AMRPA
AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

December 31, 2019

Delivered Electronically

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

Re: OIG-0936-AA10-P, 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; 84 Fed. Reg. 55,694 (October 17, 2019).

Dear Acting Inspector General Chiedi:

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we appreciate the opportunity to respond to the Office of Inspector General's (OIG's) proposed rule on the Anti-Kickback Statute (AKS) and Beneficiary Inducements Civil Monetary Penalty Regulations, published in the *Federal Register* on October 17, 2019. AMRPA is the national trade association representing more than 650 freestanding inpatient rehabilitation hospitals and rehabilitation units of general hospitals (referred to here as IRH/Us, but referred to by your office as "IRFs"), outpatient rehabilitation service providers, long-term care hospitals (LTCHs), and several skilled nursing facilities (SNFs). In 2017, IRH/Us served 340,000 Medicare beneficiaries with more than 380,000 IRH/U stays.[1]

IRH/Us provide hospital-level care, which is significantly different in intensity, capacity, and outcomes from care provided in non-hospital post-acute care (PAC) settings. Most patients in an IRH/U have had a serious accident or medical event, and have one of 13 serious conditions, including stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, brain injury and neurological disorders.[2] Patients in an IRH/U are closely supervised by a physician, who also oversees patients' overall rehabilitation treatment which must include a minimum of 15 hours per week of therapy services.[3] AMRPA members employ an interdisciplinary approach to help their patients maximize their health, functional ability, independence, and participation in society so they are able to return to home, work, or an active retirement.

[1] Medicare Payment Advisory Commission (MedPAC), "Chapter 10: Inpatient Rehabilitation Facility Services," Report to the Congress: Medicare Payment Policy, March 2019.
[2] 42 C.F.R. § 412.29(b)(2).
[3] *See id.* § 412.622

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Most IRH/U patients are referred from an acute-care hospital, and at the IRH/U they begin just one stage in their journey towards recovery. Due to the complex and serious nature of the conditions of patients treated in IRH/Us, the vast majority of these patients are referred for a wide range of medical services following their departure from the IRH/U. In 2017, approximately 18 percent of IRH/U patients were discharged to SNFs, 45 percent were discharged to the care of home health organizations, and most of the remaining continued their rehabilitation on an outpatient basis.[4] Therefore, due to the continuing services IRH/U patients require once leaving the hospital, as well as the fact that most patients are referred from an upstream acute-care hospital, IRH/Us dedicate significant resources to monitor referral relationships for inappropriate remuneration or inducements. At the same time, IRH/Us sit in a unique vantage point in the continuum of care, and with the proper regulatory flexibility will be able to take a leading role in the modernization of care coordination and value-based care.

At present, providers like IRH/Us adhere to the requirements of the AKS safe harbor regulations. Simultaneously, however, providers face increased pressure from Medicare and other insurers to better coordinate care and ensure better long-term outcomes for patients. When the AKS safe harbors were originally implemented, there was little to no accountability in Federal health programs for the effectiveness and appropriateness of the care provided. Today's environment stands in contrast, with almost all Medicare providers now held accountable for the value and appropriateness of the care provided through one Medicare mechanism or another. These mechanisms include value-based reporting programs for providers, as well as regular audits by Medicare, OIG and contractors to ensure patients are care that is appropriate and necessary.

The current AKS safe harbors were not drafted to support value-enhancing and innovative approaches to care coordination that can improve and save lives. Hospitals are hamstrung in their ability to seek innovative ways to improve outcomes for patients by partnering with both upstream and downstream providers. Fear of AKS liability as a result of remuneration exchanged between partners in collaborative care arrangements chills the innovative relationships that drive better care and outcomes. If hospitals and other providers are expected open a free flow of communication and coordination among one another to deliver superior care, it is only logical that the resources necessary to deliver that care be permitted to flow between the providers with the same ease. This should be the case both for HHS sponsored payment models as well as models arranged among private providers.

