

Via electronic submission (www.regulations.gov)

December 30, 2019

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

***Re: Revisions to Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules
Regarding Beneficiary Inducements (RIN 0936-AA10)***

Dear Acting Inspector General Chiedi:

The Association of American Medical Colleges (“the AAMC” or “Association”) welcomes this opportunity to comment on the proposed rule entitled “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalties Regarding Beneficiary Inducements,” 84 *Fed. Reg.* 55694 (October 17, 2019), issued by the Office of Inspector General of the Department of Health and Human Services (OIG).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America’s medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Together, these institutions and individuals are the American academic medicine community.

The AAMC is supportive of the work to remove obstacles to value-based care due to the anti-kickback statute (AKS) and the Civil Monetary Penalty (CMP) Rules and commends the OIG for its efforts to add to and amend the safe harbors to enable transitions to value-based care. **Expanding safe harbor protections requires a careful balance that encourages innovative value-based care, ensures program integrity, and supports efforts of providers to provide patients with the optimal care. However, additional administrative burden may be required to comply with new requirements.** We urge OIG to be mindful of this balance when promulgating its final policies.

We are committed to the shared goals of improving the value of care delivered while also preventing undue risk of fraud, waste, and abuse in Medicare and state healthcare programs, and welcome the opportunity to work with the OIG (and the Centers for Medicare & Medicaid Services (CMS) to achieve these objectives.

The following summary points reflect our comments on the proposals addressed in this letter.

- **Proposed Terminology:** OIG should include reducing costs for providers in its definition of “value-based purpose,” and ensure sufficient flexibility under its definition of “target patient population.”
- **Proposed Safe Harbor for Care Coordination Arrangements:** OIG should (1) expand protection for monetary remuneration; (2) reduce or eliminate the 15 percent recipient contribution; (3) broadly frame requirements for outcomes measurement, including measures of patient experience of care; (4) allow spillover of benefits to all patients, including those outside of the target patient population; and (5) align its definition of “commercially reasonable” with that of CMS.
- **Proposed Safe Harbor for Arrangements with Substantial Financial Risk:** OIG should simplify and lower the minimum risk threshold for arrangements seeking protection under this safe harbor.
- **Proposed Safe Harbor for Full Financial Risk:** OIG should expand its definition of full financial risk to include partial capitation risk arrangements.
- **Proposed Safe Harbor for Patient Engagement and Support:** OIG should (1) explicitly protect the provision of items and supports that broadly address social determinants of health; (2) ensure that requirements allow sufficient flexibility to enable all patients to have access to providers participating in arrangements for patient engagement and support - including that the safe harbor protection not be limited to arrangements assuming downside risk; and (3) extend the safe harbor to waivers of patient cost-sharing.
- **Revisions to Safe Harbor for Local Transportation:** OIG should expand protection to include transport provided at discharge from an inpatient facility to another facility and a broader ability to provide local transport for health-related, non-medical purposes.
- **New Safe Harbor for CMS-Sponsored Models:** OIG should finalize its proposal to create a new safe harbor to standardize protection of CMS-sponsored model arrangements.
- **Revisions to Safe Harbor for Personal Services and Management Contracts and Outcomes-Based Payment Arrangements:** OIG should (1) finalize proposed changes to the advance requirements to compensation methodology (instead of aggregate amount) and exact schedule of performance for part-time services and (2) broaden its proposed revised protections for outcomes-based arrangements to include cost reductions for providers.
- **New Safe Harbor for Cybersecurity and Revisions to Safe Harbor for Electronic Health Record (EHR) Technology:** OIG should (1) include protections for hardware necessary for cybersecurity and (2) ensure protections do not pose a barrier to the adoption of EHR technology.

PROPOSED VALUE-BASED TERMINOLOGY

In general, the AAMC supports OIG’s use of broad and flexible definitions to the underlying core concepts proposed in the new value-based safe harbors. Specifically, we support the definitions of “value-based enterprise” (or VBE), “value-based arrangement,” “value-based-activity,” and “value-based participant” (or participant). We support the OIG’s broad use of the term “value” as a non-technical term, as we believe that defining such a term may be too restrictive and frustrate the voluntary uptake of providers as participants in new VBEs.

OIG Should Amend the Definition of “Value-Based Purpose” to Remove Requirement for Care Coordination Purpose for All Value-Based Arrangements and Include Reducing Costs for Providers

As proposed, “value-based purpose” would be defined as any of the following: “(A) Coordinating and managing the care of a target patient population; (B) Improving the quality of care for a target patient

population; (C) Appropriately *reducing the costs to, or growth in expenditures of, payors* without reducing the quality of care for a target patient population; or (D) Transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanism based on the quality of care and control of costs of care for a target patient population.” (84 *Fed. Reg.* 55706-55707; *emphasis added*) The OIG further proposes to require all protected value-based arrangements “directly further the first of the four value-based purposes, which is coordinating and managing the care of the target population.” Each of the four value-based purposes should be considered of equal importance, as each represents a distinct legitimate objective critical to achieving value-based care. Participants should be able to choose among the value-based purpose(s) that fit the goals of their own initiative. **The OIG should not prescribe that all protected arrangements must further the first enumerated value-based purpose.**

Additionally, the Association is concerned that the narrow framing of the cost reduction purpose could frustrate efforts by teaching hospitals and academic medical centers to appropriately reduce costs within the hospital or health system. Reducing costs in the delivery of high-quality care is critical to improving the value of care for patients and reducing costs to federal and health care programs. **We urge OIG to revise the cost reduction purpose to “appropriately reducing the costs to, or growth in expenditures of, payors or provider VBE participants without reducing the quality of care for a target patient population.”**

“Target Patient Population” Should Be Defined Flexibly to Allow for Innovative Value-Based Care Arrangements for All Patients

OIG proposes to define “target patient population” as “an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) Are set out in writing in advance of the commencement of the value-based arrangement; and (B) Further the value-based enterprise’s value-based purpose(s).” **The AAMC supports this broad and flexible proposed definition. We caution the OIG against adopting the alternative proposal to narrow the definition to patients with a chronic condition or patients with a shared disease state that would benefit from care coordination. All patients benefit from greater care coordination and management.** For example, improving care transitions for patients discharged from the hospital, or coordinating data sharing between primary care and specialty care providers to reduce duplication of items and services, could be better served by inclusion in a VBE’s target patient population. The proposed definition would allow the VBE to frame the arrangement specifically to a target patient population with a chronic condition or a shared disease state, but appropriately does not limit protections, and thus value-based care innovations, to only that subset of patients.

OIG also asks whether parties other than VBE participants should be or could be involved in selecting the target patient population. For example, whether payors should have a role in identifying or selecting the target patient population (or establishing outcome measures with respect to arrangements). In considering this, the OIG asks whether it should favorably treat a value-based arrangement that aligns its target patient population or its outcome measures and targets with payor-driven incentives. **The Association believes that the OIG should permit and even encourage, but not require, payor involvement with defining the target patient population** or outcomes measures and targets in an effort to better recognize the role of payors in making resources available for their patient members served by value-based arrangements. In terms of favorable treatment for value-based arrangements that align with payor-driven incentives, OIG could consider a *de facto* protection from the appropriate safe harbor protections for such arrangements. This could greatly reduce burden for participants and greater incentivize cooperation between providers and payors in transitioning to value-based arrangements.

CARE COORDINATION ARRANGEMENTS TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY SAFE HARBOR (42 CFR 1001.952(ee))

The AAMC appreciates the recognition by the OIG that not all value-based arrangements designed to meaningfully improve care coordination and management for patients will necessarily involve taking on downside risk, and that care coordination as a goal is as important for the transition to value-based care as shifting financial incentives. However, the AAMC has the following concerns with several areas of the proposed safe harbor for care coordination arrangements: (1) monetary remuneration should be protected; (2) the 15 percent recipient contribution requirement is too high and will limit which providers can participate in care coordination arrangements and which patients benefit from such arrangements; (3) outcomes measurement should be broad and inclusive of patient experience of care measures; (4) protection should allow spillover of benefits to all patients, including those outside of the target patient population; and (5) the vague standard for commercial reasonableness must be better defined.

OIG Should Extend Protections to Monetary Remuneration

As proposed, monetary remuneration would not be protected under the care coordination arrangement safe harbor. **The AAMC believes that monetary remuneration in no-or-low downside risk value-based arrangements can be a critical tool to a VBE's pursuit and achievement of its value-based objectives.** For example, in the CMS Stark proposed rule,¹ the agency discusses a scenario in which a hospital pays community physicians \$10 for each instance that the physicians order dual modality screening rather than single modality screening for a certain type of cancer based on new guidelines. The new guidelines recommend screening by two modalities in order to achieve more accurate results and improve the quality of care for patients by detecting more cancers and avoiding false positives. In this instance, the provision of \$10 for each service helps to shape physician behavior to follow the recommended care protocol. The Association recommends that the OIG align its care coordination safe harbor with CMS's value-based arrangement exception to protect both monetary and non-monetary remuneration.

OIG Should Eliminate or Reduce Recipient Contribution Requirements to Ensure All Providers Have Opportunity to Participate in Care Coordination Arrangements

OIG proposes to condition safe harbor protection of permissible in-kind remuneration on the recipient's contribution of at least 15 percent of the offeror's costs for the contribution. We understand the intent of the contribution requirement is to ensure that the remuneration would actually be used for the care coordination and management of the target patient population, as a sort of "skin in the game" in the absence of substantial financial risk. We are concerned however that such a requirement, if finalized, would effectively limit care coordination arrangements to highly compensated VBE participants with adequate financial resources to invest in care coordination arrangements, and thus limit the benefits of such arrangements to only those patients treated by such financially situated participants. **The OIG should instead eliminate the contribution requirement entirely or reduce the percentage while allowing for flexibility for the offeror of the remuneration to appropriately assess the recipient's ability to contribute to remuneration and further reduce or eliminate the contribution requirement accordingly.** A more flexible contribution requirement structure would ensure that VBE participants with varying resources are appropriately invested in the care coordination arrangements seeking safe harbor protections. Teaching hospitals and academic medical centers are increasingly looking to partner in care

¹ Centers for Medicare & Medicaid Services, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 84 *Fed. Reg.* 55766, at 55784 (October 17, 2019).

coordination efforts with physicians and practices in their communities and should not be prevented from doing so if those practices cannot meet the proposed contribution requirement.

Outcomes Measurement Must Be Valid and Reliable, and Ensure Flexibility Necessary to Tailor Care Innovation

The AAMC agrees with OIG that outcome measurement is an important aspect of the transition to value-based care. However, **we urge OIG to ensure that its final requirements for outcome measures are defined broadly and flexibly, including recognition of patient experience and satisfaction of care as meaningful outcome metrics of care coordination arrangements.** OIG notes that “Care coordination arrangements...can help improve health and the patient experience of care,” (84 *Fed. Reg.* 55699) yet proposes to specifically *exclude* patient experience and satisfaction measures from meeting the outcomes measure requirement, while otherwise allowing flexibility for evidence-based, valid measures.

Additionally, OIG should not require “rebasing” of outcome measures or rely on CMS’ Quality Payment Program (QPP) measure set as a definitive list of measures. A rebasing requirement would be duplicative of the requirement that the outcome measure must “advance care coordination and management of care of the target patient population.” The QPP is solely a physician measure set that CMS acknowledged in its most current annual rulemaking does not adequately incorporate outcomes measures or measures for many specialties. Instead, OIG should consider a broad standard that is inclusive of outcomes measures endorsed by the National Quality Forum, which evaluates measures on their validity and reliability, including patient experience measures and measures of the full range of care providers across the care continuum. Finally, OIG should better clarify that its outcome measure requirement does not mean that the recipient of in-kind remuneration must meet a certain level of performance on the measure for the remuneration to be protected. Such a requirement would be challenging to meet, considering that the measure(s) being used could be relatively novel and not have prior performance data from which to benchmark performance. Simply put, ideal performance targets might not be known at the outset of the value-based arrangement.

Safe Harbor Should Protect Remuneration That Benefits Patients Outside of the Target Patient Population

It is critical that the safe harbor protect arrangements even where the remuneration benefits patients outside the target patient population. **The AAMC urges OIG not to adopt its alternative proposal to limit protection under the safe harbor and require remuneration “only benefit the target patient population.”** Such a limitation goes against the broader theory of spillover effects from value-based care delivery innovations and would likely render the protection useless due to the complexities of managing benefits without spillover to a limited population. While care coordination arrangements would be designed to coordinate and manage the care of the target patient population, participants should not be penalized if the benefits of such arrangements incidentally improve the care for other patients as well.

OIG Should Align Its Definition of “Commercial Reasonableness” with CMS To Provide Greater Continuity

OIG proposes to require that value-based arrangements under this safe harbor must be “commercially reasonable.” OIG proposes to define “commercially reasonable” as an arrangement that “would make commercial sense” if entered into by entities of similar type and size without the potential for referrals. CMS proposes two alternative definitions of “commercially reasonable” – “the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, or the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.” **The Association**

recommends OIG align its definition to CMS’s alternative definitions so that a VBE may demonstrate compliance with the definition that most closely reflects the value-based arrangement in question.

VALUE-BASED ARRANGEMENTS WITH SUBSTANTIAL DOWNSIDE FINANCIAL RISK (1001.952(ff))

OIG Should Simplify and Lower Minimum Risk Thresholds for Arrangements Protected Under This Safe Harbor

OIG proposes to vary specific risk requirements for VBEs based on type of risk arrangement (e.g., shared savings, episodic payments, population-based payments for a subset of care, and partial capitation payments) in addition to requiring stringent individual participant risk sharing thresholds. This framework is not only complicated (especially in comparison to CMS’s single risk threshold for its similar “meaningful downside risk” exception to the Stark law), but also is set too high to incentivize the uptake of such risk-based arrangements to transition to broader risk/reward-focused value-based care. Participant physicians (and non-physician participants) are unlikely to accept risk for 25 percent (or 8 percent) of the total amount for which the VBE is responsible. **We urge OIG to reduce the threshold for the VBE’s shared risk for losses to less than 10 percent and remove the requirement that individual participants be accountable for the risk of the value-based arrangement.** Existing programs have financial risk requirements set between 5 and 9 percent (5 percent for medical homes, 8 percent for Advanced APMs, and 9 percent for the Merit-Incentive Performance System). We believe that a level of financial risk below 10 percent is high enough to prevent the influence of fee-for-service volume-based payments and advances a meaningful shift of providers toward value-based care.

VALUE-BASED ARRANGEMENTS WITH FULL FINANCIAL RISK (1001.952(gg))

OIG Should Expand its Definition of Full Financial Risk to Include Partial Capitation Risk Arrangements

OIG proposes to limit the full financial risk safe harbor only to arrangements where VBEs take full financial risk, defined as being responsible for the costs of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the payor. OIG is clear that partial capitation would not qualify for this safe harbor. Setting too high a bar for meeting the full financial risk threshold will limit the creation of innovative arrangements that incentivize providers. For example, a hospital may seek to enter arrangements with payors to capitate inpatient and outpatient services it provides for a target patient population, which would be a significant undertaking of risk yet under the proposed rule it would not satisfy the risk thresholds for full financial risk protections. **The Association recommends that OIG expand this safe harbor to protect arrangements where the VBE takes responsibility for the costs of a defined subset of items and services for a target patient population,** in addition to when it takes responsibility for all items and services.

ARRANGEMENTS FOR PATIENT ENGAGEMENT AND SUPPORT TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY (1001.952(hh))

The AAMC strongly supports the OIG’s proposal to protect certain arrangements that provide patient engagement tools that are intended to improve quality, health outcomes, and efficiency, including health related non-medical items, goods, and services to address social determinants of health. The AAMC believes that patients must be engaged in achieving coordinated care and are vital partners in improving the value in healthcare. This proposed safe harbor will provide greater certainty for

providers seeking to aid their patients and advance broader population health objectives, especially in regard to the critical work of identifying and addressing patients' social determinants of health.

The Association suggests the following refinements to the proposed safe harbor: (1) OIG should explicitly protect tools and supports that address social determinants of health; (2) OIG should ensure requirements allow sufficient flexibility to ensure that all patients have access to providers participating in arrangements for patient engagement and support - including that the safe harbor not be limited to arrangements assuming downside risk; and (3) protection should extend to waivers of patient cost-sharing.

OIG Should Explicitly Protect the Provision of Items and Supports That Address Social Determinants of Health Broadly

OIG asks whether, in protecting such items and supports, there are social determinants that are most crucial to improving care coordination and the transition to value-based care in an effort to limit protections to tools and supports that address those specified social determinants. We do not yet know which patient- and community-level factors “explain” the most variance for the most health/healthcare outcomes. The AAMC has previously commented to the Assistant Secretary for Planning and Evaluation² in support of research that will identify which social risk factors, and interactions between them, explain the most variance for the most healthcare outcomes. **Until these categories of determinants are better understood based on ongoing research we urge caution against limiting protection to some tools and supports and not others.**

Teaching hospitals and academic medical centers are working hard to address social determinants of health. For example, hospitals are using hospital food “prescription programs” to connect patients to healthier food options (food access); launching job creation programs (poverty); and creating partnerships with taxi services to provide medical transport at no cost for patients (transportation). They are creating programs for both kindergarten and university readiness (education) and medical respite programs to provide recuperative care for homeless men and women who are too sick to return to a shelter or to the streets (housing). Caring for people with complex medical and social needs requires an approach that recognizes all of these potential non-medical factors. And to help address these underlying needs, many hospitals have broadened their health care teams to include community health workers (CHW) and, through Medical-Legal Partnerships (MLP), lawyers. **Providing patient engagement tools and supports that include but are not limited to these types of programs should be protected by this proposed safe harbor.**

Requirements Must Allow Sufficient Flexibility to Ensure that All Patients Have Access to Providers Participating in Patient Engagement Arrangements

OIG asks several questions related to how flexible the requirements for safe harbor protection should be, including whether participants must provide the same tools or supports to an entire target patient population, whether to expand protection to providers or practices that are not part of the VBE but otherwise satisfy the conditions of the safe harbor, and whether to limit protections only to value-based arrangements that assume downside financial risk. The AAMC believes that these requirements must be flexible. The OIG should not limit protections only to few VBEs and their participants who can afford to invest in providing such tools and supports and meet more stringent requirements for compliance.

² [AAMC Comments to ASPE Request for Information on Provider and Health Plan Approaches to Improve Care for Medicare Beneficiaries with Social Risk Factors](#) (November 16, 2018).

OIG should allow participants to consistently offer tools and supports to all patients satisfying specified uniform criteria, rather than the entire target patient population. For example, a participant could wish to install grab bars in a patients' homes to prevent falls and identify a sub-set of its target patient population to include only elderly patients at a defined risk of falls who live at home. If protection were provided only if the participant could only do so for its entire patient population, including patients not at risk of falls, it would probably decide against such a support due to the additional cost of providing the support to those patients within the broader target patient population for whom such a tool would not be useful.

OIG should provide greater flexibilities for the monetary cap. The proposed cap of \$500 on an annual basis might not be sufficient for tools or supports for certain patients with greater support needs in addition to potential financial need. While OIG proposes to allow participants to exceed that cap in the case of patients who lack financial resources, the individual case-by-case framework for determining and documenting the provision of tools and supports in excess of the cap would likely be too burdensome for many participants. Instead, OIG should allow provision of defined tools and supports in excess of the cap for a specified subset of the patient population. Take the example above, providing in-home fall prevention railings and safety screenings has the potential to be valued at more than \$500, but would be a meaningful investment for at-risk patients' ability to remain in their homes. Another example of a tool that would be likely valued at more than \$500 is the provision of an air conditioning unit for an asthmatic child. Because tools and supports must be funded by VBE participants, those participants are incentivized to target their investments in such tools and supports in excess of the cap to those patients most likely to benefit.

Similarly, **OIG should expand the protections to non-VBE participants, such as rural providers or providers serving underserved patients, who otherwise meet the conditions of the safe harbor.** These providers might not have the ability to invest resources in both VBE participation and providing patient engagement tools and supports, but their patients would equally benefit from such investments and broader coordination and management of their care.

Finally, **OIG should not finalize an alternative policy to restrict safe harbor protections only to value-based arrangements that assume downside financial risk.** Restricting protections to arrangements with downside financial risk will significantly limit the patient populations that may benefit from greater investments in patient engagement and support. Not all providers are ready to assume downside financial risk at this stage in their transition to value-based care, and the patients and communities they serve should not have less opportunity to benefit than those served by providers further along the transition to assuming risk. Such a policy would likely result in greater inequity of patient experiences in care coordination and management.

OIG Should Expand Protections to Allow Waivers of Patient Cost-Sharing

OIG guidance has long allowed for non-routine, good-faith financial need cost-sharing waivers in addition to existing safe harbors and exceptions to the beneficiary inducements CMPs that offer protection for certain reductions, waivers, and differentials in cost-sharing. The AAMC has previously commented to CMS³ that additional waivers of patient cost-sharing would be appropriate, including for certain care management services, remote monitoring, and interprofessional internet consultation services (eConsults). These are services where collecting small coinsurance amounts may either prevent patients from seeking such services or result in confusion. For example, in the case of eConsults, the patient

³ [AAMC Comments to CMS on the CY 2020 Physician Fee Schedule Proposed Rule](#), specifically beginning page 11; (September 27, 2019).

would receive coinsurance billing from both their established care provider and from the consulting specialist who may not be known to the patient. In these cases, **collecting small patient cost-sharing amounts requires significant administrative and clerical efforts and may ultimately prevent the use of these valuable services.**

REVISIONS TO EXISTING SAFE HARBOR PROTECTION FOR LOCAL TRANSPORTATION (1001.952(bb))

The OIG proposes to increase the mileage limits of patients residing in rural communities and to eliminate the distance limits for patients discharged after an inpatient stay (regardless of urban or rural setting) where transportation is to a residence. OIG also asks whether it should protect local transportation for health-related, non-medical purposes and clarified its views that ride-sharing services (e.g., Uber or Lyft) are no different than taxi services for purposes of the safe harbor. This safe harbor has been successful in helping patients in rural and underserved areas receive the care they need by being able to simply reach their healthcare providers. **The AAMC supports these revisions to the safe harbor but believes it should be expanded to maximize the benefits for patients. The safe harbor also should include protections for transport provided at discharge from an inpatient facility to another facility and a broader ability to provide local transport for health-related, non-medical purposes.** The elimination of the distance limit for transport for patients discharged from an inpatient facility should be clarified to ensure that protection covers *all* discharges from an inpatient facility, including patients treated under observation status or in the Emergency Department. Patients may have spent significant time receiving intensive treatment at the inpatient facility, regardless of how their stay has been classified for payment purposes, and have the same need for transportation assistance at the time of their departure from the hospital. Additionally, the protection should not be limited to transports only to a residence, as patients may require post-acute care and discharge to another facility, such as a skilled-nursing facility, or to a pharmacy to obtain medications or other medical equipment, as a stop on the way to a residence. As hospitals transition to value-based care and care coordination-focused healthcare delivery, it is critical that they are able to support patients fully in these transitions of care.

CMS-SPONSORED MODEL ARRANGEMENTS AND CMS-SPONSORED PATIENT INCENTIVES (1001.952(ii))

To date, OIG and CMS have collaborated and issue waivers to the AKS, beneficiary inducement CMPs, and Stark laws specific to each CMS-sponsored model. OIG proposes to standardize its protections for CMS-sponsored model arrangements under a new safe harbor that permits remuneration between and among parties to such arrangements and remuneration in the form of incentives and supports provided by model participants to patients served by the model. OIG would condition protections upon model participants satisfying programmatic requirements set forth in the CMS-model's Participation Agreement. **The AAMC broadly supports a safe harbor for CMS-model participation.** This new safe harbor would allow potential model participants the ability to review and consider protections in advance of model participation to ensure that potential arrangements under the model would be protected. The AAMC has found that in the current model-specific waiver approach waivers are often released with little time to review in advance of executing the model Participant Agreement and may not have consistency of waiver language across CMS models, requiring further review and analysis of each specific waiver.

REVISIONS TO EXISTING SAFE HARBOR PROTECTION FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS AND OUTCOMES-BASED PAYMENT ARRANGEMENTS (1001.952(d))

OIG proposes to revise the current safe harbor to require that methodology for compensation determinations be set in advance (instead of the aggregate compensation amount), eliminate the

requirement to specify the schedule, length, and exact charge for services of agents with periodic, sporadic, or part-time arrangements, and protect certain outcomes-based payment arrangements. **The Association supports changing the advance requirement to compensation methodology instead of aggregate amount and exact schedule for performance of part-time services**, as these changes harmonize with CMS's proposed changes to the Stark parallel exception. **We urge OIG to broaden its proposed revised protections for outcomes-based arrangements to include cost reductions for providers.** As we have stated earlier in our comments on the definition of value-based purpose, hospital and health system cost reductions are critical to the development of value-based care arrangements and reducing costs and expenditure growth for patients and payors, including federal health care programs.

ACO BENEFICIARY INCENTIVE PROGRAM STATUTORY EXCEPTION AND PROPOSED SAFE HARBOR (1001.952(kk))

The AAMC supports the OIG's proposal to codify the statutory exception ACO Beneficiary Incentive Programs under the Medicare Shared Savings Program (MSSP) added to Section 1899 of the Social Security Act by the Budget Act of 2018 (section 50341) and regulated by CMS (at 42 CFR 425.304(c)). **We appreciate that the OIG is not proposing to establish additional safe harbor conditions for incentive payments made by an ACO to an assigned beneficiary under an ACO Beneficiary Incentive Program that satisfies the statutory exception and regulatory requirements for such a program.** The AAMC agrees that the requirements already imposed are sufficient to prevent any improper beneficiary inducement.

CYBERSECURITY TECHNOLOGY AND RELATED SERVICES (1001.952(jj)) and ELECTRONIC HEALTH RECORDS (1001.952(y))

Data sharing and data security are two critical requirements for coordinating and managing patient care and assisting the transition to delivering value-based care. **The AAMC supports OIG's efforts to add a new safe harbor for cybersecurity technology and related services and to update the current safe harbor for electronic health records (EHRs).**

OIG Should Include Protection for Hardware Necessary for Cybersecurity

OIG proposes a new safe harbor to protect the donation of certain cybersecurity technology and related services as nonmonetary remuneration without a recipient contribution requirement. **The Association supports this new safe harbor and recommends that OIG include protection for hardware that is necessary for cybersecurity.** Many cybersecurity products require the use of a particular hardware device to operate. Health care providers are a high-value target for cyber criminals and cyber-attacks result in patient harm and high costs to the health care industry. Including hardware in this safe harbor protection would promote interconnected and interoperable health information technology (IT) systems by enabling providers to mitigate risks posed by cyber-attacks.

We support OIG's decision not to propose a requirement that recipients of cybersecurity software and technology contribute a portion of the costs. We agree that cost-sharing is not necessary for cybersecurity. A contribution requirement would serve as a barrier to participation in value-based arrangements, particularly with respect to small and rural physicians and providers who would be unable to afford the contribution.

OIG Should Ensure Protections for EHR Technology Do Not Pose a Barrier to Adoption

OIG proposes to expand the EHR safe harbor to clarify that the entity donating EHR software and providing training and other related services may also donate related cybersecurity software and services to protect the EHR, eliminate the current “sunset” provision, remove the 15 percent contribution requirement for small and rural physician practices, and allow for donations of replacement EHR technology. OIG also considers a proposal to incorporate the Office of the National Coordinator for Health IT (ONC)’s definition of “electronic health information” (EHI) for purposes of defining the type of information that is part of the EHR. OIG should also clarify whether the EHR exception includes the ability to donate telemedicine equipment.

The AAMC **supports the proposal to expand the EHR exception** to 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. We also **support the elimination of the sunset provision**, which is important to ensure widespread adoption of EHR technology. While we appreciate OIG’s proposal to remove the 15 percent recipient contribution requirement for small and rural practices, we **urge OIG to remove the contribution requirement for all physician recipients**. This will remove barriers to participation in value-based arrangements due to the critical need for EHR technology to support data sharing and care coordination. The 15 percent contribution requirement can serve as a significant barrier for physician adoption of EHR technology, even for larger, non-rural practices and providers. This is may become a greater concern for more physicians due to the ONC’s pending final rule, which as proposed, would require more complex and costly functionalities for vendors, and if finalized, is likely to increase the costs for purchasers.

Similarly, we **support the proposal to allow donations of replacement EHR technology**. Physicians may want to switch to a different EHR vendor system for numerous reasons. However, under the current requirements it would be difficult to change systems because physicians would have to pay the full amount for a new system. This change would make it more feasible for a practice to upgrade to a more advanced system with better functionality.

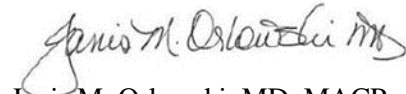
The AAMC **opposes the proposal to incorporate ONC’s definition of EHI for purposes of defining the type of information that is part of the EHR**. In comments to the ONC on the proposed interoperability rule, the AAMC opposed the definition of EHI for being overly broad.⁴ The ONC rule has not been finalized and therefore we do not know if our concerns with the definition of EHI were addressed. OIG should provide another opportunity for comment prior to finalizing an EHI definition that relies on the ONC definition.

⁴ [AAMC Comments to ONC on 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule](#), specifically page 13 (June 3, 2019).

CONCLUSION

Thank you for the opportunity to comment on the proposals to modernize safe harbors under the federal anti-kickback statute and the beneficiary inducement civil monetary penalty law. The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org and Phoebe Ramsey at pramsey@aamc.org.

Sincerely,



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Cc: Ivy Baer, AAMC
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