AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, File Code CMS-1720-P

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our views on how the physician self-referral law (Stark) imposes undue burdens on physicians and serves as an obstacle to coordinated care and efforts to deliver better value and care for patients. We commend the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) for focusing on removing unnecessary government obstacles to coordinated care, real or perceived, and reducing administrative burdens caused by the Stark law. In updating Stark, CMS 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.

a. Facilitating the Transition to Value-Based Care and Fostering Care Coordination
    i. Proposed Definitions
        1. Value-based activity

The AMA supports the definition of value-based activity. We urge caution in CMS potentially further interpreting how an activity is "reasonably designed" to achieve a value-based purpose or requiring that value-based enterprise (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. An 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 Office of the National Coordinator for Health Information Technology's (ONC) interpretation in the proposed rulemaking "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program."[1] Given the unknown impact and potential unintended consequences regarding the interpretation of information blocking, at this time, we recommend that CMS focus more on what is provided in statute regarding information blocking.

2. Value-Based Arrangement

The AMA agrees with CMS' proposal to not require the value-based arrangement to coordinate care. We believe that this approach does not pose a risk of program or patient abuse. Instead, the proposal is designed to provide needed flexibility for parties participating in alternative payment models. We also appreciate the proposed breadth to include commercial and private insurer arrangements.

3. Value-Based Enterprise

The AMA appreciates CMS providing for the ability of a VBE to be informal and be between two individuals or entities. However, CMS 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.

The AMA does not oppose the proposal that each VBE participant in the VBE 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, CMS should create a grace period of 90-days to allow for situations of technical non-compliance. In addition, CMS 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.

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. Most 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 in participation in value-based arrangements. Moreover, CMS is already requiring a governing document that should address the majority of fraud and

[1] AMA Response to the ONC Proposed Rule on Information Blocking

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 or individual VBE participants when that independent individual is one of few participating physicians.

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. CMS could help these practices by providing a checklist and/or model terms for a governing document.

4. 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.

The AMA is opposed, however, 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.

While CMS does not define "coordinating and managing care," we do have concerns as to how the Office of the Inspector General (OIG) has defined the term. We disagree 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."

5. Target Patient Population

The AMA is generally supportive of the concept of target patient population being based off of 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 off of 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 the Center for Medicare and Medicaid Innovation.

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 CMS 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 a target patient population.

ii. Proposed Exceptions
    1. 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 in 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.

That said, for those value-based arrangements that meet this definition they will most likely be able to provide other remuneration to participants (outside of what is currently allowed under the risk-sharing exception), such as staff or equipment. The AMA appreciates this flexibility as previously there was no clear pathway to supply this needed support.

The 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.

2. Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician

Generally, the exceptions involving financial risk do not capture any aspect of risk that does not involve activities or services that are reimbursable by 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, CMS 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 exception does 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 CMS 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.

The AMA believes that the "meaningful downside risk to physician" proposal seems unlikely to be widely used. Current risk arrangements are not reflected in the proposed exception. The exception does not apply where the physician's risk involves receiving less than full payment as opposed to making repayments. The common approach of value-based arrangements of conditioning a portion of payer payments on achieving cost and quality metrics is already protected under the current risk-sharing exception and indirect compensation definition. It also appears that partial risk arrangements do not meet the CMS definition of meaningful downside risk and would need to attempt meeting the no-risk exception.

The AMA is opposed to defining meaningful downside financial risk to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. Our interpretation of the definition means that the value of the remuneration the physician receives under the value-based arrangement is <u>all</u> 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 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 of 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 (Advanced APMs), 5 percent (medical homes), and 9 percent of 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, the 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 time frame.

The AMA understands that the proposal provides 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 existence of the VBE.

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.

3. Value-Based Arrangements

The AMA generally supports the value-based arrangements Stark exception at § 411.357(aa)(3) and believes that it may help with the transition to a value-based health care system. The AMA supports the proposal that the exception would permit both monetary and non-monetary remuneration between parties. The AMA is strongly opposed to limiting the scope of the proposed exception to non-monetary remuneration because it would have a negative impact on the transition to a value-based health care delivery and payment system. 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.

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The AMA supports the requirement that the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. However, the AMA is opposed to the alternative that the remuneration is not conditioned on the volume or value of referrals of any patients to the entity or of any other business generated by the physician to the entity. We believe that this alternative would impede parties' ability to achieve the value-based purposes on which their value-based arrangement is premised because a value-based arrangement may provide incentives based on the value of the services furnished (or not).