AMRPA is grateful that OIG and other components within HHS are taking steps to modernize anti-fraud regulations to align with the current practice of medicine. However, the agencies should be mindful that the evolution of the American health-care system to a value-focused system is still in its in infancy. The approaches that ultimately prove the most effective in the decades to come may vary greatly from the cutting edge approaches used today. For this reason, AMRPA recommends that OIG adopt its proposals to create new safe harbors relating to value-based enterprises (VBEs) but in a modified fashion that allows for additional flexibilities for

[4] eRehabData® Discharge Statistics for CY 2017 Medicare Part A and Part C beneficiaries (report available upon request).

providers. AMRPA also urges OIG to adopt its proposals to modify its existing safe harbors and related definitions, with similar modifications.

In general, where OIG is weighing the precise parameters or element of a safe harbor, AMRPA encourages the agency to take the approach that will afford the maximum flexibility for providers. There are numerous instances in the proposed rule, some of which are detailed below, where the OIG sets what appear to be arbitrary limits or boundaries on its new or modified safe harbors. Often these limits bear little reasonable nexus to a legitimate fraud or abuse concerns, but most certainly would stymie innovative approaches to care delivery. If OIG limits the ability of providers to innovate, progress could stall and costs could continue to rise. Put another way, the current proposals will do little to advance care coordination and better quality outcomes and will result in perhaps only minimal cost efficiencies. We therefore encourage OIG to reexamine all of its safe harbor parameters and remove any and all limitations that it reasonably can.

AMRPA offers the following specific recommendations:

I. OIG Should Not Place Arbitrary Restrictions on the Use of Outcome Measures

Under the proposed Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor, OIG proposes to require that VBEs establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured. AMRPA concurs with the use of outcome measures in the proposed safe harbors. However, AMRPA is concerned that OIG suggests that the measures may need to have been validated in medical journal or other external source. We strongly urge OIG not to finalize such a requirement, as it would cut against innovation and the ability for providers to tailor their arrangements using their clinical expertise.

Providers should not be required to wait until a journal or other third-party has reviewed the measure, when the provider is in the best position to determine the appropriateness for a particular population. In order to innovate and continue moving the health-system forward, providers need the latitude to test new and emerging approaches to care coordination. Having to wait for external validation of outcome measures cuts against this need, and ultimately undercuts the overarching goal of these new safe harbors. Rather, outcome measures should simply be medically and clinically reasonable, well-defined by the VBE participants, and have a direct connection to the unique characteristics of the target patient population. VBE participants should also be required to document these measures and how they plan to assess progress against these measures.

In addition, OIG also says it is considering incorporating CMS Quality Payment Program (QPP) measures into the measurement requirements. This again would be needlessly restrictive. Providers should be free to utilize their own internal measures and data, and as long as the measures are accurate, meaningful, and bear a direct nexus to the value-based activities undertaken by the VBE, it should be deemed sufficient.

In addition to requiring meaningful outcome measures, OIG states that the outcome measures used "should not simply reflect the status quo." While AMRPA agrees that improvement should always be the aim of a value-based arrangement, we are concerned about how this statement could be interpreted and request clarification. First, it is unclear what it means to "simply reflect the status quo." Second, OIG's proposal fails to account for providers and others who are already succeeding in significantly improving patient quality while lowering costs. For example, there may be providers that have achieved near-perfect or superior results in a certain measure. If another entity wants to enter into a VBE with that high-performing provider, the arrangement should be protected from AKS liability without the expectation that the provider needs to improve on its already superior outcomes. OIG should permit providers to decide the appropriate results of outcome measures, based on the unique situation and value-based purpose of the arrangement. It would be backwards to only permit a lesser performing entity to use a measure, while prohibiting the higher-achieving entity from participating in that same arrangement, simply because it cannot improve any further on a measure. Therefore, OIG should provide clarification in the final rule that maintaining a superior outcome is also an appropriate value-based purpose.

