July 22, 2016

Senator Orrin Hatch
Chairman
Senate Committee on Finance
Hart 104
Washington, DC 20510

Senator Ron Wyden
Ranking Member
Senate Committee on Finance
221 Dirksen
Washington, DC 20510

Re: Senate Finance Committee Hearing: "*Why Stark, Why Now? Suggestions to Improve the Stark Law and Encourage Innovative Payment Models*"

Dear Chairman Hatch and Ranking Member Wyden:

The American Academy of Orthopaedic Surgeons (AAOS), the American Association of Orthopaedic Executives (AAOE), and the OrthoForum would like to thank you for the opportunity to submit comments regarding the recent Senate Finance Committee hearing, "Why Stark, Why Now? Suggestions to Improve the Stark Law and Encourage Innovative Payment Models." We appreciate the need to improve and modify the Physician Self-Referral Law ("Stark Law") in light of the shift from Medicare fee-for-service to alternative payment models. The structure of the Stark Law has not been updated statutorily for more than two decades and is now an anachronistic hindrance to the 21st century delivery of health care and limits the full potential envisioned by Congress when it enacted MACRA. Additionally, the overly complex regulatory restrictions have negatively impacted the efficiency of patient care while serving to drive many private practice physicans into hospital employment.

Two issues we would like to emphasize are the importance of protecting the In-Office Ancillary Services Exception (IOASE), which allows for an integrated continuum of care, and the need to lift the physician-owned hospital (POH) ban on expansion and new construction, which increases access to quality care. These issues will be addressed further.

What changes need to be made to the Stark Law to implement the Medicare Access and CHIP Reauthorization Act (MACRA, 2015) and Accountable Care Organizations (ACOs)/ Medicare Shared Savings Program (MSSP)?

Issue of continued relevance: The wide-range of regulations governing physician financial incentives are an impediment to the transition to value-based Medicare reimbursement. The US Department of Health and Human Services (HHS) set a goal to tie at least 30 percent of the fee-for-service Medicare payments to quality/value through Alternative Payment Models (APMs) by 2016 and to 50 percent of payments by the end of 2018. CMS announced in March 2016 that the

agency was ahead of schedule in the realization of its 30 percent goal. However, a significant portion of that goal was accomplished through demonstration initiatives such as the Bundled Payments for Care Improvement (BPCI) initiative in which multiple waivers were required to allow physician groups and hospitals to work in concert to lower costs and improve quality. BPCI along with the more recently implemented Comprehensive Care for Joint Replacement (CJR) model reveal weaknesses in current Stark Law which is structured to have some control over volume of referred services. Rewarding providers for the value of care and not the volume of services, such as in these current initiatives, renders a driving intent of the Stark Law obsolete.

Costs for compliance: As MACRA is implemented, regulations should make it less burdensome for physicians to participate in APMs and earn incentives through the Merit-based Incentive Payment System (MIPS). The costs of compliance and disclosures required per the Stark Law can be prohibitive for small and medium-sized physician practices. We are concerned that this cost will lead to a drop of specialty providers in the Medicare program as the cost of compliance continues to grow.

Recommended waivers: Existing Stark Law requirements are highly technical and the waivers can get very complex. For example, physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark Law requirements through fraud and abuse waivers. There should be similar exceptions/protections to physicians participating in APMs. However, we anticipate that as MACRA provisions are implemented, such waivers will become more complex. An alternative to waivers may be a statutory exception modeled on the Medicare pre-paid plan enrollees under Section 1877 (b)(3) of the law. On the whole, regulatory agencies such as CMS should have greater flexibility to refine the regulations as the health care policy and delivery environment changes.

Other Recommendations

The complexities of the Stark Law regulatory infrastructure make it burdensome for clinicians to comply. The "group practice" definition places strict limits on the ways that a physician practice may compensate its owners. Agreements with physician contractors must satisfy seven distinct regulatory conditions, making them prone to technical infractions. Unlike other laws that regulate healthcare, the Stark Law does not require demonstration of intentional offers of remuneration to induce referrals or any risk to patient care. Current waivers are skewed toward primary care and financial relationships with hospitals. It is critical to incorporate protections for independent specialty groups. Finally, the Stark Law impedes care coordination needed to quality for alternative payment models in MACRA due to the Law's consideration of "other business generated" in its limitations on referrals. There are five fundamental revisions that we would like to see in order to align the law with MACRA:

- Revise the definition of "group practice" by removing the current "volume" or "value" standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark Law.
- Provide the same protections from the Stark Law for physicians operating in an Alternative Payment Model for those provided waivers through Accountable Care Organizations eligible for the Medicare Shared Savings Program.
- Permit physician compensation for providing high-quality and efficient care without violating the Stark Law's "fair market value" standard even if the compensation is related to the volume or value of the referrals.
- Define Stark Law "technical violations" as compensation arrangements that do not otherwise violate the Anti-Kickback statute.
- Empower CMS to create new regulatory exceptions to the Stark Law now and in the future for purposes of promoting non-fee-for-service payment structures.
- Quality- and value-based physician reimbursements may violate the Stark Law fair market value or reasonableness standards. Under the current delivery and payment system, these standards should be repealed by Congress or CMS should be able to issue new and relevant standards.