The AMA does not object to the proposal requiring that the performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable. We appreciate CMS' recognition that performance or quality standards may not be applicable to all value-based arrangements. We are opposed to requiring that performance of quality standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. While the goal of value-based arrangements 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.

a. Alternative Safeguard: Contributions

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 Department. In return, certain requirements—like this contribution one—would not apply to that value-based arrangement.

Alternatively, if CMS goes forward with a contribution amount, CMS **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. CMS 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, CMS 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).[2] 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 Department of Health and Human Services, including this proposed and forthcoming final rule related to the physician self-referral law/anti-kickback statute.[3]

Alternatively, CMS 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.[4] 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.

"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).

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.

b. Alternative Safeguard: Monitoring

The AMA supports CMS' statement that monitoring is an implicit requirement of any Stark exception and thus, no explicit regulatory requirement is necessary. We also believe that CMS should provide flexibility in monitoring and assessing progress toward achieving the evidence-based, valid outcome measures. While progress is the intent of these measures, progress may not actually be achieved for a variety of

[2] 13 CFR § 121.201 (Sector 62, Subsector 621).
[3] 84 Fed. Reg. 55766, 55836 (Oct. 17, 2019)(Stark); 84 Fed. Reg. 55694, 55756 (Oct. 17, 2019)(AKS).
[4] *See* 42 CFR § 414.1305.

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.

Any monitoring must 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.

4. Indirect Compensation Arrangements to which the Exceptions at Proposed § 411.357(aa) are Applicable (Proposed § 411.354(c)(4))

The AMA supports the proposal that, when the value-based arrangement is the link in the chain closest to the physician, the indirect compensation arrangement would qualify as a value-based arrangement for purposes of applying the proposed exceptions at § 411.357(aa). The AMA also supports the CMS alternative to define "indirect value-based arrangement" and specific in regulation that the exceptions proposed at § 411.357(aa) would be available to protect the arrangement. We believe that either proposal is necessary to protect an unbroken chain of financial relationships that includes a value-based arrangement because an indirect compensation arrangement that includes a value-based arrangement may not satisfy the requirements of the indirect compensation exception because the compensation paid to a physician may take into account the volume or value of referrals or other business generated by the physician or the compensation may not meet fair market value standards.

5. Price Transparency

The lack of complete, accurate, and timely information about the cost of health care services prevents health care markets from operating efficiently. As the health care market evolves, patients increasingly are becoming active consumers of health care services. Achieving meaningful price transparency can help lower health care costs and empower patients to make informed care decisions. The AMA supports price transparency and recognizes that achieving meaningful price transparency may help control health care costs by helping patients to choose low-cost, high-quality care.

The AMA supports the following specific measures to expand the availability of health care pricing information that allows patients and their physicians to make value-based decisions when patients have a choice of provider or facility:

- Patient confusion and health literacy should be addressed by developing resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving;
- All health care professionals and entities should be required to make information about prices for common procedures or services readily available to consumers;
- Physicians should communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status of the patient (e.g., self-pay, in-network insured, out-of-network insured) where possible;

- Health plans should provide plan enrollees or their designees with complete information regarding plan benefits and real-time, cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs;
- Health plans, public and private entities, and other stakeholder groups should work together to facilitate price and quality transparency for patients and physicians;
- Entities promoting price transparency tools should have processes in place to ensure the accuracy and relevance of the information they provide;
- All-payer claims databases should be supported and strengthened; and
- Electronic health record (EHR) vendors should include features that assist in facilitating price transparency for physicians and patients.

The AMA fully supports price transparency. However, we believe that using the physician self-referral law is an inappropriate mechanism to promote price transparency because **the desired pricing information is generally held and controlled by health plans**. These plans are not subject to Stark and therefore do not have the same incentives to share pricing information. Accordingly, CMS would be holding the wrong party accountable under a strict liability statute who does not have the means or methods to effectuate the desired outcome of patients receiving pricing information.

The lack of transparency in health care pricing and costs is primarily the result of a health care financing system that depends largely on the complex arrangements between and among employers, third-party payers, providers, and patients. These arrangements can make it difficult to identify accurate and relevant information regarding costs associated with specific medical services and procedures. For example, contracts offered by payers to providers frequently delineate contracted rates as proprietary information.

