitly meet the definition of “shared savings payment.” Moreover, we recommend that OIG add a definition of “population-based payment” given the focus on population health by the HHS.

2. Outcome Measures

The AMA has similar concerns under this proposal to protect outcomes-based payments and the proposed care coordination arrangements safe harbor at §1001.952(ee). This proposal is administratively burdensome, confusing, and does not reflect the lack of valid outcome measures for many specialty practices. For example, OIG never defines “outcome measure,” which is a new and evolving science in health care.

Mandating an outcome measure as a requirement for safe harbor protection may disadvantage certain specialties as well as rural practices and practices that treat high risk patients. A number of methodological issues exist that must be addressed before requiring using outcome measures, such as the development of better risk-adjustment models at the measure level (not just the program level as proposed) and stratification by specialty. In addition, infrastructure challenges may prevent physicians from having the ability to be measured on outcome measures, such as not having appropriate data elements in the EHR. Practices may also experience interoperability issues that may interfere with the exchange of information needed to use outcome measures or may be unable to do longitudinal tracking due to the lack of uniform patient identifiers and patient attrition when tracking outcomes.

There are very few outcome measures in the Medicare program and it has proven difficult to measure through a quality measure. A specialty should not be penalized because they have good outcomes on a procedure or process measure but lack a valid outcome measure. OIG should be incentivizing and encouraging good patient care and not the existence of outcome measures for the sake of having outcome measures. While we understand that outcome measures can come from internal sources, only sophisticated health systems with advanced data analytics have the capability to internally develop outcome measures. Small, underserved, and rural practices do not have the resources to develop these measures internally, which could lead to further consolidation of the health care system.

OIG also needs to address issues regarding individual physician participant measurement compared to group measurement. OIG is assuming that individual physicians can wield sufficient influence on which measures are developed and available to meet the needs of their target patient population. Outcome measures at the physician level can also be particularly challenging to construct for two primary reasons—small sample sizes and the difficulty of identifying outcomes for which the physician can and should be held accountable (i.e., outcomes that are largely dependent on the quality of care received, not other factors). Thus, holding physicians accountable through the application of safe harbor protection for something that is not necessarily within their direct control would be imprudent.

Given these concerns and the definition of “outcome” being vague, it appears that simply carrying out a planned activity successfully would count as a successful outcome. We believe it would be hard for OIG to be more restrictive than this result, since there are relatively few outcome measures being used in CMS models or anywhere else. While beneficial, this result also means that there would not necessarily be any benefit for those who actually are using real outcome measures, particularly given the requirement for continuous improvement. Thus, the AMA is concerned that the OIG will decide later to restrict what counts as an outcome measure, and any participant who relied on using something else would suddenly be out of compliance. One compromise might be to require improvements on process measures and maintenance or improvement on outcome measures that are already high.

Overall, valid and reliable outcome measures could potentially lead to more direct measures of quality and their development by medical specialties should be encouraged and funded. However, we also recognize that certain types of measures might be more appropriate for certain specialties and practice settings than for others. Furthermore, process measures that are evidence-based can be integral to improved outcomes and in some specialties, this foundational step must first be addressed before moving on to outcome measures.

Thus, alternatively, the AMA recommends that the outcome measure requirement be expanded to include process measures. Process measures, for which there is strong evidence that fulfillment of the measure intent, such as providing or not providing a specific treatment will improve patient outcomes or safety, should be included. Process measures continue to serve a purpose, especially when coupled with cost, because it is often the breakdown in a process that contributes to poor outcomes and increased resource use. If the Medicare program was structured to allow physicians to focus on a targeted clinical or disease area, such as preventing diabetes and the measures correlated with the clinical episode, process measures would be seen as more valuable.

The AMA generally agrees with OIG by not considering patient satisfaction or convenience to be valid outcomes measures for this proposed requirement because of the lack of evidence tying patient satisfaction to better clinical outcomes.