Stark Law technical violations vs. more serious violations—where is the line?

We would like to point out that the Stark Law is a liability statute unlike other health care legislation. Thus, the physician's actual intent to improperly refer services is not pertinent to the liability. Thus, unintentional and technical errors of physicians and their staff may lead to heavy penalties. Such liability statutes are not encouraging of physicians to participate in new demonstrations and payment models. These requirements are also not helpful toward developing coordinated care models such as the CJR, led by hospitals but coordinated by several stakeholders including physicians.

Lifting the moratorium on new construction for Physician-owned Hospitals

The Whole Hospital Exception to the Stark Law allows for a physician to have an ownership or investment interest in a hospital to which the physician refers designated health services when the physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself. The Affordable Care Act (ACA) amended the Whole Hospital Exception to impose additional restrictions on physician-owned hospitals (POHs). The ACA restricted a POH from new construction or facility expansion after March 23, 2010.

There are approximately 250 POHs operating in 34 states across the country. These hospitals have a long history of providing the highest quality care for affordable prices. They are often the most efficient, state-of-the-art facilities in the country, which is the result of a doctors' desire to be involved in making detailed decisions. In CMS' Value Based Purchasing Program results, seven of the top ten hospitals, and 40 of the top 100 hospitals, receiving quality bonuses in FY 2016 were

POHs. A POH has been the top bonus recipient in each of the four years of the program. This is impressive, considering that POHs represent less than 5% of the 5,700 hospitals nationwide. Likewise, more than 40% of POHs earned CMS' top 5-star rating for patient satisfaction in October 2015, while less than 4% of non-physician-owned hospitals received that distinction.

POHs treat similar patient populations as other hospitals. A 2015 British Medical Journal study, published by a Harvard University researcher, found that there is no "clinically or statistically significant differences in patient mix between POHs and non-POHs." The study found that "POHs and non-POHs admitted similar proportions of Medicare patients … Medicaid patients … Black patients … and Hispanic patients," as well as patients with "comparable numbers of comorbidities … and similar predicted mortality scores."

Despite the strong track-record of superior performance, POHs serving Medicare and Medicaid patients have been restricted from growing and expanding through the ACA's change to the Stark Law Whole Hospital Exception. The restrictions have limited POHs from developing or expanding services in numerous rural and urban communities where additional care is desperately needed. In many instances, local community hospitals are simply not able to handle the caseload and patients do not have access to the care they need.

We strongly believe that the ACA change to the Whole Hospital Exception is detrimental to the US healthcare system, and Medicare and Medicaid beneficiaries. POH's are a model that encourage the move from volume to value and are therefore consistent with the current trends in physician reimbursement.

Maintenance of current exceptions for In-Office Ancillary Services

We would like to conclude by stressing the importance of maintaining current exceptions. For orthopaedic surgeons, current exceptions such as the IOASE, are absolutely essential for providing necessary care. For example, in high shortage and low resource rural areas, having magnetic resonance and other imaging services in the physician's office is often the only way that our surgeons can deliver and their patients can get timely diagnoses and care. The IOASE provision has enabled our practices to provide convenient, integrated and less expensive high-quality care.

Several recent studies have made it clear that utilization of ancillary services in physician practices does not lead to overutilization. In a study published by Health Economics Review found that there was no statistically significant difference between physicians who self-refer for Magnetic Resonance Imaging (MRI) and those who do not. A June 2015 study by Milliman Inc. – commissioned by the American Medical Association and the Digestive Health Physicians Association – showed utilization of ancillary services in physician practices is a small percentage of total spending on ancillary services and is declining or growing more slowly than in hospital settings. Additionally, a study by Braid-Forbes Health Research, LLC found that financial ownership was not related to MRI referral rates for practices that owned MRI equipment during the period of the study. A 2014 Government Accountability Office (GAO) study on physician-

owned physical therapy services showed that physicians owning physical therapy services utilize the services less than physical therapy provided in non-physician owned settings. Finally, in a June 2011 report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended against limiting the Stark Law exception for ancillary services, citing potential "unintended consequences, such as inhibiting the development of organizations that integrate and coordinate care within a physician practice." Any effort to repeal the in-office ancillary services exception should be rejected.

We sincerely appreciate your endeavor in updating the Stark Law requirements and regulations and should you have any questions, please feel free to get in touch with AAOS's Senior Manager of Government Relations, Ms. Julia Williams, at jwilliams@aaos.org, or AAOE's Government Affairs Manager, Mr. Bradley Coffey, at bcoffey@aaoe.net, or Joel James, OrthoForum Advocacy Committee member at jjames@signaturehealth.net.

Sincerely,

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