



*Advancing Health in America*

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December 18, 2019

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

***RE: OIG-0936-AA10-P Proposed Rule—Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements***

Dear Ms. Chiedi:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office of Inspector General (OIG) proposed rule revising the safe harbors under the federal anti-kickback statute (AKS) and civil monetary penalty (CMP) rules regarding beneficiary inducements.

We welcome OIG's acknowledgment that the federal AKS and beneficiary inducement provisions of the CMP statute have been significant brakes on innovation and obstacles in the transition to value-oriented care – both inside and outside the value-based arrangement context. OIG's decision to promulgate new safe harbors intended specifically to foster and support efforts to achieve a system of value-based care is extremely significant. Several aspects of the proposed rule provide a crucial foundation for this necessary transformation in health care. However, when compared to the parallel exceptions the Centers for Medicare & Medicaid Services (CMS) has proposed for exceptions to the Stark self-referral prohibition, OIG's proposed safe harbors are too narrow and too burdened by conditions that are likely to outweigh the reward of



participating in value-based arrangements. As a result, OIG's proposal may close the very doors to innovation that CMS is attempting to open. In finalizing the rule, OIG should adapt its proposed safe harbors to protect a broader universe of the innovative, value-based arrangements made possible by the CMS exceptions.

OIG has taken the first steps toward much needed reform of these rules by proposing a new safe harbor for patient engagement tools and by creating three new safe harbors for value-based arrangements, parallel to the exceptions proposed by CMS in its Stark Law proposed rule. OIG can – and should – do more to remove the barriers presented by outdated AKS rules and open the way to a value-based system. The most pressing improvement needed in the final rule is to create a robust safe harbor for non-risk value-based arrangements, modeled on CMS's proposed exception for the same type of arrangements. While CMS's flexible non-risk exception makes significant progress in fostering and supporting efforts to achieve a system of value-based care, OIG's equivalent safe harbor for care coordination arrangements is significantly more constrained and is unlikely to allow or incentivize innovation in payment models, beyond what is already permitted under the AKS.

- There would be no protection for value based arrangements that are not tied to a physician's shared risk of losses. At least initially, many coordinated care networks and other arrangements have found that initiatives, including monetary awards or incentives for higher quality, lower cost, or improved clinical practices, are essential to early hospital and physician value-based efforts.
- Physicians would have to share at least 15% of the cost of protected remuneration (e.g., infrastructure support), creating a significant impediment to the development of value-based initiatives, especially for many small and rural providers and others who are unable to afford any initial capital investment.
- The arrangement would have to meet the cornerstone requirements of the current safe harbors – commercial reasonableness, fair market value, taking into account volume or value of referrals – that are the primary obstacle today to a value-based system. All of these requirements would be inconsistent with arrangements where compensation is based on achieving certain clinical or cost improvements that, in most cases, are explicitly tied to and result from changes in referral patterns.

It is especially important that there be strong and comprehensive protection for non-risk value-based arrangements under the AKS in today's environment. The law is no longer predominantly enforced as a criminal statute, with the high standard of knowing and willful to establish a violation. Instead it is enforced overwhelmingly through civil suits under the False Claims Act, which heightens the importance of certainty that an arrangement is protected under a safe harbor. If CMS's proposed rule is finalized as proposed (or significantly similar), the Stark Law will no longer be the impediment it has

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been to a value-based care system. The AKS will be the primary and substantial regulatory obstacle to the movement toward value-based care.

The AHA and America's hospitals and health systems stand ready to assist OIG in modernizing the AKS and CMP regulations for the world of value-based care and payment.

Again, we thank you for your attention to these important issues and for your consideration of our comments. Please contact me if you have any questions at [mhatton@aha.org](mailto:mhatton@aha.org) or (202) 626-2336.

Sincerely,

/s/

Melinda Reid Hatton  
General Counsel

## **AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS ON ANTI-KICKBACK AND CMP RULE**

OIG's decision to promulgate new safe harbors designed specifically to foster and support efforts to achieve a system of value-based care is extremely significant. Several aspects of the proposed rule provide a crucial foundation for this necessary transformation in health care. The AHA appreciates OIG's intention in the proposed rule to enable and support the movement toward a more effective, more efficient, and more patient-centered health care system – but much work remains. A fundamental rethinking of the non-risk-based value-based arrangement safe harbor, along with the other refinements described in these comments, are needed to make AKS regulations a facilitator, rather than impediment, to a value-based system.