Insurer payment policies, coverage rules, and cost-sharing requirements are difficult to communicate in a common manner. Moreover, determining whether a provider is in-network may be difficult because of outdated provider directories or confusion associated with multiple plan contracts. Price also varies depending on where the service is performed, which impacts cost and a patient's cost-sharing. The cumulative effects of each of these factors often make it difficult to provide accurate pricing information for an individual patient in the absence of an actual service claim.

Anticipating the need for health care services is often difficult. The urgent nature of some medical care, the inability to predict the particular course of treatment that might be indicated or identified subsequent to the initial complaint, and the intensity and scope of service required often leave patients without time or ability to evaluate their options prior to receiving care. Even scheduled care may prove difficult because a visit may result in unanticipated orders or tests.

The AMA strongly supports education of the public about the costs associated with inappropriate use of emergency transportation services including ground and air services. However, the discussion of costs is precluded at the point of care in the case of emergencies under the Emergency Medical Treatment and Labor Act (EMTALA),[5] and we continue to support this prohibition.

[5] In 1986, Congress enacted the EMTALA to ensure public access to emergency services regardless of ability to pay. Section 1867 of the Social Security Act imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide a medical screening examination when a request is made for examination or treatment for an emergency medical condition, including active labor, regardless of an individual's ability to pay. Hospitals are then required to provide stabilizing treatment for patients with emergency medical conditions.

To make value-based health care choices, consumers need pricing information paired with quality information. Consumers must be able to understand and anticipate costs by knowing the price and quality of services before receiving them to be able to choose high quality lower-cost services and providers. However, integrating meaningful cost and quality information in a useable format in transparency efforts is challenging. Aggravating this challenge is the fact that many health care services still lack relevant quality metrics. Studies indicate that patients are willing and able to make choices based on value as long as the information is presented clearly.

The methodologies used by health plans, including Medicare, to assess a physician's quality and cost are not always transparent or easy to interpret, which makes it extremely difficult for physicians to improve quality and provide better value. Often the methodologies used to assess a physician's quality and/or cost conflict with the methodologies used for public reporting. Based on the AMA's analysis of available Medicare data, in several instances, physicians deemed to be of similar quality by one methodology were classified as having different levels of quality by another methodology. Additionally, some physicians classified in the highest (or lowest) level of quality by another one methodology were not classified as such by the other methodology. The inconsistencies may result in physician frustration and dissatisfaction, and lead to a lack of confidence in the quality programs. Furthermore, it could lead to patients making incorrect assumptions about physician quality when deciding where to seek care.

The AMA appreciates Congressional concern surrounding unnecessary or additional burdens as it relates to price and information transparency. Successful implementation of any price transparency program will require cooperation and collaboration by all stakeholders, and there is risk of placing untenable and time-consuming requirements on entities and individuals who, ultimately, will not be able to offer a full or meaningful picture of patients' costs.

With approximately 87 percent of Americans covered by private or public health insurance, insurance companies control most of the information necessary to help patients understand the costs associated with the health care services they receive. Thus, health plans need to provide enrollees with complete information regarding plan benefits and cost-sharing information, such as the amount paid toward the deductible and annual out-of-pocket maximum, patient cost-sharing responsibilities associated with specific in-network providers or services that are up-to-date, and specific amounts the insurance company would pay for out-of-network providers or services.

For the above reasons, the AMA is opposed to adding price transparency requirements in any existing or proposed Stark exceptions. At the same time, the AMA will continue to encourage physicians to provide patients with information about the cost of their professional services and empower patients with understandable information.

b. Fundamental Terminology and Requirements
    i. Commercially Reasonable

The AMA appreciates the CMS proposal to define commercially reasonable. Of the two definitions proposed, the AMA prefers "commercially reasonable" to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and condition as like arrangements. This definition offers more certainty and more continuity to current interpretation of the term because the "legitimate business purpose" language is used in current Stark exceptions including the personal services

arrangements and fair market value compensation exceptions. That said, any additional guidance from CMS as to interpreting "legitimate business purpose" would be beneficial beyond non-criminal activity.