OIG also states it is considering whether to require providers to rebase outcome measures according to a specified timeframe. AMRPA opposes such a requirement. In many instances, participants examine data on a real-time, sometimes daily, basis. As such, providers will continuously collaborate to make adjustments as needed. Requiring an arbitrary timeframe for adjustments to the outcome measures would be an unnecessary administrative burden, as providers would need to engage in some sort of documentation process at these set timeframes to demonstrate compliance. Providers have ample incentive to rebase outcome measures to continually improve both clinical and financial results, and should have the leeway to do so in accordance with their judgement and expertise. Otherwise, OIG risks providers building their processes around the safe harbors' arbitrary timeframes, rather than real world experiences. Therefore, OIG should not set a timeframe for rebasing outcomes measures.

Similar to the idea of setting timeframes for rebasing, the proposed requirement that providers must terminate an arrangement within 60 days of determining that the arrangement is unlikely to achieve the evidence-based outcome measure is equally arbitrary. As was noted, providers can often monitor progress on a real-time basis, which also allows for continual adjustments to practices to optimize outcomes. Prudent providers, who are intensely aware of the consequences of violating the AKS, will err on the side of caution in these matters. Due to providers' fear of running afoul of the AKS, if a 60-day requirement is in place, providers will be hesitant to persevere and attempt to improve on the unsatisfactory outcomes. Instead, providers will quickly terminate the arrangement – even if, for example, they might expect to see improvements at 75 days, based simply upon the scope, breadth, and nature of the arrangement at issue or the medical conditions being addressed. Patient improvement and outcomes do not operate on a calendar basis. From this perspective, 60 days seems to be an arbitrarily selected timeframe that will stifle innovation and run against the goals of this proposed rule. Therefore, rather than require that arrangement be terminated

when there is concern about effectiveness, OIG should simply require providers to take proactive steps to correct deficiencies when identified in a reasonable time period.

The OIG also solicits comments on the extent to which payers should be involved in selecting the outcome measures used in an arrangement. AMRPA opposes a strict requirement that payers must be involved in selecting outcome measures. IRH/Us, as explained earlier, are centrally positioned in the continuum of care. A typical value-based arrangement may be between an acute-care hospital, and IRH/U and a home health agency, with the goal of seeking to improve outcomes and reduce costs by avoiding hospital readmissions. An arrangement of this type would not always involve a payer, whether it be a commercial insurer, CMS or other government payer, but nonetheless could be serving a bona fide value-based purpose. The requirement that a payer must be involved in selection of these measures would indirectly eliminate a wide swath of arrangement types that would otherwise fall under these safe harbors, or add an unnecessarily complex layer of administrative burden. Therefore, the involvement of a payer in selecting the outcome-based measures should not be mandated by the safe harbors.

II. OIG Should Not Set Contribution Requirements For Participants in Value-Based Arrangements

In several of OIG's proposals, the agency is proposing to require that any recipients of any remuneration contribute at least 15% of the cost of the remuneration. This requirement would not only be administratively taxing, it would also be imprecise and ultimately bears little nexus to fraud and abuse concerns. The care coordination, electronic health record and cybersecurity safe harbors, as currently proposed, already require there to be a legitimate and verifiable value-based purpose in order for these safe harbors to apply. Further, OIG has offered little explanation as to why giving 85 percent of the cost of a service or product, as opposed to say 75 percent or 100 percent, is any more likely to result in legitimate, value-focused arrangements.

The 15 percent threshold again seems to be an arbitrary figure put forward with little nexus to a legitimate fraud or abuse concern. In reality, if OIG is going to permit in-kind remuneration in value-based arrangements, it is not realistic to think that requiring 15 percent of the cost to be borne by the recipient will be any sort of deterrent. By imposing an exact percentage, which will require additional compliance activities by providers, OIG is imposing an administrative burden that *will* increase costs to providers. Therefore, OIG should not require a percentage of the cost of in-kind remuneration to be borne by the recipients.

The proposed rule also seeks comment on what methodology should be required to calculate the contribution amounts of each participating entity. If, despite AMRPA's urging, OIG does proceed to finalize a contribution requirement, OIG should not require a specific methodology be used to calculate the contribution percentage. Instead, OIG should permit providers to utilize any reasonable accounting of the costs and contributions of the service or product. Given the variety of different scenarios that may be arranged as value-based care evolves, and the difficulty of calculating shared costs, AMRPA questions the utility of

requiring a specific methodology for assigning contributions. Rather, providers should be able to tailor the accounting to the particular arrangement in question. This will allow for maximum flexibility and innovation when providers work to design value-based arrangements within the confines of these new safe harbors.

