AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

October 26, 2018

The Honorable Daniel R. Levinson
Inspector General
Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

***RE:* OIG-0803-N; *Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP* (83 Fed. Reg. 43607, August 27, 2018).**

Submitted Electronically

Dear Mr. Levinson:

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we appreciate the opportunity to respond to the Office of Inspector General's (OIG) Request for Information (RFI) on the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty published in the *Federal Register* on August 27, 2018.

AMRPA is the national trade association representing more than 625 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 2016, IRH/Us served 350,000 Medicare beneficiaries with more than 391,000 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 one of 13 serious conditions, which include 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 utilize this 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, Executive Summary, in Report To The Congress, Medicare Payment Policy xx. (Mar. 2018).
[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 following a serious injury or illness, and at the IRH/U they will 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, they must be 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 wide-range of services their patients require, IRH/Us are keenly aware of the need to properly monitor any referral relationships for inappropriate remuneration or inducements.

While providers like IRH/Us must continue to adhere to the complex and burdensome anti-kickback regulations, they are also facing increasing pressure from Medicare and other insurers to better coordinate care and ensure better long-term outcomes for patients. When the Anti-Kickback Statute was put in place, there was little to no accountability in Federal health programs for the effectiveness or efficiency of the care provided. Today's environment stands in stark contrast, with almost all Medicare providers now held accountable for the value of the care provided through one Medicare mechanism or another. In addition to value-based accountability programs for providers, hospitals regularly undergo audits by Medicare or its contractors to determine the medical necessity of claims submitted.

Due to multiple checks on the quality, cost and medical necessity of care delivered to Medicare beneficiaries, it is no longer appropriate to maintain such expansive definitions of remunerations. This is especially true when the transactions in question are legitimate, value-enhancing endeavors that aim to improve the care received through Medicare. In general, IRH/Us and other providers require much more flexibility to pursue legitimate value-based arrangements, both via models sponsored by Medicare and arranged independently among Medicare providers, without risk of violating of anti-kickback or beneficiary inducement regulations. This is why, as discussed more fully below, AMRPA recommends that OIG create a broad, value-based safe harbor under the anti-kickback and beneficiary inducement regulations.

Coupled with our recommendation to provide more flexibility under anti-kickback regulations, AMRPA also recommends that OIG ensure there are sufficient patient safeguards in place to ensure that beneficiary access to needed care is protected. Value-based arrangements have inherent pressures to reduce spending and, in turn, drive patients toward less expensive but potentially also less effective settings of care. This dynamic is particularly true for the types of patients whom IRH/Us serve. The medically complex patients treated in IRH/Us are always resource-intensive and in need of significant ongoing treatment and therapy to regain function, even after discharge from an IRH/U. Therefore, AMRPA recommends below that OIG proceed cautiously with anti-kickback reforms in order to ensure that there is ample accountability for the quality of care provided and to prevent care stinting as a result of the financial incentives and cost pressures inherent in value-based arrangements.

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

I. OIG Should Create a Broad Safe Harbor Exclusion That Applies To All Legitimate Value-Based Arrangements.

OIG has issued numerous waivers for specific Medicare alternative payment models (APMs), and in doing so recognized that many value-based initiatives, such as shared savings programs, run afoul of anti-kickback or beneficiary inducement regulations.[5] However, these existing safe harbors are limited to specific APMs, and are also time-limited exclusions. This leaves no exclusion for providers attempting to engage in value-based arrangements outside of these specific Medicare models.

As an example, IRH/Us currently report to the IRF Quality Reporting Program (IRF QRP), which tracks outcomes of patients after IRH/U discharge. However, it can often be challenging to ensure that a patient who is moving through the continuum of care and being treated by multiple providers continues to have all of their needs met. One strategy to tackle this difficult task is to engage a care coordinator who oversees the transitions and communication between providers. The care coordinator, usually a clinician, works to ensure all care needs are met for patients who may be moving from an acute-care hospital, to an IRH/U, and then to less intensive settings of care or home. This care coordinator ensures smooth transitions across settings and helps the patient to avoid any interruptions in care during the crucial recovery period. These care coordinators are an efficient way to break down of the silos of care that can exist in the current fee-for-service environment, and can be instrumental in ensuring positive long-term outcomes for patients.