We commend OIG for recognizing the need to provide assistance to patients to achieve care coordination and strongly support the proposed safe harbor for patient engagement tools and the expansion of the transportation safe harbor.

### **NEW VALUE-BASED SAFE HARBORS**

The AHA supports safe harbor protection for value-based arrangements (VBAs). Much of the framework that underlies OIG's proposed value-based safe harbors, including many of the proposed definitions that set out the contours of protected VBAs, serves this purpose, but, they should be refined in certain key respects.

We believe that OIG's two proposed risk-based safe harbors, would offer some new protection for hospitals seeking to transition to a more efficient, more patient-centered, value-based system. We encourage OIG to finalize these proposals with the addition of the important clarifications and revisions suggested in these comments. The proposed safe harbor for care coordination arrangements, though, requires substantially more work to achieve OIG's stated goal of allowing and incentivizing innovation in payment models beyond what is already permitted under the AKS. Non-risk value-based arrangements are of critical importance because few physicians or other health care professionals have the financial resources to invest in the infrastructure necessary to build coordinated clinical care networks, especially since the success of such efforts are speculative. The AHA urges OIG to complete the suite of value-based safe harbors and match the strength of the parallel Stark Law exception proposed by CMS.

**VBA Definitions.** We support OIG's use of broad and flexible definitions of the core concepts underlying the proposed VBA safe harbors. **Inclusion of broad definitions will protect and incentivize a wide range of beneficial and innovative payment models, including models that have not yet been imagined.** It is important that the

definitions used in the final rule be broad, flexible and clear. Narrow definitions based on models that already exist – or that carry forward old, volume-based principles – will cut off innovation and unnecessarily stifle further progress toward a value-based world.

**Value-based Arrangement. We support OIG’s proposed definition of a VBA, which is flexible enough to accommodate many diverse and innovative models.**

**Value-based Enterprise (VBE).** The AHA endorses the proposed definition of VBE, which would not require any particular legal structure for the VBA to be protected. Protected VBEs (networks of participants) should not require any particular type of payment structure (such as a shared savings or capitation model), nor should they be defined by reference to Alternative Payment Models (APMs) under the Quality Payment Program (QPP) or any other preexisting payment models. As OIG appears to recognize, constructive innovation can take many forms, depending on the varied circumstances and goals of patients, providers, and payors across the health care system. Indeed, one essential purpose of the VBA safe harbors should be to give providers and others the flexibility to test new and different models, including those that do not match a well-established legal form or payment structure.

**Accountable Body.** We support the broad proposed definition of a VBE accountable body, and we do not believe that OIG should impose more specific monitoring or oversight responsibilities on the accountable body. As OIG has recognized in its many compliance program guidance documents for different sectors of the health care system, the appropriate scope, methodology, and targeted risk areas for monitoring and oversight efforts will vary widely based on the activities an entity is engaged in. Monitoring and oversight are most effective when they are not cabined by requirements developed in advance, but can be molded and adapted to reflect changing risk factors.

**Value-based Activity.** The AHA generally endorses the proposed definition of a value-based activity, but we encourage OIG to modify certain aspects of the proposal to lend further clarity and flexibility to the VBA safe harbors. The proposed regulation would provide that a value-based activity “does not include the making of a referral,” and OIG states in the preamble to the proposed rule that “under no circumstances would simply making a referral constitute a ‘value-based activity.’” **We are concerned that this regulatory text and related commentary could be misread as prohibiting safe harbor protection for VBAs in which payments or other remuneration may depend in part on the referrals made within the network.** A basic premise of value-based care is to improve quality and reduce unnecessary care by building a network of practitioners and providers willing to agree to certain care protocols and coordination mechanisms. **Rewarding physicians for utilizing those network participants pursuant to applicable protocols is critical. We seek confirmation that such arrangements would not be considered a prohibited payment for referral.**

We also have concerns about OIG's alternate proposal to limit value-based activities to those that are "reasonably designed" to achieve a value-based purpose only in accordance with a process that is "evidence-based." Including vague standards like "evidence-based" in any of the final VBA definitions would introduce uncertainty and litigation risk, ultimately dissuading parties from pursuing VBAs. Instead, OIG should establish a presumption that value-based activities are reasonably designed to meet their stated value-based purposes, though OIG certainly could retain the right to challenge that presumption in cases where the activity bears no rational relationship to any value-based purpose.