The AMA cautions OIG on requiring parties to rebase the outcome measures where rebasing is feasible because of the number of factors that go into rebasing and the flexibility in determining whether and when it is appropriate to rebase. Any time frame must be beyond one year and should be looking at a five-to-ten-year horizon. When value-based arrangements are created or when a patient is new to a value-based arrangement, the patient will generally initially see increased costs because they are now receiving more preventative care to reduce the risk of a more serious health event. For example, Clinician A may take preventive care steps to prevent colon cancer or to identify cancer at an earlier stage (e.g.,

colonoscopies, blood work) in the first year that reduces the risk of cancer for five years. Clinician B may not take any preventative care steps for a patient and the patient later develops cancer four years later. If rebasing is done on a year basis, Clinician B would be rewarded for providing care at no cost and good outcomes, while the Clinician A would not be rewarded because the clinician provided high cost care with no discernible improvement of outcomes.

The AMA supports incorporating the CMS Quality Payment Program measures as an option to demonstrate compliance with the requirement to establish outcome measures because it would help with aligning measures across different aspects of the HHS.

3. Methodology

The AMA recommends that the set in advance requirements be softened to permit substitution of metrics and other adjustments as long as the substitute metrics are consistent with the value-based purposes. With value-based arrangements, metrics often change, and payers often change formulas or requirements. Moreover, distribution of savings may be received far after the fact (e.g., Advanced APM bonus). Accordingly, the set in advance requirements should be softened to allow for changes in methodology while a value-based arrangement is “active” as long as the substitute metrics are consistent with a value-based purpose.

a. Fair Market Value

The AMA is opposed to requiring that the aggregate compensation be consistent with fair market value. Determining fair market value poses challenges because there are no industry standards yet developed to determine fair market value for outcomes-based payment arrangements and some of these arrangements may not necessarily correlate payments with actual services performed. While industry will evolve and adapt, requiring fair market value when a major current constraint to value-based care is requiring fair market value (e.g., services may be provided above or below fair market value to save costs or incentivize better outcomes) is not practical.

b. Volume or Value of Referrals

The AMA does not object to the concept of a volume or value of referrals of other business requirement. We would welcome additional thoughts from OIG in the preamble regarding how to draw the line between direct and indirect referrals in this context.

4. Writing and Monitoring

The AMA understands the need for a written agreement and asks OIG to provide flexibility in enforcing this requirement. The AMA is concerned about arrangements technically falling outside the requirement of all services being documented considering the innovative and flexible nature of value-based arrangements. While parties can amend the agreement, finding anti-kickback violations for minor details could result in less participation in these types of arrangements.

5. Technical Amendment

If OIG goes forward with this proposed safe harbor, the AMA requests that “made by a principal to an agent as compensation for the services of the agent” be added to the regulatory text at §1001.952(d)(2) to mirror §1001.952(d)(1). Although implicit, currently proposed (d)(2) does not mention the principal-agent relationship. For example:

(2) As used in §1128B of the Act, “remuneration” does not include any outcomes-based payment made by a principal to an agent as compensation for the services of the agent, as long as all of the standards in paragraphs (d)(2)(i) through (ix) of this section are met:

- j. Warranties
 - i. Bundled Warranties

The AMA supports OIG’s proposal to revise the warranties safe harbor to protect bundled warranties for one or more items and related services, when certain conditions are met. This modification would allow manufacturers and suppliers to warrant that a bundle of its items or one or more items in combination with related services, such as product support services, will meet a specified level of performance under a warranty agreement.

1. Inclusion of Services in Bundled Warranties

The AMA shares the concerns of OIG regarding patient outreach services, such as medication adherence services, being provided by manufacturers and suppliers because they do not necessarily have direct patient care responsibilities. To protect against risks of patient harm, we recommend additional safeguards for patient outreach services to include that such outreach be approved by a licensed medical professional. While the AMA is not opposed to a safeguard allowing the seller to pay an independent intermediary to perform services that require direct patient outreach, we are concerned about how drug manufacturers may abuse this safeguard similar to patient assistance programs.