The very nature of these care coordinators' responsibilities means they are involved in referrals between and among multiple providers, triggering the need for compliance with anti-kickback regulations. Unfortunately, there is no broad exclusion from anti-kickback liability under current regulations for such an arrangement, despite its potential to enhance outcomes and improve efficiency. This leaves providers hesitant to engage in this type of venture for fear of potential liability. Additionally, because of variance in how differently situated hospitals and providers operate, advisory opinions issued by OIG can be only vaguely informative as to the legality of a specific provider's desired arrangement. The net result is that providers are squeezed in both directions, with pressure to ensure the highest quality long-term outcomes, but also restricted from, or at least unsure of the legality of, directly engaging with other entities or providers in ways that can assist in achieving positive outcomes.

This is why the OIG should create a broad, bona fide value-based safe harbor for such activities. This bona fide value-based safe harbor should apply to all legitimate value-based arrangements, whether as part of an APM, a demonstration under Medicare, or arranged independently among Medicare providers. This safe harbor should be proposed and established through notice and comment rulemaking and propose definitions and permitted objectives for legitimate, value-

[5] 80 Fed. Reg. 66725; Medicare Program; Final Waivers in Connection With the Shared Savings Program (October 29, 2015.)

based arrangements. The permitted objectives for value-based arrangements covered by this safe harbor should include, but not be limited to, care coordination, interoperability of electronic medical records, transitions of care, and other safety or quality-enhancing objectives.

While "cost" or "resource use" is often included as an objective in value-based arrangements, we urge OIG to proceed cautiously and ensure these metrics are not weighted too heavily in newly permitted arrangements. As AMRPA explains further in the following section, an arrangement with an over-emphasis on cost is more likely to lead to care stinting than to more efficient care delivery. Therefore, any definitions or objectives of value-based arrangements should include robust accountability for the quality and outcomes of patient care, without a disproportionate focus on cost reduction.

II. Value-Based Arrangements Carry Inherent Risk of Stinting on Patient Care and OIG Should Ensure Safeguards Are in Place to Protect Beneficiaries.

As discussed above, AMRPA encourages OIG to take steps to facilitate more innovative, value-based approaches to care delivery by creating a value-based safe harbor under the anti-kickback regulations. However, whenever a value-based arrangement places too much emphasis on cost reduction, without corresponding and robust accountability for patient outcomes, there is obvious risk that providers will be incentivized to stint on care. This is why, while supporting a regulatory change to more easily accommodate value-based arrangements, AMRPA also recommends OIG take further steps to ensure Medicare beneficiaries are not denied needed medical services due to these arrangements, given the susceptibility to stinting evident in other popular model designs.

As providers move patients from one stage of their recovery to the next, they must often make a decision between PAC options with widely varying intensity of services, and thus widely varying costs. AMRPA has found that the types of patients treated in an IRH/U are at particular risk for care-stinting due to their need for continuing, resource intensive treatments. More specifically, as value-based payment arrangements with a disproportionate emphasis on cost reduction have advanced, patients with conditions like stroke are inappropriately diverted away from IRH/Us based on cost considerations alone. In fact, recent data from the Medicare Payment Advisory Commission (MedPAC) suggests that this may be the case for hospital-led accountable care organizations (ACOs). Specifically, MedPAC found that these organizations have generated savings not through reducing unnecessary hospital admissions, but largely by decreasing PAC utilization.[6]

It is also clear that care stinting is not isolated to these newer Medicare demonstrations or APMs. Medicare Advantage (MA) plans, which operate on a capitated basis and thus bear risk for utilization, also show significant differences in access to IRH/U care. MedPAC has consistently found that MA enrollees are admitted to IRH/Us at approximately one-third the

[6] Medicare Payment Advisory Commission, Medicare Accountable Care Organization Models: Recent Performance and Long-term Issues. 230. June 2018.

rate of Medicare fee-for-service beneficiaries.[7] In addition, just last month your office raised serious concerns about access to needed services for MA beneficiaries in a report examining MA denial and appeal rates. This report cited the high overturn rate of MA denials and suspect accountability mechanisms for noncompliant MA organizations.[8]

As the prevalence of value-based models increases, we are seeing a growing propensity to engage in these problematic practices. Providers can too easily achieve improvement on "benchmark" performance measures such as Medicare Spending Per Beneficiary (MSPB) by diverting patients to less costly, but also less intense, settings of care. It is also relatively easy to reduce PAC costs by limiting or restricting the amount, duration, and scope of rehabilitation services and devices available upon discharge from facility-based care. These risks are heightened when APMs and other value-based arrangements are not held accountable for functional status outcomes and other short- and longer-term health outcomes.