**Target Patient Population.** The breadth of the proposed definition of target patient population will allow hospitals the latitude to identify and focus on health issues specific to their community. However, language in the regulation and in commentary requires modification or clarification.

Requiring that the criteria for selecting the population be "legitimate" introduces ambiguity that in the current enforcement climate is likely to lead to endless litigation over its meaning. OIG's commentary indicates that the legitimacy standard is intended to protect against arrangements that "selectively include patients in a target patient population for purposes inconsistent with the objectives of a properly structured value-based arrangement (e.g., cherry picking or lemon dropping patients)." **The AHA supports clear and unambiguous language in the regulatory text to preclude those and any other types of targeting behaviors that OIG believes are abusive.** We also support the requirement that criteria be verifiable.

OIG should not adopt additional limitations on what is an acceptable target patient population, which would only further restrict participants' ability to adapt VBAs for their communities. The term should not be defined only as patients with a chronic condition (as OIG suggests), which would preclude protection for beneficial VBAs that are designed to improve acute or emergent care, for example. Nor should the term be limited to patients with a shared disease state (e.g., diabetes), which would preclude protection for beneficial VBAs that are designed to improve care across a particular hospital's or practice group's entire patient population (e.g., a primary care physician asking patients about drug and alcohol use to determine if there are signs of dependence that would prompt a referral to a specialist for treatment). To maximize the flexibility of VBA design, a target patient population should be defined to give VBEs discretion to include government and/or commercial enrollees. Finally, as addressed below, OIG should make clear in the regulatory text that VBA benefits need not be limited to the members of a target patient population for the VBA to be protected under any of the VBA safe harbors.

**Value-based purpose.** The proposed definition of value-based purpose is sufficiently flexible to accommodate a wide range of beneficial VBAs, but important refinements are needed. Most important, OIG should not finalize a requirement that any protected VBA

must “directly further the first of the four value-based purposes: The coordination and management of care for the target patient population.” Each of the four value-based purposes is consistent with what CMS, OIG and others historically have considered legitimate value-based purposes. Offering four distinct definitions of a value-based purpose is a significant recognition of the spectrum of objectives important to achieve a value-based system. VBA participants should have the latitude to choose which among the value-based purpose(s) fit the goals of their own initiative – and not have OIG prescribe their choice.

**In addition, protecting only efforts to reduce costs for payors under the “appropriately reducing cost” value-based purpose is too limiting. Cost reductions for provider participants in a value-based enterprise also should be protected.** The benefit of hospitals reducing costs would extend to the federal health care programs in the form of lower costs reported to Medicare and other programs, and as a result, lower reimbursement to hospitals. In addition, internal cost savings programs are some of the longest-standing types of VBAs (e.g., gainsharing). Achieving efficiencies that appropriately reduce costs should be rewarded and protected.

OIG should not add a provision precluding protection under the safe harbors for arrangements between entities that have common ownership. Given the trend toward integrated health care systems that provide a full continuum of patient care, adding this provision would seriously undercut the development of VBAs. As OIG points out, this could prevent beneficial care coordination between entities under common ownership that are naturally well positioned to coordinate care. Moreover, an arrangement that purely involves “abusive cycling of patients for financial gain” (a stated concern of OIG) would not meet any of the proposed “value-based purposes” or the proposed definition of “coordination and management of care,” and therefore would be outside the safe harbor already. In rural areas, it is often more likely that there is shared ownership or other financial relationships between medical and non-medical service providers in light of fewer providers in the community overall, and providers in those areas should not be penalized for the paucity of referral options.

In addition, OIG should be clear on what it intends to exclude from the safe harbor when it states in the commentary that “the provision of billing or administrative services” does not qualify as “the management of patient care.” Certain services that could qualify as “administrative,” such as more effective management of patient records, could markedly improve the coordination and management of patient care and it is not clear why those should be excluded from the definition of a “value-based purpose.”