III. Entities That Have Common Ownership Should Not be Excluded from Safe Harbor Protections

OIG seeks comment on whether it should exclude entities with common ownership from protection under safe harbors in order to prevent abusive practices. OIG offers very little explanation as to why this would be effective in preventing abusive practices, and seems to have overlooked how substantial of a barrier this would create for providers. Indeed, rather than being an arrangement ripe for fraud, entities with common ownership may be in a unique situation to test new innovative approaches to care coordination.

As an example, if this prohibition was finalized, an acute care hospital and a post-acute care setting such as an IRH/U would be prohibited from exchanging remuneration as part of a legitimate value-based arrangement aimed at preventing post-hospital complications, simply because they have common ownership. At the same time, that same acute-care hospital could exchange remuneration with the other post-acute settings in the community that do not have common ownership. Therefore, rather than take the logical approach and begin testing innovative approaches to care delivery within its own system, a hospital system would only be permitted to test the endeavor with entities outside its system. This is counterproductive - particularly in light of Medicare's continued movement from volume-based to value-based care delivery - and again contrary to the purpose of these new safe harbors.

OIG has not given an explanation as to why the parameters proposed for these safe harbors would not adequately protect against fraud for arrangements involving commonly owned entities. The commonly owned entities would still be required to adhere to all the guardrails OIG is proposing to put in place, such as ensuring the arrangement serves a value-based purpose, that meaningful outcome measures are used, and many others, which should be more than sufficient to root out abusive practices. This commonly owned prohibition is an unnecessary blanket prohibition on an otherwise promising type of endeavor, and would not be beneficial to patients, providers, nor federal health programs. Therefore, OIG should not arbitrarily place a restriction on commonly owned entities gaining protection under AKS safe harbors.

IV. OIG and CMS Should Reconcile Conflicts Between the Proposed Rule and the Finalized Discharge Planning Rule

In September, CMS released a final update to regulations pertaining to discharge requirements under Medicare hospital Conditions of Participation regulations (CoPs).[5] This

[5] Medicare and Medicaid Programs: Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, Final Rule, 84 Fed. Reg. 51,836 (September 30, 2019).

discharge planning rule placed a number of restrictions on hospital's ability to designate providers as preferred post-acute care providers for patients being discharged from its facility. Specifically, the rule stated that "Hospitals must not develop preferred lists of providers."[6] In direct contradiction to this statement, OIG proposed that under the Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor, "a hospital could develop a 'preferred network' of post-acute care providers that meet certain quality criteria." Clearly, these two statements need to be reconciled.

AMRPA encourages OIG to collaborate with CMS to resolve this conflict. Specifically, the agencies should clarify that under the discharge planning rules, a hospital engaged in a value-based arrangement will be permitted to have preferred providers so long as the arrangement is compliant with the safe harbors proposed. Without the ability to designate preferred providers within a VBE, the entire purpose of the arrangement – to seek better outcomes for patients through coordination – will be undercut by providers' inability to transition patients into the downstream VBE provider. Issuing this clarification will ensure hospitals are not prevented from coordinating care with downstream providers, while also ensuring the arrangement serves a legitimate value-based purpose. If this discrepancy is not resolved, hospitals, a large portion of the care continuum, will be unable to fully participate in VBEs under these new safe harbors.

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AMRPA is committed to continuing to collaborate with the Department of Health and Human Services and the Office of Inspector General update the safe harbor regulations to enable Medicare and other beneficiaries to receive highly coordinated and efficient care. If you have any questions about AMRPA's recommendations, please contact AMRPA's Director of Government Relations and Regulatory Counsel, Jonathan Gold, JD at jgold@amrpa.org or 202-860-1004.