The AMA is also in strong support of proposed regulatory language that clarifies that an arrangement may be commercially reasonable even if it does not result in profit for one or more parties. This clarification will reduce administrative burden and legal costs for physicians.

ii. The Volume or Value Standard and the Other Business Generated Standard

The AMA generally supports the CMS approach in providing an objective test for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties. Defining when compensation will be considered to take into the account the volume or value of referrals provides needed clarity and the AMA believes that the proposed approach will be simpler and easier to apply.

iii. Patient Choice and Directed Referrals

The AMA supports prohibiting directed referrals if the patient expresses a preference for a different supplier or provider, an insurer requires a different provider/supplier or the patient's physician determines that the referral is not in the patient's best medical interests. However, by making these requirements affirmative, AMA is concerned about the additional burden placed on physicians and other providers. The referral requirement must be a signed, written agreement, so many entities may need to amend their physician agreements. For example, under an employment arrangement, health care entities will need to set in advance the compensation methodology and have a signed written document setting forth the referral requirements for whom the entity directs referrals.

c. Group Practices

i. Special Rules for Profit Shares and Productivity Bonuses

1. Distribution of Revenue Related to Participation in a Value-Based Enterprise

The AMA supports the proposal to add a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a VBE. The current restriction discourages physician participation in value-based arrangements because physicians cannot be suitably rewarded for their accomplishments in advancing value-based purposes. Moreover, physician decisions drive health care spending and patient outcomes. Thus, it is not possible to transform health care without the participation of physicians in value-based health care delivery and payment models with other clinicians. Accordingly, by removing the restriction, physicians in a group practice setting can be rewarded for providing value-based care.

2. Clarifying Revisions

a. Overall Profits

The AMA is opposed to the modification to clarify the guidelines for the distribution of "overall profits" from designated health services. The AMA believes that group practices should be able to distribute profit shares of only some types of designated health services provided by a group practice without distributing the profits from the other types of Designated Health Services (DHS) provided by the group practice.

Moreover, group practices should also be able to share the profits from each of the types of DHS independently making it permissible to share profits from one type of DHS with a subset of physicians in a group practice and the profits from another type of DHS with a different subset of physicians in the group practice. Thus, CMS should interpret Stark to allow for split pooling on a service-by-service basis rather than having the DHS income pool include all the DHS generated by the participating physicians. This would allow physicians to receive profit shares or productivity bonuses more closely related to the services performed or their specialty. If CMS goes forward with this modification, CMS must provide a sufficient timeframe of at least a year for all group practices to come into compliance with this interpretation because many group practices currently use split pooling.

The AMA seeks clarification from CMS on whether a group practice must use a single methodology for distributing the profits from DHS. For example, group practices have formed a single income pool but have used different methodologies based on the type of DHS (e.g., imaging on a per capita basis and laboratory on clinical productivity) that are permissible methodologies and do not directly take into the account the volume or value of any referrals. As above, the AMA would oppose an interpretation that when all income pooling is used for all participating physicians in all of the pool that a practice must use a single methodology for determining each physician's overall profits.

The AMA supports removing the reference to Medicaid from the definition of overall profits because the definition of DHS includes only those services payable in whole or in part by Medicare.

The AMA appreciates the revising of the deeming provision related to the physician's total patient encounters or relative value units personally performed by the physician. We would oppose limiting the methodology to physician relative value units as defined at § 414.22. Instead, any personally-performed relative value units should be an acceptable basis for calculating a productivity bonus.

ii. Virtual Groups and the Group Practice Definition

Starting on January 1, 2017, eligible clinicians began participation in the Quality Payment Program in one of two ways: (1) MIPS or (2) Advanced APMs. To encourage broader MIPS participation for solo practitioners and groups with 10 or fewer eligible clinicians, CMS created a virtual group option. Many solo practitioners and groups of 10 or fewer MIPS eligible clinicians have limited resources and technical capabilities. Virtual groups will involve preparation of health information technology systems and training staff to be ready for implementation, sharing and aggregating data, and coordinating workflows. While these are necessary steps to ensure the success of virtual groups, these steps could raise concerns involving Stark.

By pooling resources together to participate in MIPS, individual physicians may receive an ownership interest in the virtual group or other compensation arrangement from the virtual group (e.g., disbursement of any incentive payments). Moreover, physicians may prefer to refer patients within their own virtual group to control unnecessary costs and provide higher quality care because both physicians' performance is tied to the same virtual group's MIPS score. Any of these referrals within the virtual group between physicians could violate Stark. This outcome is different from a normal "group practice" where some of these referrals are protected from Stark through exceptions.

"Virtual groups," by definition, are not "group practices" as that term is specifically defined under Stark because virtual groups do not constitute a "single legal entity." Virtual groups consist of at least two legal

entities. Thus, because virtual groups do not meet this definition, the Stark in-office ancillary services exception and the physician services exception does not apply. Furthermore, the anti-kickback safe harbor for investments in group practices also does not apply. Accordingly, physicians in a virtual group with a financial relationship with such a virtual group may not be eligible to make referrals for designated health services payable by Medicare to the virtual group.