## **VBA SAFE HARBORS**

**Care Coordination Arrangements.** The AHA strongly supports the creation of a new safe harbor to protect VBAs that are not linked to an agreement with a payor to take on

financial risk. Collaborations among hospitals and other providers have taken initial steps in a non-risk-based environment to smooth coordination of care, incentivize higher quality, and reduce inefficiency. They would like to go further and are dependent on a dedicated safe harbor for these efforts to expand and thrive. **Unfortunately, OIG's proposed safe harbor for non-risk-based VBAs would have the opposite effect.**

**The proposed rule would take away flexibility and impose requirements so voluminous and prescriptive that the safe harbor would be of little use to entities seeking to collaborate to deliver better care. We urge OIG to fundamentally rethink and revise this proposed safe harbor, including the following critical changes.** Simply put, OIG's proposed non-risk safe harbor does not match the reality of innovative value-based relationships, nor does it match the scope of CMS's proposed reforms to the Stark exceptions in opening the way to more of these potentially beneficial relationships.

**The AHA encourages OIG to broaden the safe harbor to allow monetary remuneration that will advance a value-based purpose.** Limiting the safe harbor to in-kind remuneration would stand in the way of many beneficial arrangements, such as financial incentives to adhere to care protocols. The proposed rule suggests this limitation reflects OIG's "long-standing view that the exchange of monetary remuneration poses heightened and different fraud and abuse risks and thus should be subject to safeguards such as a fair market value requirement." This reasoning is jarringly out of place in a value-based system, where the whole idea is that an entity's eligibility for (and the amount of) financial compensation depends on whether the entity pursues and achieves certain value-based objectives – not on the volume or value of specific services furnished, fair market value for those services, or any other vestige of a fee-for-service world.

**OIG also should reduce or eliminate the requirement that recipients share at least 15% of the cost.** This requirement would make the safe harbor useful only when both parties to a VBA are able and willing to invest capital in a joint initiative. But that often is not the case, for example, when a small health care provider would like to join an initiative to standardize care protocols across a voluntary provider network but lacks the capital to hire staff or purchase equipment necessary to achieve that goal. Even a relatively small contribution requirement could be enough to dissuade such providers – many of which are barely breaking even as it is – from engaging with laudable initiatives to improve coordination and value. All communities should have the benefit of these arrangements and not be limited by the size or financial resources of the local providers.

**Any required outcome measure should be defined broadly and flexibly.** To that end, OIG should not require the use of measures from the Quality Payment Program (QPP) in the outcome measure requirement; CMS itself acknowledged in the CY 2020 QPP rulemaking that the current measures under that program are inadequately outcome-oriented and that there are inadequate measures for many specialties. We



also encourage OIG to allow the use of patient satisfaction and experience of care measures to qualify as outcome measures under the safe harbor. Such measures are an important aspect of quality and are part of many of CMS's own value-based payment programs. OIG also should clarify that the requirement of an outcome measure does not mean that a certain level of actual performance on the measure is required for the VBA to be protected. From a practical perspective, we are concerned that such a requirement would be arbitrary, especially in cases where the measure(s) being used is relatively novel and did not have prior performance data. Such data would be essential to establishing a data-driven target performance rate. A basic premise of VBAs is to improve performance, and especially in innovative models, the ideal target level of performance will not be known prospectively. Finally, we encourage OIG not to require regular "rebasings" of outcome measures, which would be duplicative of the requirement that the measure must "advance the coordination and management of care of the target patient population." Moreover, maintaining a good clinical practice can be just as important and challenging as achieving that clinical practice in the first place, and we see no reason why the safe harbor should not protect a VBA that measures a participant's ability to maintain beneficial improvements.

**We agree that the safe harbor should be available even if the remuneration benefits patients outside the target patient population, and we urge OIG not to adopt its alternative proposal to require that the remuneration "only benefit the target patient population."** The accrual of benefits for patients outside the target population should be an expected, organic outgrowth of VBAs that improve the value and quality of care. While protected VBAs would be designed to improve care coordination and management for a specific group of patients, VBE participants should not be penalized if a VBA designed to improve care coordination and management for a specific group of patients incidentally improves care for other patients as well. The alternative would be unworkable and bad policy. OIG should not impose rules that silo advances made through collaboration in VBAs and restrict access to techniques proven to work in a target patient population. Such a prohibition would result in fragmented care rather than the integrated care we should be pursuing, and most likely discourage the adoption of VBAs.