2. Requirement for Federally Reimbursable Items and Services Subject to Bundled Warranty Arrangements to Be Reimbursed by the Same Federal Health Care Program and in the Same Payment

The AMA is opposed to the requirement that items and services be reimbursed by the same payment methodology. While we agree with OIG that this could create incentives for overutilization or inappropriate utilization of items and services included in the bundle, care coordination and potential cost reductions require payments from different payment methodologies. For example, a joint replacement can occur in a hospital or ambulatory surgical center and then a patient may be discharged to a Skilled Nursing Facility or to home health care. Any warranty could not cover this episode of care because of the different payment methodologies. AMA is concerned that warranties under the same payment methodology will force patients to remain in the facility longer than necessary to ensure that the safe harbor is met. Instead, OIG should allow for warranties under these circumstances to promote better care coordination and more appropriate facility utilization. To protect against inappropriate utilization, OIG could add safeguards including limiting the application of the safe harbor to medically necessary items

and services, prohibiting stinting, and requiring the warranty to a part of written care plan by a licensed medical professional.

k. Local Transportation

The AMA generally supports OIG's proposals to expand the distance 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 is discharged to the patient's residence.

i. Expansion of Mileage Limit for Patients Residing in Rural Areas

The AMA supports increasing the limit on transportation of residents of rural communities to 75 miles because the current 50-mile limit for rural residents is insufficient considering many rural residents need to travel more than 50 miles to obtain medically necessary services. We do not believe that there needs to be a demonstration of financial, medical, or transportation need for transportation more than the current 50-mile limit. OIG already requires that the care be for medically necessary items or services, which is the appropriate safeguard to prevent program abuse. Moreover, no additional safeguards are necessary to prevent abuse of an expansion on these limits for rural or other patients because the current safeguards under 1001.952(bb) are sufficient protection.

ii. Elimination of Distance Limit on Transportation of Discharged Patients

The AMA supports the proposal to eliminate any distance limit on transportation of a patient who has been discharged from a facility after admission as an inpatient to a patient's residence or another residence of the patient's choice. The AMA also supports expanding the proposal to also protect transportation to any location of the patient's choice as long as there is a medically justifiable reason for the patient's choice. For example, the patient should not be transported to a sports stadium to attend a game after being discharged from a hospital (although if the sports stadium has physical therapy services that the patient is seeking, transportation would be appropriate). While some fraud and abuse risk may exist in transporting to a health care facility, OIG already requires that a patient be an established patient of the entity that is providing the transportation and such transportation would further promote the coordination of care between facilities.

OIG should also expand such transportation beyond inpatient discharges to include a patient that has been seen in the emergency room, under observation status at a hospital but not admitted, and after a procedure at an ambulatory surgical center or other facilities that can also perform the procedure (e.g., hospital outpatient department). The AMA is concerned that without expanding such transportation the anti-kickback statute may unnecessarily increase costs because a patient must be admitted for a procedure to receive transportation rather than receiving the same procedure in an ambulatory surgical center at a lower rate of payment. The AMA believes that an appropriate safeguard to limit the potential fraud concerns would be to require a medical justification to receive these transportation services outside of an inpatient discharge. Thus, after a colonoscopy or receiving stitches after a fall, a licensed medical professional could determine that the patient is unable to travel home unaccompanied safely. This decision making could be a part of the policy that is required under §1001.952(bb)(A)(i)(A).

As stated above, we do not believe that there needs to be a demonstration of financial, medical, or transportation need for transportation to a patient's residence. With this proposed expansion, the AMA

still believes that a need to increase the distance limit for transportation of patients who reside in rural areas still exists.

iii. Local Transportation for Health-Related, Non-Medical Purposes

The AMA is 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 or food banks, social services facilities (such as to apply for food stamps or housing assistance), exercise facilities, or chronic disease support groups. The AMA would preach caution in limiting a potential expansion of a safe harbor to certain beneficiary populations like chronically ill patients because of the potential unintended consequences. For example, the AMA believes that receiving safe harbor protection should not wait until a patient develops diabetes before going to a food bank or getting food stamps. Instead, the safe harbor should focus on both prevention and treatment of a disease.

