August 24, 2018

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

RE: CMS-1720-NC Request for Information: Centers for Medicare & Medicaid Services, Physician Self-Referral Law (83. Fed. Reg. 29524).

Submitted Electronically

Dear Administrator Verma,

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on the physician self-referral law ("Stark") published in the *Federal Register* on June 25, 2018.

AMRPA is the national trade association representing more than 625 freestanding inpatient rehabilitation hospitals and rehabilitation units of general hospitals (IRH/Us, but referred to by CMS as "IRFs"), outpatient rehabilitation service providers, long-term care hospitals (LTCHs), and several skilled nursing facilities (SNFs). In 2016, inpatient rehabilitation hospitals and units 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* 42 C.F.R. § 412.622

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IRH/Us are keenly aware of the impediments created by Stark. Most IRH/U patients are referred from an acute-care hospital due to a complex condition requiring interdisciplinary and intensive rehabilitation treatment. However, a patient's treatment does not stop at discharge 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] IRH/Us and their physicians face the difficult task of monitoring compliance with Stark for both referrals for admission to the IRH/U as well as discharge from the IRH/U to a different setting.

The rigid, strict-liability of Stark creates a presumption that any self-referral is fraudulent, which is inconsistent with the plethora of CMS' initiatives to hold providers accountable for patients after they are discharged or leave a provider's care. Unlike when Stark was created, many Medicare providers are now held accountable for the value of the care provided through one Medicare mechanism or another. Acute care hospitals, for example, submit measures to the Hospital Value Based Purchasing Program (VBP), which adjusts payment based on quality and cost metrics. In addition, Medicare providers, including IRH/Us, undergo frequent and rigorous audits to determine the medical necessity of the care provided at their hospitals. Further, many physicians within IRH/Us are now subject to the Merit-Based Incentive Program, which adjusts payment based on cost and quality measures.[5]

Due to multiple checks on the quality, value and medical necessity of care delivered to Medicare beneficiaries, it is no longer appropriate to presume a referral from which the physician may benefit was improper. In general, IRH/Us and other providers require much more flexibility to pursue legitimate value-based arrangements, both via models sponsored by Medicare and outside of Medicare, without risk of running afoul of Stark. This is why, as discussed more fully below, AMRPA recommends that CMS create a broad, bona fide value-based waiver for Medicare providers under Stark. This waiver would need to be widely applicable to all types of value-based payment arrangements due to the fact that current waivers are narrow and relatively ineffective.

Coupled with our recommendation to provide more flexibility under Stark, AMRPA also recommends that CMS implement sufficient patient safeguards for any such changes. Any value-based arrangement has inherent pressures to reduce spending and, in turn, drive patients toward less expensive and less intensive settings of care. This dynamic is particularly important for patients with disabilities and chronic illnesses whom IRH/Us serve, because these incentives risk the denial of access to necessary and appropriate rehabilitative care. 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 CMS proceed cautiously with Stark reforms in order to ensure

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

[5] See 42. C.F.R. Part 414 (Under the Quality Payment Program (QPP) eligible clinicians either participate in the Merit-Based Incentive System (MIPS), participate in an Advanced Alternative Payment Model or face a payment reduction).

that there is sufficient quality accountability and consumer protections for beneficiaries to prevent care stinting as a result of the financial incentives and cost pressures inherent in value-based arrangements.

I. CMS Should Create a Bona Fide Value-Based Arrangement Waiver Under Stark.

CMS already recognizes that many value-based initiatives, such as shared savings programs, run afoul of Stark and require waivers. This is why, for example, the agency issued waivers for participants in the Medicare Shared Savings Program (MSSP) and most of its other innovative payment models and demonstrations.[6] However, these waivers are limited not only to a specific program, but also only to direct participants. This is restrictive in several ways. First, it means there is no waiver for hospitals trying to create value-based incentives for their providers outside of these specific Medicare programs. Second, even preferred providers who contract with an Accountable Care Organization (ACO) cannot utilize this waiver, since it is for only direct members of the ACO. This can present a problem for IRH/Us, which for other reasons may not be able to be directly included in the ACO, but nonetheless would like to offer its services as a preferred provider to ACO patients in a value-based arrangement.

Instead of offering narrow Stark waivers for specific types of Alternative Payment Models (APMs), CMS should create a broad, bona fide value-based waiver under Stark. This waiver, which should be proposed and established through notice and comment rulemaking, would establish parameters for what constitutes a bona fide value-based arrangement that would create a safe-harbor from Stark violations. Within these parameters, CMS should lay out several permitted objectives of such an arrangement. Among other considerations, these objectives should include accountability for the quality and outcomes of patient care, as well as encouraging care management and coordination among providers.