**OIG should not introduce the vague standard of commercial reasonableness into the standards required for protection of a VBA, especially not with its proposed new definition.** If commercial reasonableness is included at all in the value-based safe harbors, OIG should not define "commercially reasonable" as an arrangement that "would make commercial sense" if entered into by entities of similar type and size without the potential for referrals. This definition flies in the face of OIG's historical and sensible understanding of the term. In 1994, OIG proposed to add a condition to the space and equipment lease and personal services safe harbors to require that the services contracted for "do not exceed those which are reasonably necessary to accomplish the legitimate business purpose of the services." In 1999, OIG finalized the proposed modifications to the safe harbors but changed the language from "legitimate

business purpose” to “commercially reasonable business purpose.” That definition has been clearly understood for over 20 years. **Moreover, few arrangements would ever satisfy the additional requirement of making commercial sense without the potential for referrals. Simply put, VBAs do not make any commercial sense without the potential for referrals.**

OIG’s apparent concern about the link between VBA remuneration and referrals also suggests the need for a fundamental clarification. Changes in referral patterns alone are not the goal of a VBA, but they may well be the consequence. The goal, of course, is the clinical or cost improvements that *result* from those new referral patterns – the patient with a chronic condition who receives a much-needed specialist visit (or an eliminated barrier to the referral) or the patient who switches to an equally effective, less expensive treatment regimen as a result of his and her physician’s participation in a care protocol that included the use of incentives. Whether or not such arrangements “make commercial sense” on some stand-alone basis, they clearly make value-based sense when viewed in the context of a VBA, which should be OIG’s primary concern when designing a safe harbor for arrangements that reward providers for working together to improve the value of care.

Nor should OIG apply any of the additional requirements suggested in the preamble to the proposed rule, such as a requirement that remuneration exchanged under a VBA must be fair market value; a prohibition on determining the amount, nature, or recipient of remuneration under a VBA based on volume or value of referrals; a prohibition on shifting the cost of remuneration under a VBA to federal health care programs; or a requirement that the VBE accountable body make a “bona fide determination” that the VBA is commercially reasonable and directly connected to care coordination and management for the target population. Many of these additional requirements would be duplicative of other requirements in the safe harbor, and many are fundamentally incompatible with or irrelevant in a value-based system. Most important, any additional requirements would create even more barriers to VBAs rather than breaking down those that already exist, and would move the proposed safe harbor from unworkable to outright unusable.

**Safe Harbors for VBAs with Full or Substantial Downside Risk. The AHA supports OIG’s proposals to create two new AKS safe harbors for risk-based VBAs.** While the spectrum of value-based care extends well beyond arrangements that require an entity to assume financial risk, we agree that risk-based VBAs are an important part of the movement toward value-based care and these safe harbors will provide important protections for entities that are willing to enter into such arrangements.

**Substantial Downside Financial Risk Safe Harbor. We encourage OIG to adopt lower thresholds for “substantial downside financial risk.” The proposed thresholds are unlikely to incentivize use of such risk-based VBAs.** OIG’s proposed thresholds – shared losses of at least 40%; shared losses of at least 20% for

episodic or bundled payment arrangements; or a partial capitated payment with a discount of at least 60% off of total expected FFS payments – are much higher than necessary to incentivize providers to seek new efficiencies in care delivery. We also encourage OIG to explicitly allow protected VBAs to include stop-loss thresholds for shared loss arrangements that are set at a certain percentage of historical benchmark costs, as under the Medicare Shared Savings Program (MSSP).

We also are concerned that OIG will unduly chill beneficial risk-based arrangements by its statement that protected remuneration “must be used primarily to engage in value-based activities that are directly connected to the items and services for which the VBE” is at financial risk. This requirement would be administratively burdensome and could subject VBE participants to undue scrutiny of whether the purposes for which remuneration is used are in fact “directly connected” to the shared risk arrangement. There is no analogous requirement, for example, under the MSSP or Innovation Center models, where participants may use shared savings or performance-based payments however they wish. That is as it should be: shared savings and other remuneration earned under a beneficial VBA nevertheless may be best used to invest in other quality or practice improvement activities that are unrelated to the original VBA.

**Full Financial Risk Safe Harbor. We encourage OIG to finalize a broader definition of “full financial risk.”** Under the proposed rule, “full financial risk” is defined such that the VBE is accountable for the cost of all patient care items and services covered by the applicable payor(s) in the target population. **This should be revised to focus on whether the enterprise has full financial risk for the items and services to which the protected remuneration relates.** For example, if the enterprise is financially accountable for inpatient and outpatient services, the enterprise should be able to construct financial incentives that encourage cost reductions with respect to those services – even if the enterprise is not accountable for office visit services. In that situation, there is little risk of encouraging inappropriate utilization.

For example, OIG commentary interprets “full financial risk” to include an arrangement where a VBE has responsibility for all items and services covered under Parts A and B. Given hospitals’ well-established accountability for inpatient and outpatient services under the inpatient and outpatient prospective payment systems (and readmission penalties tied specifically to inpatient admissions), we believe the “full financial risk” safe harbor should also allow hospitals to furnish incentives related to inpatient and outpatient care alone, regardless of whether the VBE also is accountable for other items and services reimbursed under Part A and Part B.

## **NEW PATIENT ENGAGEMENT TOOLS SAFE HARBOR**

**The AHA strongly supports OIG's proposal to create a new safe harbor for patient engagement tools.** We commend OIG for recognizing the need both to engage patients in their own care and to assist them in overcoming societal obstacles to obtaining necessary care. We believe the proposed safe harbor will provide much needed clarity regarding such assistance and advance population health efforts that are already under way. However, we recommend the following refinements and clarifications to lend further clarity and protection to providers seeking to deliver more patient-centered and well-coordinated health care.

**The AHA strongly supports a broad definition of "social determinants of health."** We appreciate OIG's proposal to protect supports and services designed to identify and address a patient's social determinants of health. It is critical that providers have the flexibility to work with patients to identify and mitigate obstacles to executing a plan of care or environmental factors that adversely affect an individual's health. **We strongly urge that OIG not distinguish between certain categories of social determinants, as suggested in the commentary, effectively suggesting only some would be worthy of protection and others would not.** A limited number of categories may address the needs of many patients, but would risk excluding tools and supports that could benefit many others. Bright line protection for any tool or support that helps to overcome social determinants of health also is preferable to a complex, multi-layered safe harbor that may introduce too much ambiguity for providers to use the safe harbor in practice. The safe harbor's many other carefully drawn restrictions are sufficient to protect against improper inducements or overutilization, so long as any provision of assistance is based on a good faith determination of need and the advancement of a value-based purpose.

The proposed safe harbor would protect patient engagement tools that are offered to patients in a target population, but **the safe harbor also should protect giving the same tool to patients who present with conditions or in circumstances similar to those of the target population.** Hospitals are deeply committed to providing equitable care to all patients. Restricting the safe harbor to just the target population could hinder the ability of hospitals to apply the tools to additional patients who could also benefit from them, and as a consequence hinder health equity improvement work. In addition, it is a logistical nightmare for providers to have to identify at the point of care which patients are eligible for which patient support tools. As long as the patient has a condition that would benefit from the tool that the provider is offering to a target population, the provider should not be penalized for offering that same tool to patients who are technically outside the target population.

Similarly, the **AHA supports extending the safe harbor to protect frontline providers in rural or underserved areas even if they are not part of a VBE.** In many cases, these providers will not have sufficient patient populations or resources to create or participate in a VBE, but their patients will benefit as much (if not more) from the provider's engagement with them in coordinating and managing their care.

**The AHA strongly opposes OIG’s alternative proposal to limit the safe harbor to VBAs involving assumption of financial risk.** There is no logical connection between the provider’s financial risk and the benefits of patient engagement. Indeed, despite OIG’s statement that such a restriction might “better align protected remuneration with value-based purposes,” not one of the proposed rule’s definitions for a “value-based purpose” relies on assumption of financial risk. **We also oppose requiring offerors of patient engagement tools to engage in reasonable efforts to retrieve items or goods furnished under the safe harbor.** Such a rule would be administratively burdensome for the provider -- and deny a patient a resource that is important to maintaining her health. For example, if a provider is participating in the Oncology Care Model (OCM) and wishes to offer support tools for patients who trigger an OCM episode, would the provider have to retrieve those tools from the patient when the episode is over, even if the patient is still receiving cancer treatment? If the treatment triggers another episode, could the provider then give the tool back to the patient? This retrieval would be wasteful and unnecessary, especially because the other requirements of the safe harbor are strong enough to prevent abusive arrangements.

**The AHA supports extending safe harbor protection to the waiver of copayments for care coordination services.** OIG’s longstanding concern about cost-sharing waivers is that they can improperly induce the patient to use the service without exercising prudence about the cost of the service. But CMS covers and pays for care coordination services to promote the same objectives that OIG is pursuing in this proposed rule – better managed, better coordinated care. Too often, patients decline care coordination services when they learn about cost. We believe it would be self-defeating to withhold protection from providers who seek to maximize the benefit of these care coordination services by covering the beneficiary contribution.