Thus, the AMA recommends amending 42 CFR § 411.352 (Group Practice) by adding an additional subsection (j) stating that "notwithstanding the above, a virtual group (as defined in 42 CFR § 414.1305) is considered a group practice for the purposes of this subpart." While this solution will allow virtual groups to operate in the same manner as group practices, we believe that additional changes under Stark are needed to allow both virtual groups and group practices to be successful as the health care system transitions to more value-based care models.

d. Recalibrating the Scope and Application of the Regulations
    i. Decoupling the Physician Self-Referral Law from the Federal Anti-Kickback Statute and Federal and State Laws or Regulations Governing Billing or Claims Submission

The AMA strongly supports decoupling the Physician Self-Referral Law from the federal anti-kickback statute and federal and state laws or regulations governing billing or claims submissions. CMS should eliminate all regulatory requirements in Stark exceptions that a financial arrangement does not violate the anti-kickback statute. This regulatory requirement unnecessarily changes a strict liability statute into an intent-based one and causes confusion without any additional benefit or protection to the Medicare program. The AMA recommends that CMS also decouple the referral services and obstetrical malpractice subsidies exception from the anti-kickback statute.

    ii. Definitions
        1. Designated Health Services

The AMA supports the proposal to revise the definition of "DHS" to clarify that a service provided by a hospital on an inpatient basis does not constitute a DHS if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Hospital Inpatient Prospective Payment System (IPPS). While the AMA agrees with revising the definition because physicians have no financial incentive to over-prescribe services that do not affect the rate of payment, we believe that this definition should also include outpatient services. Thus, if the furnishing of the service does not affect the amount of payment to the hospital or physician practice under the Outpatient Prospective Payment System, then the service provided does not constitute DHS. Including outpatient services will also help solve potential complexity in determining when an individual is inpatient, outpatient, or in observation status.

Moreover, the AMA seeks clarification as to what constitutes an admission or a referral for admission to a hospital and whether any impact exists on whether the services is a DHS. Patients can come into a hospital in different ways including a local physician instructing a patient to go to the emergency department of a local hospital, emergency doctor indicates in the medical record that a patient should be admitted that causes the patient to be admitted (although the physician does not have formal admission powers), or the patient was sent to the hospital to receive hospital services.

2. Physician

The AMA broadly opposes the current definition of "physician" under § 1861(r) of the Social Security Act because the term physician must be limited to those people who have a Doctor of Medicine, Doctor of Osteopathic Medicine, or a recognized equivalent physician degree and who would be eligible for an Accreditation Council for Graduate Medical Education residency. Therefore, we oppose the definition of "physician" under § 411.351.

3. Remuneration

The AMA supports the proposal to remove "not including surgical items, devices, or supplies" from the definition of "remuneration." We agree with CMS that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that it is not used solely for one of the permitted purposes. We also appreciate CMS confirming that this proposal does not exclude from the definition of remuneration those items, devices, or supplies whose main function is to prevent contamination or infection.

4. Transaction

The AMA opposes the CMS proposal to amend the definition of "isolation financial transaction" to expressly exclude payment for multiple services provided over an extended period of time, even if only one payment for the services is made because the statutory exception allows for this conduct and the new proposal would increase administrative burden.

The statutory exception at § 1877(e)(6) allows for a single payment for multiple services. Congress did not intend to limit the exception to a one-time sale of property and a one-time sale of practice because these examples are illustrative and not-exhaustive. Congress also did not desire to exclude services from this exception because to meet the statutory exception the requirements for the bona fide employment exception of § 1877(e)(2)(B) and (2)(C) must be met. Section 1877(e)(2)(B) requires that the amount of the remuneration under the employment exception is "consistent with fair market value of the services." Why would Congress intend to exclude services from the isolated transaction exception when Congress requires that the transaction be consistent with fair market value of services? Moreover, the new proposal would also increase administrative burden. This proposal effectively decreases flexibility because parties can no longer use it to protect certain arrangements. Accordingly, CMS should retain the original definition of isolated financial transaction.

iii. Ownership or Investment Interests

1. Titular Ownership or Investment Interest

The AMA supports the CMS proposal to extend the concept of titular ownership or investment interests to CMS' rules governing "ownership or investment interests." We agree with CMS that the proposal would afford physicians with greater flexibility and certainty especially in states where the corporate practice of medicine is prohibited.