Managed care and APMs are diverting patients away from more intensive settings of PAC despite a broad consensus that many of the patients being systematically denied access to PAC are in the greatest need of these services. For example, recent clinical guidelines published by the American Heart Association and the American Stroke Association recommend acute hospital-level care for post-stroke rehabilitation.[9] In addition, your department's own research on the Bundled Payments for Care Improvement Initiative (BPCI) Models showed better functional outcomes for stroke patients treated at IRH/Us when compared to other settings of PAC.[10]

The evidence that current value-based payment arrangements may be leading to care stinting, as well as the potential for this care stinting to proliferate with more relaxed regulations, should be of great concern to OIG. As your office knows, any short-term savings to Medicare through underutilization of PAC services are ultimately offset by significant unnecessary long-term costs to Medicare or other federal and state programs. Disability, lack of function, hospital readmissions, and institutionalization create far greater expenditures in the long-term than any savings achieved through reduced payments for underutilization. Of course there are also the

[7] Medicare Payment Advisory Commission, Report To The Congress: Medicare Payment Policy, 298 (Mar. 2017) (finding that 2015 Medicare admissions to IRFs were 10.3 for every 1,000 FFS patients compared to 3.7 for every 1,000 MA patients).

[8] U.S. Department of Health and Human Services Office of Inspector General, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, Report (OEI-09-16-00410) (September 25, 2018).

[9] American Heart Association/American Stroke Association, Guidelines for Adult Stroke Rehabilitation and Recovery. May 4, 2016.

[10] The Lewin Group, CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 3 Evaluation & Monitoring Annual Report (Oct. 2017). 260. Lewin states: "Seven of eight measures using assessment data pointed to a relative decline in functional improvement for BPCI [Model 2 stroke] patients who received post-acute care (PAC) in home health agencies (HHAs) and skilled nursing facilities (SNFs) long enough to have two patient assessments, although only two of the changes from the baseline to intervention period were statistically significant. In contrast, both measures assessing functional limitations for patients treated by inpatient rehabilitation facilities (IRFs) pointed to relative improvements for BPCI patients."

indirect costs of these negative outcomes on society, including in lost productivity, as well as unquantifiable costs in patients' reduced quality of life, which can be dramatic when they are denied a chance to return to a full and fulfilling life through proper rehabilitation.

OIG has recognized the impermissible nature of Medicare-participating entities denying beneficiaries access to medically necessary services to which they are legally entitled. One such example is the aforementioned report raising serious concerns that the capitated payment model used for MA plans may be incentivizing these organizations to inappropriately deny access to services.[11] It would be irresponsible for your department to plow forward with permitting arrangements that may incentivize providers and other organizations to stint on critical PAC services unless or until there are mechanisms to hold these entities accountable for ong-term outcomes.

To ensure Medicare beneficiaries are not denied access to the benefits that they are legally entitled, and to avoid unnecessary costs to Medicare and other federal programs, OIG should make certain the arrangements permitted under any safe harbor are truly quality enhancing ventures that have strong safeguards in place so patients can access medically necessary and appropriate care. The safeguards that should be in place include ample functional outcome measurement and quality accountability for any arrangements, since they are staples of any legitimate value-based arrangement. At a minimum, any permitted value-based arrangement should require providers to be held more accountable for the quality of care and outcomes for patients, than the cost of care delivered. OIG should look skeptically upon any arrangements with too heavy an emphasis on cost control—driven by a quest to increase the amount of shared savings among participating providers—without equal weight placed on quality and outcomes.

AMRPA also encourages OIG to assist in the development of additional consumer protections for any beneficiaries being treated under a value-based arrangement. Such protections should include continued freedom of choice so that Medicare beneficiaries are permitted to seek treatment outside of the value-based arrangement if they so desire, as well as a disclosure requirement that providers inform beneficiaries that they are being treated as part of a value-based arrangement. AMRPA also encourages OIG to thoroughly investigate the effect that value-based payment arrangements have on beneficiary access to health care. Specifically, your office should use its audit and investigation resources to examine utilization in APMs and other similar arrangements to help ensure there is not inappropriate care stinting.

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AMRPA welcomes continued opportunities to collaborate with the Department of Health and Human Services and the Office of Inspector General to create value-based safe harbor regulations while ensuring access to necessary medical care and high-quality outcomes for all

[11] U.S. Department of Health and Human Services Office of Inspector General, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, Report (OEI-09-16-00410) (September 25, 2018).

Medicare beneficiaries. If you have any questions about AMRPA's recommendations, please contact me or AMRPA's Regulatory and Government Relations Counsel, Jonathan Gold, J.D. (jgold@amrpa.org / 202-860-1004).

Sincerely,

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