Finally, the **AHA opposes adding a requirement that the patient’s licensed health care provider certify in writing that a particular item or service is recommended solely to treat a documented chronic condition of a patient in a target patient population.** Such a requirement is far too narrow and would undercut providers’ flexibility to offer patient engagement tools and support that more broadly allow patients access to and engagement with primary preventive care, immediate support for an acute care episode, or interventions to address social determinants of health. We also are concerned that a rigid documentation requirement (with criminal penalties attached) would be a significant obstacle to making broader support for patient engagement a reality.

## **REVISIONS TO THE LOCAL TRANSPORTATION SAFE HARBOR.**

**The AHA supports the proposed revisions to the safe harbor for local transportation.** This safe harbor has helped to protect transportation services for patients in rural and underserved communities, where a patient’s inability to get a ride to

or from care usually means that the patient simply does not receive the care that she needs. **We appreciate OIG's recognition that the current mileage limits were insufficient to meet patient needs.** To maximize the benefit of the proposed revisions, we encourage OIG to refine the safe harbor further as follows.

Given the variability of rural settings and the continuing trend of rural providers closing their doors, allowing providers to offer transportation within 75 miles still may not suffice to allow certain patients to gain access to necessary care. **We encourage OIG to provide a pathway for providers to offer transportation services beyond 75 miles for such patients,** for example, by extending safe harbor protection to transportation for patients who reside in a rural area where the provider certifies in writing that there is no alternative provider available within 75 miles of the patient's residence.

The AHA strongly supports removing the mileage limit for transportation when a patient is discharged from an inpatient facility to the patient's residence or to another residence of the patient's choice. **We encourage OIG to extend this policy to cover situations where a patient is discharged from an inpatient facility to another facility,** such as a skilled nursing facility. In many cases, a patient's medical needs require that she be discharged from an inpatient facility directly to post-acute care. Given the limited access to such facilities in rural communities, it is critical that providers be able to support transportation from one facility to another without limitations on mileage. We also ask OIG to clarify that the mileage limit would not apply to transportation following discharge from an inpatient facility, even when the patient was treated in observation status or as an outpatient. Many patients treated under observation status or in an outpatient procedure will have spent significant time or undergone significant treatment at the facility, and their need for transportation home or to another facility is not necessarily any less pressing because of how the stay has been classified.

**Finally, we encourage OIG to extend the safe harbor further to cover transportation to services that promote and assist with social determinants of health, even if those services do not constitute medical care.** For example, in some rural areas, senior centers or other elder service hubs provide opportunities for social connection, health education, nutrition, and other services that contribute to improved well-being and health outcomes by fostering physical, mental, and emotional health. The safe harbor should protect transportation to these services as well, as they are an important part of promoting a patient's overall health.

## **CHANGES TO OTHER EXISTING SAFE HARBORS**

**Personal Services Arrangements.** The AHA strongly supports OIG's proposed changes to the safe harbor for personal services arrangements to conform to the Stark exception. We welcome OIG's proposal to remove the requirements that aggregate compensation for the year be set in advance and that the exact schedule for the performance of part time services be set out in the contract, and we commend the

OIG for harmonizing the AKS safe harbor with CMS's proposed changes to the Stark law regulations' parallel exception.

**However, the AHA believes that the proposed revisions related to outcomes-based payments are unnecessarily limited and would protect only arrangements that do not need protection because they do not implicate the AKS.** OIG proposes to exclude from the outcomes-based component of the safe harbor any payments that "relate solely to the achievement of internal cost savings for the principal," meaning that payments for reducing provider costs would not be protected under that provision of the safe harbor.