2. Employee Stock Ownership Program

The AMA supports the proposal to remove participation in an employee stock ownership plan (ESOP) from the definition of "ownership or investment interest." An interest in an entity arising through participation in an ESOP merits the same protection from Stark as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity. The safeguards on ESOPs that are imposed by the Employee Retirement Income Security Act of 1974 (ERISA) are sufficient to ensure that the ESOP does not pose a risk of program or patient abuse including the fiduciary duty to act with care, skill, prudence, and diligence under the circumstances of a prudent person acting in a similar capacity.[6] Furthermore, under Internal Revenue Code § 401, ESOPs are required to have an independent appraiser to establish value for all securities which are not readily tradeable on a market.[7] Accordingly, the AMA believes that no additional safeguards need to be added to ensure that the participation in an ESOP does not pose a risk of program or patient harm.

iv. Special Rules on Compensation Arrangements

The AMA supports the modifications to the special rules on compensation by deeming that the writing and signature requirements be satisfied if the parties obtain the required writing and signatures within 90 days after the date on which the arrangement fell out of compliance. This proposal would likely reduce administrative burden associated with these requirements and allow for situations of technical noncompliance where parties begin performance under the arrangement before reducing the key terms and conditions of the arrangement to writing.

v. Exceptions for Rental of Office Space and Rental of Equipment

The AMA supports the proposal to clarify that the rental of office space and rental of equipment exceptions does not prohibit multiple lessees from using the space or equipment or prevent a lessee from inviting another party other than the lessor to use the office space or equipment rented by the lessee. The current interpretation by some of "exclusive use" as prohibiting the lessee from sharing the space or equipment with any other party is problematic because multiple physicians commonly use the same space or equipment at the same time when treating patients. Thus, we welcome this clarification from CMS.

vi. Exception for Physician Recruitment

The AMA supports the CMS proposal to remove the signature requirements of a recruitment arrangement on a physician practice when such practice passes all of the remuneration from the hospital directly to the physician. Eliminating the signature requirement for a physician practice that receives no financial benefit under the recruitment arrangement would reduce burden without posing a risk of program and patient abuse.

vii. Exception for Remuneration Unrelated to the Provision of Designated Health Services

The AMA generally supports the proposal that remuneration from a hospital to a physician does not relate to the provision of designated health services if the remuneration is for items or services that are not

[6] 29 U.S.C. § 1107(a)(1)(B).
[7] 26 U.S.C. § 401(a)(28)(C).

related to patient care services. In describing the concept of items that are related to the provision of patient care services, CMS should limit this concept to remuneration paid explicitly for a physician's provision of designated health services to a hospital's patient. This limitation would provide a clear, more bright-line determination that is closely linked to the heart of Stark's intent in preventing inappropriate referrals of designated health services.

Alternatively, AMA believes that the CMS proposal describing patient care services greatly improves on the exception's extremely limited application because the remuneration must be currently "wholly unrelated." If CMS goes forward with their proposal, the AMA seeks clarification as to the application of the exception for items or services that fit within both proposed § 411.357(g)(3)(i) and (3)(ii). For example, how would the exception apply to a physician who repairs or fixes medical equipment or a medical device when a person who is not a licensed medical professional could also repair the equipment or device? The medical equipment or device is equipment or a device that is used in the diagnosis or treatment of patients. Thus, it would meet the (3)(i) prong, be considered related to patient care services, and not receive protection. However, the repairing of the equipment is a service that could be provided by a person who is not a licensed medical professional. Thus, the service would also meet the (3)(ii) prong, not be considered related to patient care services, and receive protection. The AMA believes that meeting the (3)(ii) prong should take precedence over the (3)(i) prong and receive protection because a physician should be able to receive compensation for a service that can be provided legally by a person who is not a licensed medical professional.

viii. Exception for Payments by a Physician

The AMA supports the proposed amendment to the payments by a physician exception by expanding when the exception can be used. The current interpretation of this broad catch-all exception that only applies when no other exception applies substantially narrows the use of the exception.

ix. Electronic Health Records Items and Services

i. Deeming

The AMA supports CMS' 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 the exception to recognize the significant updates regarding information blocking since 2013. 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 CMS focus more on what is provided in the statute regarding information blocking.