As for potential safeguards, the OIG may want to consider the safeguards from the beneficiary inducement civil monetary penalty including being unlikely to interfere with, or skew, clinical decision making; being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and not raising patient safety or quality-of-care concerns. From the proposed patient engagement tools and supports, we believe that safeguard like the transportation is not used for patient recruitment or marketing of items or services would be appropriate. Moreover, as stated above, the AMA believes that the proposed patient engagement tools and supports should be expanded beyond value-based enterprise. Thus, if OIG agrees with AMA's comments, the expansion to local transportation for health related, non-medical purpose that improve or maintain health could fit within that safe harbor.

iv. Use of Ride-Sharing Services

The AMA appreciates the explanation on the application of ride-sharing services and does not believe that additional regulatory language is necessary. OIG should repeat or reference its discussion in the proposed rule preamble in the final rule preamble as further guidance.

II. Provisions of the Proposed Rule Beneficiary Inducements

a. Statutory Exception for Telehealth Technologies for In-Home Dialysis

The AMA supports the concept of requiring that telehealth technologies be furnished to the individual by the provider of services or the renal dialysis facility that is currently providing the in-home dialysis, telehealth visits, or other ESRD care to the patient. The AMA shares the concerns of OIG of providers and supplies offering telehealth technologies to patients with whom they do not have a prior clinical relationship in an attempt to inappropriately steer patients to a particular provider or supplier. The AMA believes that a valid patient-physician relationship must be established before the provision of telemedicine services, through:

- (1) A face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine;

- (2) A consultation with another physician who has an ongoing patient-physician relationship with the patient. The physician who has established a valid physician-patient relationship must agree to supervise the patient's care; or
- (3) Meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies, such as those of radiology and pathology.

Exceptions to the foregoing include on-call, cross coverage situations; emergency medical treatment; and other exceptions that become recognized as meeting or improving the standard of care. Thus, although potentially rarely used in the in-home end-stage renal disease (ESRD) context, the AMA would recommend adding these exceptions in either the regulatory requirement itself or in preamble language as guidance.

We oppose expanding the statutory exception to include suppliers given that the congressional intent of the statutory exception was to expand patient access to in-home dialysis care furnished by a patient's physician.

The AMA supports OIG's interpretation of "for the purpose of furnishing telehealth services related to the individual's end stage renal disease" to mean that the technology contributes substantially to the provision of telehealth services related to the individual's ESRD, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes.

The AMA would preach caution on requiring the provider or facility to retain ownership of any hardware and make reasonable efforts to retrieve the hardware once the beneficiary no longer needs it for the permitted telehealth purposes. Such a requirement adds unnecessary burden in tracking and monitoring compliance especially when the telehealth technology is of low dollar value.

We are also opposed to any interpretation of this provision in a more restrictive manner including only allowing protection of telehealth technologies that provide the beneficiary with no more than a de minimis benefit. This potential requirement adds unnecessary burden and uncertainty. Furthermore, we are uncertain how this requirement of no more than a de minimis benefit coincides with a proposed requirement that the technology contributes substantially to the provision of telehealth services.

The AMA strongly supports OIG's interpretation of "telehealth services related to the individual's end stage renal disease" to mean only those telehealth services paid for by Medicare Part B. Medicare telehealth services are limited by statute and regulation to two-way audio-visual, real time communication between a patient and a physician or other qualified health professional. CMS notes that §1834(m) of the Social Security Act applies only to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional. A consistent statutory definition of telehealth does not exist among various federal agencies. The telehealth definition is even varied within the Social Security Act. However, for the Medicare Part B program, which includes ESRD, the statutory definition remains unchanged and encompasses a limited modality. Thus, for purposes of defining "telehealth technologies" under §50302(c), OIG should adopt the technologies that address the services under the current Part B definition of telehealth so that all Part B telehealth services—ESRD or otherwise—are treated consistently and in the same manner.