Sincerely,

Richard Kathrins, Ph.D.
Chair, AMRPA Board of Directors
President and CEO, Bacharach Institute for Rehabilitation

Mark J. Tarr
Chair, AMRPA Legislative and Regulatory Committee
President and Chief Executive Officer, Encompass Health

[6] *Id*. at 51,861

AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

December 31, 2019

Delivered Electronically

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1720-P, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations 84 Fed. Reg. 55,766 (October 17, 2019).

Dear Administrator Verma:

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we appreciate the opportunity to respond to the Center for Medicare and Medicaid Services' proposed rule on the Physician Self-Referral (Stark) Regulations, published in the *Federal Register* on October 17, 2019. AMRPA is the national trade association representing more than 650 freestanding inpatient rehabilitation hospitals and rehabilitation units of general hospitals (referred to here as IRH/Us, but referred to by your office as "IRFs"), outpatient rehabilitation service providers, long-term care hospitals (LTCHs), and several skilled nursing facilities (SNFs). In 2017, IRH/Us served 340,000 Medicare beneficiaries with more than 380,000 IRH/U stays.[1]

IRH/Us provide hospital-level care, which is significantly different in intensity, capacity, and outcomes from care provided in non-hospital post-acute care (PAC) settings. Most patients in an IRH/U have had a serious accident or medical event, and have one of 13 serious conditions, including stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, brain injury and neurological disorders.[2] Patients in an IRH/U are closely supervised by a physician, who also oversees patients' overall rehabilitation treatment which must include a minimum of 15 hours per week of therapy services.[3] Rehabilitation physicians practicing in IRH/Us oversee an interdisciplinary approach to care, which helps patients maximize their health, functional ability, independence, and participation in society so they are able to return to home, work, or an active retirement.

[1] Medicare Payment Advisory Commission (MedPAC), "Chapter 10: Inpatient Rehabilitation Facility Services," Report to the Congress: Medicare Payment Policy, March 2019.
[2] 42 C.F.R. § 412.29(b)(2).
[3] *See id.* § 412.622

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Most IRH/U patients are referred from an acute-care hospital, and at the IRH/U they begin their journey towards recovery. Due to the complex and serious nature of the conditions of patients treated in IRH/Us, the vast majority of these patients are referred for a wide range of medical services following their departure from the IRH/U. In 2017, approximately 18 percent of IRH/U patients were discharged to SNFs, 45 percent were discharged to the care of home health organizations, and most of the remaining continued their rehabilitation on an outpatient basis.[4] Therefore, due to the continuing services IRH/U patients require once leaving the hospital, as well as the fact that most patients are referred from an upstream acute-care hospital, rehabilitation physicians and IRH/Us must monitor referral relationships for inappropriate remuneration from both an upstream and downstream perspective. At the same time, IRH/Us and rehabilitation physicians sit in a unique vantage point in the continuum of care, and receiving proper regulatory flexibility will equip IRFs to take a leading role in the modernization of care coordination and value-based care.

At present, providers like physicians practicing in IRH/Us adhere to the requirements of the Stark exceptions regulations. Simultaneously, however, providers face increased pressure from Medicare and other insurers to better coordinate care and ensure better long-term outcomes for patients. When the Stark exceptions were originally implemented, there was little to no accountability in Federal health programs for the cost-effectiveness and appropriateness of the care provided. In contrast, almost all Medicare providers are now held accountable for the value and quality of the care provided through one Medicare mechanism or another. These mechanisms include value-based reporting programs for providers, as well as regular audits by Medicare, the Office of Inspector General (OIG) and other contractors to ensure patients receive care that is appropriate and necessary.

The Stark regulations have not been modernized to support the new value-enhancing and innovative approaches to care coordination that can improve and save lives. Hospitals and their physicians are hamstrung in their ability to seek innovative ways to improve outcomes for patients by partnering with both upstream and downstream providers. Fear of Stark liability as a result of remuneration exchanged between partners in collaborative care arrangements chills the innovative relationships that drive better care and outcomes. If hospitals and physicians are expected open a free flow of communication and coordination among one another to deliver superior care, it is only logical that the resources necessary to deliver that care be permitted to flow between the providers with the same ease. This should be the case both for HHS-sponsored payment models as well as models arranged among private providers.