Hospital and other provider cost reductions are critical to the development of a value-based health care system. Often, arrangements that achieve provider cost reductions (.e.g., protocols related to choosing among available drugs to meet the needs of individual patients) are the first step for hospitals and physicians to engage in efforts to reduce unnecessary costs. The development of trust and teamwork is essential to achieving the goals of a value-based system. Further, as we noted with respect to the value-based purpose definition, lower costs for hospitals means savings for federal health care programs, as well. **Accordingly, the AHA urges OIG to broaden the protection of the outcomes-based provisions to include cost reductions to providers. The numerous other restrictions in the safe harbor are more than enough to protect federal health care programs from concerns like improper utilization or stinting on necessary care.**

At a minimum, OIG should include in the final rule a clear statement that outcomes-based payments that do not qualify for the safe harbor do not necessarily implicate or violate the AKS and may be protected under the other provisions of the safe harbor for personal services arrangements. By excluding payments for cost reductions from the outcomes-based provisions of the safe harbor, OIG casts doubt on the legality of such arrangements and threatens to undo much of the progress that has been made. Without necessary clarifications, we are concerned that the proposed rule will subject widespread and longstanding arrangements to frivolous and expensive litigation by calling such arrangements into question.

## **ELECTRONIC HEALTH RECORDS AND CYBERSECURITY**

We appreciate OIG's inclusion of updates to the current EHR provisions and urge the removal of remaining barriers and uncertainty from the exception in connection with the adoption of EHR technology.

**Removal of the "Sunset" Provision will Provide Needed Certainty to the Field.** It will support EHR adoption by new physicians entering the market as well as assist late adopters in implementing technology critical to supporting patient care.

**We urge removal of the 15% recipient contribution requirement for all physician recipients.** Removing it for small and rural practices, as proposed, is helpful; however, removing it for all recipients would make an important difference in achieving the shift to value-based care arrangements. It would remove a barrier to the kind of data integration and real-time information sharing that is essential.

**For similar reasons, the AHA supports OIG's proposal to allow for donation of replacement EHR technology.** There are many situations where a physician practice may wish to migrate to a different EHR product, including to achieve advanced functionalities or to improve health information exchange capabilities. Switching to a new EHR vendor system often presents financial and technical challenges because, as CMS observed, under the current exception, physicians are forced to choose between keeping the substandard system and paying the full amount for a new system. This change aligns well with efforts underway at the Office of the National Coordinator for Health Information Technology (ONC) to require increased technical functionality in order to make exporting patient records more feasible and to thus mitigate vendor "lock-in."

**OIG should not finalize its proposal to incorporate ONC's definition of "electronic health information" (EHI) for purposes of defining the type of information that is part of an EHR.** The AHA opposed ONC's proposed definition as overly broad, specifically regarding price information. At the time of this submission the final Information Blocking Rule has not been released. As a result, we do not know if our concern has been addressed, nor can we be certain how that will play into the EHR exception. **CMS should provide another opportunity for comment prior to finalizing a definition that relies on an ONC definition.**

**The cybersecurity exception should be adopted with a modification providing protection for hardware.** The creation of this exception, long advocated for by hospitals and health systems, will support more robust capabilities for health care providers to protect against and respond to growing cybersecurity threats. It appropriately recognizes the imperative for all physicians to have appropriate access to tools and services to secure and protect patients' health information. **However, the AHA recommends adding protections for hardware necessary for cybersecurity within the proposed exception's definition of technology.** Protecting hardware necessary for fully functioning cybersecurity systems is important, and the protection should be broad enough to encompass advances in cybersecurity technology, including advances in hardware. An example of an important cybersecurity hardware component is a two-factor identification token for identity verification and system access control. Cybersecurity is necessary to enable safe, effective health information exchange, and thus is crucial to improved care coordination and improved health outcomes at the individual and population levels.



The proposed rule also omits the word “reestablish” in the first condition for the new safe harbor, making it inconsistent with the new exception to the Stark Law as proposed by CMS. **The AHA urges OIG to adopt text that includes “reestablish” in the first condition.** Specifically, AHA that the final text for the first condition to the safe harbor should read, “The technology and services are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.” The health care system is increasingly the target of cyberattacks. It is no longer a matter of “if” but “when” an attack will occur against a hospital. While there is no doubt that investment in prevention and detection is critical, the inclusion of “reestablish” cybersecurity in the safe harbor would make explicit that the safe harbor’s protection extends to post-incident activities, such as the donation of a consultant’s time to assist with conducting root cause analyses and identifying needed procedural improvements.

AHA supports a deeming provision that would allow donors and recipients to demonstrate that donations are “necessary and used predominantly to implement and maintain effective cybersecurity.” **Specifically, the AHA supports OIG’s suggestion to deem that donors and recipients satisfy this condition if the donation furthers a recipient’s compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework, such as those developed by National Institute of Standards and Technology.**