b. Additional Proposed Conditions for the Telehealth Technologies Exception

The AMA has no objection to the proposed prohibition on cost-shifting as an additional condition for this exception.

c. Defining Telehealth Technologies

The AMA supports OIG's proposal to define "telehealth technologies" for the purposes of the definition of the term "remuneration" as set forth in 42 C.F.R. §100.110 that is based in part by the definition of interactive telecommunications system found at 42 C.F.R. §410.78. The AMA appreciates the clarification that smart phones that allow for two-way, real-time interactive communication through secure, video conferencing applications would not be considered a "telephone." We are also supportive in defining "telehealth technologies" to include technologies such as software, a webcam, data plan, or broadband internet access that facilitates the telehealth encounter because these technologies can, in part, provide greater access to medically necessary care.

d. Other Potential Safeguards

i. Consistent Provision of Telehealth Technologies

While the AMA is supportive of the concept prohibiting parties from discriminating in the offering of telehealth technologies, small, underserved, and rural providers may not be able to uniformly provide such telehealth technologies to all of the practice's population because providing such technologies in the aggregate could be cost prohibitive. Thus, the practices would not be able to provide any telehealth technologies to any of their in-home dialysis patients, which would defeat the intent of the statutory exception to expand patient access to in-home dialysis care furnished by a patient's physician.

ii. Necessary Technology

The AMA is also opposed to the potential requirement that the donor make a good faith determination that the individual to whom the technology is furnished does not already have the necessary telehealth technology. We believe that the current proposal provides adequate protection against duplicative or unnecessary telehealth services being furnished with the requirement that the technology is not of excessive value and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes.

We are also opposed to requiring the person who furnishes the technology to take reasonable steps to limit the use of the technology by the individual to the telehealth services described on the Medicare telehealth list. This proposal adds unnecessary burden and complexity because no good definition exists as to what "reasonable steps" look like and whether such steps are actually feasible and not cost prohibitive.

iii. Notice to Patients

The AMA supports communicating to patients the benefits and risks of telehealth technology. However, no need exists for a formal, technical requirement to comply with the civil monetary penalty statute. This communication should be a part of the normal physician-patient relationship.

iv. Patient Freedom of Choice

The AMA supports a patient's freedom of choice among health care providers and the way a patient receives dialysis services under arrangements that would use the proposed exception. The AMA is concerned about the documentation burden in requiring advising patients when they receive such technology that they retain the freedom to choose any provider or supplier of dialysis services and to receive dialysis in any appropriate setting. Moreover, some patients may not want to receive this information. Instead, the AMA recommends that freedom of choice be more broadly protected similar to the prohibition on restricted referrals under the proposed value-based arrangement safe harbors.

For example:

(iii) Does not direct or restrict referrals to a particular provider, practitioner, or supplier if:

- (A) A patient expresses a preference for a different practitioner, provider, or supplier;
- (B) A patient expresses a preference for a different, appropriate setting; or
- (C) Such direction or restriction is contrary to applicable law or regulations under titles XVIII and XIX of the Act.

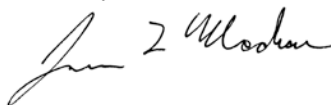
v. Materials and Records Requirement

The AMA agrees with OIG that no materials and records requirements should be required for this exception.

As initiatives advance to align payment and care coordination to improve the quality and value of care delivered, physician leadership is instrumental to optimizing care, improving population health, and reducing costs. Physicians provide the care, take care of the patients, and see the cost inefficiencies and overutilization. In helping physicians achieve the goals of value-based care, we urge OIG to create an anti-kickback statute regulatory safe harbor to facilitate coordinated care and promote well-designed alternative payment models.

Thank you for the opportunity to comment. The AMA is committed to engaging with OIG and other stakeholders going forward on ensuring that legal structures keep pace with evolving health care delivery and payment systems. We offer our assistance as OIG considers the impact of the anti-kickback statute on physician participation in innovative payment and delivery models. Should you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD