February 19, 2019

Dear Senator Cassidy and Senator Warner,

The Healthcare Leadership Council (HLC) applauds your efforts to advance a value-driven healthcare system. The Patient Affordability, Value and Efficiency (PAVE) Act demonstrates your commitment to promoting better safety and value in healthcare delivery and payment. We are grateful for the very constructive discussion our members had with Jeff Lucas and Greg Mathis about the draft version of the PAVE Act back in December.

HLC is a coalition of chief executives from all disciplines within American healthcare and the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Supportive of the move toward a healthcare system based on providing better value, HLC has convened a broad group of organizations that recognize the transformational effect of this shift on the existing legal framework governing U.S. healthcare. In order to better coordinate and deliver patient care, the legal framework must allow appropriate patient-serving care delivery and payment models involving broader collaboration among stakeholders in order to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth. The Physician Self-Referral (Stark) Law and Federal Anti-Kickback Statute workgroup of HLC (the "Workgroup") includes a wide array of hospital, patient/consumer, physician, health insurance, medical device, pharmaceutical, information technology vendor, and supplier organizations.

With the move toward a healthcare system based on providing better quality and value, we share your recognition of the need for an aligning shift in the existing legal framework governing U.S. healthcare. The current framework was built for a fee-for-service environment and is intended to address arrangements by and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources and/or inappropriately influence provider decision-making. To improve quality of care and reduce cost growth, new care delivery and payment models are designed to encourage greater integration, coordination of care, and reimbursement for healthcare services and products that are linked to outcomes. In large part, these new models

eliminate the financial incentive to provide more services and replace it with an incentive to provide more value-driven care across the healthcare continuum.

However, healthcare stakeholders have been deterred from implementing value-based payment and care delivery approaches that would support delivering more efficient, coordinated care. This chilling effect is at least in part due to an outdated legal framework, specifically the Federal Anti-Kickback Statute and regulatory safe harbors and the Physician Self-Referral (Stark) Law and regulatory exceptions. For example, compensating partners in a value-based arrangement with savings generated from care plan coordination among clinical and non-clinical partners as well as new contracting approaches that allocate risk based on outcomes may trigger scrutiny. While "safe harbors" to the Anti-Kickback Statute and "exceptions" to the Stark Law exist to protect certain financial arrangements in healthcare, these protections are too narrow in scope.

In general, we support federal legislation that would provide a safe harbor and exception under the Anti-Kickback Statute and Stark Law respectively exempting activities or initiatives that involve the integration of care, items, services, and payment across stakeholders (i.e., providers, payers, medical device and pharmaceutical manufacturers, other industry stakeholders) that meet certain established value-based healthcare criteria and that are designed to improve patient outcomes and reduce the overall cost of providing care. Other existing protections would, of course, remain in place, to deter fraudulent activity beyond the scope of eligible value-based arrangements. A new safe harbor and exception should be available to all stakeholders participating in a value-based arrangement regardless of the payor or payor mix for the patient population.

With regard to the new Anti-Kickback statutory safe harbor and Stark Law statutory exception included in the PAVE Act, we provide the following comments:

1) The phrase "value-based arrangement or VBA" has been the subject of great variation in interpretation. We encourage you to consider providing greater clarity as well as examples to help guide the CMS and OIG rule-making process as well as industry interpretation and application. We emphasize, however, the importance of balancing clarity with flexibility to ensure that stakeholders are not restricted to only those examples given. Further clarity in defining VBAs is important for purposes of both the Anti-Kickback safe harbor as it relates to the protection of VBAs as well as Stark where all amounts determined under a VBA would be protected by the new safe harbor. Further clarification should include:
    a. specifying goals or characteristics of VBAs, similar to what is included in the current CMS and OIG waivers
    b. specifying that VBAs could involve patient populations that receive services reimbursed by various healthcare payers and beyond arrangements covered by a Medicare waiver
    c. specifying that VBAs in the context of the Anti-Kickback Statute could involve a range of clinical and non-clinical participants such as medical device manufacturers, pharmaceutical manufacturers, payers, and other health industry stakeholders

d. specifying that VBAs may involve arrangements to which not all parties assume financial risk, but still receive remuneration (either in-kind or monetary payments)

In addition, with regard to the four elements included in the current draft's description of a VBA, must all of these be met in order to qualify as a VBA? If any of these activities would be sufficient to meet the standard for VBA, we recommend modifying this language to separate the subclauses with "or." In Section L(ii), we encourage you to consider adding "quality" metrics in addition to clinical or economic targets and changing "without negatively affecting patient outcomes" to "with the aim of maintaining or improving patient outcomes." In Section L(iii), the word "optimize" is unclear; we suggest replacing with "measurably improve."

2) The use of the term "varying levels" as it applies to financial risk is unclear especially in light of both Anti-Kickback Statute and Stark Law provisions that require payment amounts be identified and set in advance. We encourage you to replace "varying" with "predetermined" or "specified allocation."
3) The language "relative to a participant's contribution to the achievement" of the targeted outcomes with regard to the levels of financial risk assumed is unclear. Many parties (including the provider, facility, patient, medical and/or pharmaceutical manufacturers, EHR vendor) may contribute to the successful outcome of a given procedure, including those who may or may not be direct parties to the VBA. The existing language may suggest that quantification of risk and contribution is required in order for an arrangement to qualify as a VBA. Further, calculating each participant's contribution to an achievement of a targeted outcome is a complex, resource-intensive, and somewhat subjective obligation. In order to avoid confusion over methods of compliance with the statutory language and to avoid creating burdensome standards that may stifle innovation, we encourage you to either:
    a. Delete or rephrase the "relative to" language; or
    b. Replace "relative to" a participant's contribution with "that takes into account each" participant's contribution.
4) Much confusion currently exists in relation to various terms applicable to both the Anti-Kickback Statute and the Stark Law. Terms such as "fair market value," "commercial reasonableness," and "volume or value of referrals" either lack a statutory definition (such as the case with "fair market value" with respect to the Anti-Kickback Statute) or are vaguely and imprecisely defined. This has a chilling effect on stakeholder's development of value-based arrangements, an environment within which the existing definitions do not clearly align. We encourage the inclusion of clarifying definitions or language directing the OIG and CMS to issue guidance or regulation clarifying these definitions within the context of new and changing payment settings.

Finally, and equally important, the transition to value-based care delivery and payment also implicates the Civil Monetary Penalties (CMP) Law.[i] In the 2016 gainsharing report, CMS stated that these fraud and abuse laws including Stark, Anti-Kickback and CMP

"may serve as an impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste."[ii] We urge you to consider modifying the CMP framework in alignment with corresponding changes to the Anti-Kickback Statute and the Stark Law to ensure consistency across the entire fraud and abuse framework.

Again, we appreciate the opportunity to comment on this draft legislative language and your leadership to advance modifications to the existing legal framework to better enable patient-centered, value-based care and payment models.

Sincerely,

Mary R. Grealy
President

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[i] 42 U.S. Code § 1320a–7a.
[ii] Gainsharing Report at 7-8 (2016).