AMRPA is grateful that CMS and other HHS branches are taking steps to modernize anti-fraud regulations to align with the current practice of medicine. However, the agencies should be mindful that the evolution of the American health-care system to a value-focused system is still in its in infancy. The approaches that ultimately prove the most effective in the decades to come may vary greatly from the cutting edge approaches used today. For this reason, AMRPA recommends that CMS adopt its proposals to create new Stark regulation exceptions relating to value-based enterprises (VBEs) with a few modifications, described below, to allow for greater flexibility for VBE participants to further encourage innovation.

[4] eRehabData® Discharge Statistics for CY 2017 Medicare Part A and Part C beneficiaries (report available upon request).

In general, where CMS is weighing the precise parameters or elements of an exception or definition, AMRPA encourages the agency to take the approach that will afford the maximum flexibility for providers. There are several instances in the proposed rule, some of which are detailed below, where the CMS sets what appear to be arbitrary limits or boundaries on its new or modified exceptions. Often these limits seem to bear little discernable nexus to legitimate fraud or abuse concerns, but most certainly would stymie innovative approaches to care delivery. If CMS limits the ability of physicians and other providers to innovate, care delivery advancements could stall and costs could continue to rise. If made too restrictive, the current proposals will do little to advance care coordination and better quality outcomes and will result in perhaps only minimal cost efficiencies. We therefore encourage CMS to reexamine all of its proposed parameters and remove any unnecessary limitations that could impede the transition to a truly value-based system.

AMRPA offers the following specific recommendations:

I. Providers Should Have Maximum Flexibility to Determine Appropriate Value-Based Purposes and Performance Standards

Under the new proposed Value-Based Arrangement exception, CMS proposes to require that VBEs establish in writing the performance or quality standards against which the recipient of remuneration will be measured. CMS states that the standards used by providers for these arrangements "should not simply reflect the status quo." In addition, in its definition of a "value-based purpose," CMS says it is considering only allowing VBEs to engage in an arrangement with the value-based purpose of reducing costs *after* it has achieved some meaningful improvement in quality for the target patient population. AMRPA is concerned that CMS' approach to these new exceptions will potentially stifle innovation.

First, AMRPA is concerned about how the statement that performance or quality standards used in a VBE must not "simply reflect the status quo" will be interpreted. By imposing this standard, CMS' proposal fails to account for providers and others who are already succeeding in significantly improving patient quality while lowering costs. For example, there may be providers that have achieved near-perfect or superior results in a certain measure. If another entity wants to enter into a VBE with that high-performing provider, the arrangement should be protected from Stark liability without the expectation that the provider improve on its already superior outcomes. It would be backwards to only permit a lesser performing physician to use a measure, while prohibiting the higher-achieving physician from participating in that same arrangement, simply because they cannot improve any further on a measure. CMS should permit providers to have the flexibility to decide the appropriate performance and quality standards based on the unique arrangement in question. This includes permitting physicians to be measured on how well they *maintain* a certain performance measure.

AMRPA has similar concerns with CMS' statement that providers will be prohibited from selecting cost reduction as a value-based purpose of an arrangement until after they have already achieved some improvement in the quality of care for the target patient population in

question. This restriction is unnecessary and ultimately may stifle providers' ability to engage in innovative practices. First, the definition of this value-based purpose already requires that the value-based purpose must at a minimum *maintain* the current quality of care provided. This is sufficient to ensure that arrangements are not improperly stinting on patient care. Further, and as was the case with CMS' statement regarding the "status quo," this definition may needlessly exclude highly achieving physicians from participating in value-based arrangements. If an entity wishes to seek out a physician with superior outcomes, this physician should not need to demonstrate some recent improvement in order to use cost control as a value-based purpose under this exception. In fact, CMS should make it easier, not harder, for physicians with longstanding high-quality outcomes to gain an exception under the Stark regulations. Therefore, CMS should not require physicians demonstrate some recent improvement in quality before being permitted to use cost control as a legitimate value-based purpose.

