"Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program"

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Chairman Roskam, Ranking Member Levin, and members of the Subcommittee, I thank you for the opportunity to testify. My name is Dr. Brian DeBusk, and I am the President and CEO of DeRoyal, a medical device manufacturer with approximately 2,000 employees worldwide.

I appreciate the opportunity to speak with you today about ways to improve delivery of health care through better provider coordination. Legislation regarding physician self-referrals codified through the Omnibus Reconciliation Act of 1990 and the Omnibus Reconciliation Act of 1993, commonly referred to as the "Stark Law", play a critical role in ensuring adequate financial separation between doctors and the Designated Health Services to whom they commonly refer patients.

Induced utilization created by potential conflicting interests places the beneficiaries of both Medicare and Medicaid as well as taxpayers in harm's way. Therefore, I would like to emphasize the need for caution when considering ways to make significant changes to amend the Stark Law in an unfettered fee-for-service environment.

Yet today, physicians and facility-based providers need to align both their activities and their incentives in unprecedented ways in order to be more patient-centric, improve care coordination, and facilitate delivery system change. Many would argue, and I would agree, that our current healthcare system is unsustainable given our fiscal constraints. And to support this transformation, the Stark Law should be modernized.

Waiving certain elements of the Stark Law is not without precedent. Even in its earliest form, the Stark Law exempted what we now refer to as the Medicare Advantage program from many of its provisions. Policymakers recognized that in a capitated, risk-borne environment, checks and balances exist that curtail the potentially inductive effects of physician-provider financial relationships, thus mitigating the primary risk the Stark Laws set out to prevent. Simply said, when providers have a share in potential savings due to sharing risk, there is diminished financial benefit to increasing utilization through referral.

Today, Medicare has another set of tools for managing cost and quality created through the Patient Protection and Affordable Care Act of 2010. It is within these tools that significant opportunities for Stark modernization arise.

Both the Medicare Shared Savings Program and numerous demonstration projects managed by the Center for Medicare and Medicaid Innovation currently serve as Alternative Payment Models designed to spur healthcare innovation, with the hope of higher value care for beneficiaries and reduced taxpayer burden.

Many, but not necessarily all, of these Alternative Payment Models incorporate some form of downside risk. If the responsible entity fails to achieve cost and quality targets, a financial penalty is incurred that results in lower payments than would otherwise occur in the traditional fee-for-service paradigm. While these penalties often fall below those associated with the risk-borne capitation found in Medicare Advantage, they do represent a significant waypoint between unmanaged fee-for-service and private plans.

Note that these two-sided risk models also compliment the implementation of the Medicare Access and Chip Authorization Act of 2015, or MACRA, which provides financial incentives to physicians who participate in qualifying Alternative Payment Models. Since these financial incentives encourage

physicians to seek out these specific payment models, it is safe to say APMs and MACRA interact in a complimentary manner.

There is significant opportunity to begin modernizing the Stark Law within these Alternative Payment Models that carry downside risk. The possibility of a negative financial outcome ensures that the proper checks-and-balances are in place. And it is within this context that I would recommend starting with significant modifications to Stark.

Many of the Alternative Payment Models (APMs) already include multiple waivers, including some related to the Stark Law. It is then reasonable to ask why these waivers are not used to their fullest. One is an issue of past practice. The Stark Law has cast a long, burdensome shadow over physician-provider financial arrangements for decades, which is a testament to the underlying, and intended, strong deterrent factor as a result of the legislation.

But in last decade, policymakers have looked to counter those forces to enable more coordinated care through new types of provider alignment. I would now like to focus on one specific subset of Alternative Payment Models – Accountable Care Organizations, or ACOs. These models represent the most promising platform for moving Medicare toward a managed fee-for-service model as opposed to its current unmanaged state. ACOs already have generous waivers that exempt them from major portions of the Stark Law. For example, the Next Generation ACO Model waives most of Stark's financial arrangement provisions, particularly around how Shared Savings can be distributed.

So it is again reasonable to ask why these waivers are not used to their fullest. I believe the reason is two-fold. First, because the waivers are issued on a case-by-case basis by CMS and the HHS Inspector General, and because of potential changes through the annual regulatory process, there is inherent uncertainty as to their evolution over time. Codifying these waivers into law would give both physicians and the Designated Health Services defined by the Stark Law the certainty they need to pursue financial relationships that support the transition to value-based care.

Second, we need to strengthen ACOs themselves, particularly models that incorporate downside risk. Much progress has been made in attribution of beneficiaries to specific ACOs as well as incorporating both historical and regional spending into their benchmarks. But much more needs to be done. ACOs serve as the substrate for the transition to value-based care and care coordination, which is the underlying driver for these hearings today on Stark Modernization. It is safe to say that the issues of Stark Modernization, the proliferation of successful ACOs with downside risk, and the successful implementation of MACRA are all inextricably linked.

In summary, there is an exciting opportunity to modernize the Stark Law so as to support the transition from volume to value. But caution must be observed in that Stark must continue to protect beneficiaries and taxpayers in an unfettered fee-for-service environment. APMs, particularly ACOS with downside risk in particular, represent the optimal environment for modernizing Stark.

Thank you for the opportunity to speak to you today and I look forward to answering any questions you may have.