Moreover, while the reasoning behind alignment is not to change the purpose of the exception condition, the AMA notes that CMS is incorporating an intent-based element into a strict liability payment rule. 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 exception. 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" standard because of the current dynamics between physicians and health plans, including the trend towards health plans 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 exception.

Alternatively, CMS should decline applying any knowledge standard to health plans at this time for the EHR exception. 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 exception 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 exception. Therefore, Congress did not apply any intent standard to health plans and CMS should respect Congress's intent.

iii. Cybersecurity

The AMA supports the proposal to expand the EHR exception 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. 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 Department'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 CMS' 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 exception.

For example, electronic health record shall "mean a repository of electronic health information <u>used for clinical diagnosis and treatment for a broad array of clinical conditions</u> 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

3. 15 Percent Recipient Contribution

The AMA is opposed to the contribution requirement from the recipient to receive protection under the current EHR exception. The contribution requirement adds unnecessary burden, complexity, and

potentially 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 CMS continues with the contribution amount, CMS must have an exception for small, underserved, and rural practices. While we oppose contributions generally, the contribution amount imposes a significant financial burden on small, underserved, and rural practices that could negatively impact patient care. CMS 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, CMS 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 Department of Health and Human Services, including this proposed and forthcoming final rule related to the physician self-referral law/anti-kickback statute.

Another option is that CMS 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.

"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 section 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. CMS 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, CMS 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.

4. 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.

vii. Exception for Assistance to Compensate a Nonphysician Practitioner

The AMA supports the clarifications to the exception for assistance to compensate a nonphysician practitioner and CMS' recognition that "patient care services" only relates to tasks performed by a physician only.

e. Providing Flexibility for Nonabusive Business Practices

i. Limited Remuneration to a Physician

The AMA supports the proposed limited remuneration to a physician exception. This exception would provide protection for numerous nonabusive arrangements under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician's provision of items and service to the entity including ongoing service arrangement where services are furnished sporadically or at a low rate of compensation. The AMA does not object to the $3,500 limit and would oppose any decrease to this amount.

The AMA would oppose a requirement that the arrangement must not violate the anti-kickback statute or other federal or state law or regulation governing billing or claim submission. It would unnecessarily change a strict liability statute into an intent-based one and causes confusion without any additional benefit or protection to the Medicare program.

The AMA recommends that the regulatory text at § 411.357(d)(1)(ii) and § 411.357(l)(2) should be modified to explicitly state that CMS: (1) for purposes of § 411.357(d)(1)(ii) not require an arrangement for items or services that satisfies all of the requirements of the proposed exception for limited remuneration to a physician to be covered by a personal service arrangement protected under § 411.357(d) or listed in a master list of contracts and (2) for purposes of § 411.357(l)(2) not consider an arrangement for items or services that is protected under the proposed exception at § 411.357(z) to violate the prohibition on entering into an arrangement for the same items and services during a calendar year. Adding these policies to regulatory text brings certainty and uniformity.

ii. Cybersecurity Technology and Related Services

The AMA strongly supports the proposed cybersecurity technology and related services exception. We applaud CMS 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 National Institute of Standards and Technology (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 supports 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, 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 proposal to limit the exception to donated technology and services that are necessary and used predominantly to implement, maintain, and reestablish effective 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, CMS 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 CMS 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, CMS 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. 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, CMS 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]

The AMA supports exempting contributions for the upgrades, updates, or patches of remuneration that was 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.

[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 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.

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 CMS goes forward with a contribution amount, CMS **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, CMS 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 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 Department of Health and Human Services, including this proposed and forthcoming final rule related the physician self-referral law/anti-kickback statute.[10]

Alternatively, CMS 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 consistent 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 section 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.

f. Repealing the Ban on Physician-Owned Hospitals

The federal ban on physician-owned hospitals reduces and restricts competition and choice in health care markets. Prior to the enactment of the Affordable Care Act (ACA), physicians enjoyed a "whole hospital

[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.

exception" from the Physician Self-Referral Law (also known as the Stark law). If physicians had an ownership interest in an entire hospital and were authorized to perform services there, physicians could refer patients to that hospital. However, provisions within the ACA eliminated the Stark exception for physicians who do not have an ownership interest as of December 31, 2010.[12] Furthermore, existing physician-owned hospitals cannot expand their treatment capacity unless certain restrictive exceptions can be met. In order to promote competition and choice in health care markets, the federal ban on physician-owned hospitals must be repealed.

The AMA believes physician-owned hospitals should be allowed to compete equally with other hospitals in the delivery system. Limiting the role of physician-owned hospitals only reduces access to high-quality health care for patients. Physician-owned hospitals are a benefit to patients and their communities and represent the type of coordinated care that is needed for the future of health care delivery. These hospitals provide: patient access to the best quality health care available; tens of thousands of jobs nationally; and a local economic engine through property taxes and higher-wage jobs. Furthermore, the presence of physician-owned hospitals has not had an impact on the financial viability of surrounding hospitals, without evidence of an effect on inpatient volumes, revenues, or profits.[13]

Physician-owned hospitals can also serve the role of adding much-needed competition into the hospital market. Hospitals continue to merge and consolidate. Hospital mergers and consolidation generally result in higher prices. This is true across geographic markets and different data sources. When hospitals merge in already concentrated markets, the price increases can be dramatic, often exceeding 20 percent.[14] Thus, the appropriate role of physician-owned hospitals includes having physician-owned hospitals act as a true competitor with other hospitals. Competition forces traditional hospitals to improve and innovate. This benefits patients and the health care system as we work to improve care. In addition, in physician-owned hospitals, physicians—who are fundamentally responsible for the existence of the hospital and the maintenance of its standards—can manage hospital costs through innovation and improved efficiency, which increases value. Physician-owned hospitals already are more likely to have operating rooms that they use more efficiently than traditional hospitals.[15] Physician-owned hospitals are also more engaged in general medical and surgical care than other hospitals.[16] Accordingly, by lifting the ban and allowing physician-owned hospitals to compete with other hospitals, the delivery system benefits by increasing competition and patient choice.

The current restrictions on physician-owned hospitals have also had a negative effect on health care delivery and patient choice. The restrictions on physician-owned hospitals have effectively eliminated the formation of new hospitals and additional choices for patients to receive quality care. For example, the restrictions resulted in freezes on the construction and expansion of 45 partially completed physician-

[12] ACA § 6001 (42 U.S.C. § 1395nn).
[13] D M Blumenthal, *Access, quality, and costs of care at physician owned hospitals in the United States: Observational Study*, British Medical Journal (2015), available at https://doi.org/10.1136/bmj.h4466.
[14] Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation – Update*, Robert Wood Johnson Foundation (June 2012), available at http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261
[15] Elizabeth Plummer & William Wempe, *The Affordable Care Act's Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, Health Affair 35, no. 8 (2016), available at http://content.healthaffairs.org/content/35/8/1452.full.pdf+html.
[16] *Id.*

owned hospitals.[17] In Texas, 13 physician-owned hospitals were formed after enactment of the ACA; however, because of the restrictions; they did not accept any Medicare or Medicaid patients.[18] Currently, all of these physician-owned hospitals have either been sold or are part of bankruptcy filings.[19]

The restrictions on physician-owned hospitals are without merit and have no valid justifications. Physician-owned hospitals provide better or same quality care at the same costs as other hospitals and do not cherry-pick or lemon drop patients. Several studies have shown high levels of quality care and patient satisfaction in physician-owned hospitals. Recently, the *British Medical Journal* found that physician-owned hospitals performed comparably with other hospitals on both disease-specific and composite measures of mortality, congestive heart failure, readmissions for myocardial infarction, and pneumonia.[20] Studies have also shown that these hospitals provide more net community benefits through uncompensated care and taxes than not-for-profit competitors as a share of total revenues.

Accordingly, physician-owned hospitals should play an integral role in the delivery system as a true competitor with no restrictions. The inability of physician-owned hospitals to address the growing demand for high-quality health care services in their community is bad for the entire health care market and does nothing but penalize patients who should have the right to receive care at the hospital of their choice. **Thus, the federal ban on physician-owned hospitals should be repealed and the President's Budget for the next fiscal year should include such a legislative proposal.**

Thank you for the opportunity to comment. 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. The AMA is committed to engaging with CMS 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 CMS considers the impact of Stark 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

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[17] D M Blumenthal, *Access, quality, and costs of care at physician owned hospitals in the United States: Observational Study*, British Medical Journal (2015), available at https://doi.org/10.1136/bmj.h4466.

[18] Elizabeth Plummer & William Wempe, *The Affordable Care Act's Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, Health Affair 35, no. 8 (2016), available at http://content.healthaffairs.org/content/35/8/1452.full.pdf+html.

[19] *Id.*

[20] D M Blumenthal, *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, British Medical Journal (2015), available at https://doi.org/10.1136/bmj.h4466.