II. CMS Should Not Set Contribution Requirements For Stark Exceptions

In several of CMS' proposals, the agency is considering requiring or continuing to require that recipients of any remuneration contribute at least 15% of the cost of the remuneration. This requirement would not only be administratively taxing, it would also be imprecise and ultimately bears little nexus to fraud and abuse concerns. The value-based exceptions will already only apply when there is a legitimate and verifiable value-based purpose shown to exist. In light of these and other safeguards that are already in place, AMRPA does not think that requiring 15 percent of the cost to be borne by the recipient will be any sort of added deterrent to improper activity, and would in fact only serve as a barrier, potentially pricing out well-intentioned physicians from participating in value-based arrangements. In addition, imposing an exact percentage requirement will require additional compliance activities by physicians, which is ultimately an unnecessary administrative burden that could be avoided.

Rather than setting an arbitrary contribution requirement, participants should be able to tailor the cost-sharing to the particular situation at hand. This will allow for maximum flexibility and innovation when designing value-based arrangements within the confines of these new safe harbors. Absent this requirement, participants in a value-based arrangement will be able to better dedicate resources and attention toward achieving the goal of these exceptions - enhancing care coordination and quality and reducing costs. Therefore, CMS should not impose contribution requirements as a requirement of its proposed exceptions.

III. CMS Should Reconcile Conflicts Between the Proposed Rule and the Finalized Discharge Planning Rule

In September, CMS released a final update to regulations pertaining to discharge requirements under Medicare hospital Conditions of Participation regulations (CoPs).[5] This discharge planning rule placed a number of restrictions on a hospital's ability to designate

[5] Medicare and Medicaid Programs: Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, Final Rule, 84 Fed. Reg. 51,836 (September 30, 2019).

providers as preferred post-acute care providers for patients being discharged from its facility. Specifically, the rule stated that "Hospitals must not develop preferred lists of providers."[6] However, in this proposed rule, CMS suggests that the purpose of these new and modified Stark exceptions is to permit networks of providers to form a network to coordinate care.[7] Further, in its parallel proposed rule regarding new Safe Harbors under the Anti-Kickback Statue, OIG proposed that under the Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor, "a hospital could develop a 'preferred network' of post-acute care providers that meet certain quality criteria."[8] These conflicting statements have left providers confused as to what type of network arrangements are and are not permissible under CMS and OIG regulations.

AMRPA encourages CMS to resolve this conflict. Specifically, the agency should clarify that under the discharge planning rules, a hospital engaged in a value-based arrangement will be permitted to have preferred providers so long as the arrangement is compliant with the Stark exceptions or AKS safe harbors for value-based arrangements. Without this ability to designate preferred providers within a VBE, the entire purpose of the arrangement – to seek better outcomes for patients through coordination – will be undercut by providers' inability to transition patients into the downstream VBE participant provider. Issuing this clarification will ensure providers are not prevented from coordinating care with downstream providers, while also ensuring the arrangement serves a legitimate value-based purpose. If this discrepancy is not resolved, a large portion of the care continuum will be unable to fully participate in VBEs under these new Stark and AKS exceptions.

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AMRPA is committed to continuing to collaborate with the Centers for Medicare and Medicaid Services to update the Stark regulations to enable Medicare and other beneficiaries to receive highly coordinated and efficient care. If you have any questions about AMRPA's recommendations, please contact AMRPA's Director of Government Relations and Regulatory Counsel, Jonathan Gold, JD at jgold@amrpa.org or 202-860-1004.

Sincerely,

Richard Kathrins, Ph.D.
Chair, AMRPA Board of Directors
President and CEO, Bacharach Institute for Rehabilitation

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[6] *Id*. at 51,861

[7] CMS, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55,766, 55,779 (Oct. 17, 2019) ("Rather, networks of physicians, entities furnishing designated health services, and other components of the health care system collaborating to achieve the goals of a value-based health care system, organized with legal formality or not, may qualify as a value-based enterprise.").

[8] 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, 84 Fed. Reg. 55,711 (October 17, 2019).

Mark J. Tarr
Chair, AMRPA Legislative and Regulatory Committee
President and Chief Executive Officer, Encompass Health