The bona fide value-based waiver should apply to all value-based arrangements, whether as part of an APM, a demonstration under Medicare, or arranged independently among Medicare providers. Further, as discussed more fully below, the analysis of whether a relationship is value-based should also include an evaluation of the safeguards to prevent stinting on patient care due to the financial incentives involved in the arrangement. **Therefore, AMRPA recommends CMS create a broad, bona fide value-based waiver to allow for legitimate value-based arrangements within the Medicare program.**

II. When Creating More Flexibility Under Stark, CMS Should Also Enhance Efforts to Prevent Stinting of Patient Care by Ensuring Accountability for Long-Term Functional Outcomes.

As described above, AMRPA supports CMS' efforts to reform Stark regulations to improve the effectiveness of innovative, value-based approaches to care delivery. However, CMS should take great precaution to ensure any value-based arrangement that it sponsors or permits does not lead to stinting on patient care, particularly PAC. Whenever a value-based arrangement places too much emphasis on cost reduction, without corresponding and robust

[6] 76 Fed. Reg. 67992, Medicare Program; Final Waivers in Connection With the Shared Savings Program (November 2, 2011).

accountability for patient outcomes, there is obvious risk that providers will be incentivized to stint on care.

Stinting on patient care is a particular risk in the PAC sector, where a treating physician must make a decision between discharge options with widely varying intensity of services, and thus widely varying costs. AMRPA members have found that 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 ACOs under the MSSP. The Commission found that organizations have generated savings not through reducing unnecessary hospital readmissions, but largely by decreasing PAC utilization.[7]

This diversion of patients away from the more intensive settings of PAC is occurring in spite of recent clinical guidelines published by the American Heart Association and the American Stroke Association which recommend acute hospital-level care for post-stroke rehabilitation.[8] It is also in spite of CMS' own research on the Bundled Payments for Care Improvement Initiative (BPCI) Model, which showed better functional outcomes for stroke patients treated at IRH/Us when compared to other settings of PAC.[9]

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 per-capita payment basis and thus bear risk for utilization, also show significant differences in access to IRH/U care. In its March 2017 Report to Congress, MedPAC found that MA enrollees are admitted to IRH/Us at approximately one-third the rate of Medicare fee-for-service beneficiaries in 2015, which is also consistent with previous years' data.[10]

Without proper accountability, it can be far too easy for providers to achieve "benchmark" performance on measures such as Medicare Spending Per Beneficiary (MSPB) by denying patients access to timely and intensive inpatient rehabilitation hospital services and diverting

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[7] Medicare Payment Advisory Commission, Medicare accountable care organization models: Recent performance and long-term issues. 230. June 2018.

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

[9] 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."

[10] 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).

beneficiaries to less intense levels of PAC. 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 a facility. These risks are heightened when APMs and other value-based arrangements are not held accountable for functional and other outcomes.

Ultimately, and as CMS knows, any short-term savings to Medicare through underutilization of PAC services are offset by significant unnecessary long term costs. Disability, lack of function, and hospital readmissions create far greater expenditures in the long term than any savings achieved through reduced payments in the short-run. Less independent living, more sedentary lifestyles, greater dependence on home care, and greater reliance on mobility aids and equipment could be averted through timely, intensive and appropriate rehabilitation services and devices. Needless to say, the unquantifiable cost of these negative outcomes on a patient’s quality of life is even more dramatic.

Therefore, as CMS considers reforming Stark regulations to help promote value-based arrangements, the agency should ensure the arrangements are truly quality enhancing ventures that have strong safeguards in place so patients can access medically necessary and appropriate care. To accomplish this, CMS should ensure that ample functional outcome measurement and quality accountability are included in any value-based program. This would, at a minimum, require providers to be held more accountable for the quality of care and outcomes for patients than the cost of care delivered. CMS should look skeptically upon any arrangements with too much of 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.

In addition, CMS should consider requiring additional consumer protections for any beneficiaries being treated under a value-based arrangement. Such protections should include 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 they are being treated as part of a value-based arrangement and have the option to seek treatment elsewhere using their Medicare coverage.

AMRPA supports CMS efforts to find ways to eliminate impediments to value-based care created by Stark. However, value-based arrangements can create a concomitant risk of stinting on patient care. Therefore, AMRPA recommends CMS proceed cautiously with providing additional flexibility for value-based arrangements under Stark and ensure all arrangements contain sufficient safeguards to protect beneficiaries from being denied necessary care.

AMRPA welcomes continued opportunities to collaborate with the Department of Health and Human Services (HHS) and CMS to reform Stark in a way that modernizes Medicare while also continuing to ensure access to all needed medical care. 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,

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