AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY

AAO-HNS Summary of the Stark Law and Anti-Kickback Statue Final Rules

On December 2, the Department of Health and Human Services (HHS) published two final rules that have broad reaching implications for otolaryngologists and their patients. The final rules include one issued by the Centers for Medicare & Medicaid Services (CMS) addressing changes to the Stark law and one issued by the Office of Inspector General (OIG) addressing changes to the Anti-Kickback Statute and Civil Monetary Penalty rules**.** These updates are long overdue as the antiquated, burdensome, and overly restrictive Stark law had not been significantly updated since its enactment in 1989. The Academy has been actively advocating for required changes to the Stark law for many years and applauds the agency's release of this final rule. Both final rules incorporate feedback and address over 650 comments submitted by stakeholders in response to the proposed rules released on October 17, 2019. These new rules took effect on January 19, 2021 except for some changes to the definition of group practice that take effect on January 1, 2022.

HHS had previously indicated that these rules would be finalized in 2021 due to their complexity; however, the Administration included modernization of Stark/anti-kickback rules as one of its top priorities. Both final rules implement and expand on existing safe harbors for physicians and other providers engaged in value-based care arrangements.

***The information provided below does not, and is not intended to, constitute legal advice; instead, all information, and content included in this summary are for general informational purposes only.*

Stark Law

The final rule creates new, permanent exceptions to the Stark law for value-based arrangements. The exceptions apply regardless of whether the arrangement relates to Medicare or other patient arrangements.

Specific Exceptions

The financial risk exception requires that physicians be responsible for a minimum of 10% of the value of the remuneration the physician receives in the value-based arrangement. This is a significant improvement from the earlier proposed rules where physicians were responsible for 25% of the value.

There is a new exception in place for limited remuneration to a physician. CMS finalized a new exception to protect compensation not exceeding an aggregate of $5000 per calendar year, adjusted for inflation, to a physician for items and services. These services can be provided without needing signed compensation agreements in advance if certain conditions are met. The new exception is an increase of $1500 from the proposed rule. This exception includes employees hired by the physician to do the work or service.

CMS finalized a new exception for donors of cybersecurity products. Given the complexity of cybersecurity, this exception includes training services. Please note that this exception is different from the electronic health records exception which was also updated in this rule. The final rule expressly permits donations of cybersecurity software and services that protect electronic health records (EHR) under the EHR exception. CMS declined to limit the types of donors protected under this exception; instead, the final rule protects all donors. This supports a broad scope of protected donors, including individuals or entities, hospitals, health plans, EHR vendors, manufacturers, and ancillary service providers. Given the complexity of cybersecurity, donations may also include training services, such as training a physician's staff on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology. Physicians and their staff may also be provided access to a donor's primary technology help desk (for example, to report cybersecurity incidents).

Guidance and Clarifications

CMS finalized clarifications to the regulations defining a "group practice" for purposes of the Stark Law. While the profits from all designated health services (DHS) of any component of the group that consists of at least five physicians (which may include all physicians in the group) must be aggregated before distribution, CMS clarified that a group practice may utilize different distribution methodologies to distribute shares of the overall profits from all DHS of each of its components of at least five physicians, provided that the distribution to any physician is not directly related to the volume or value of the physician's referrals and the same methodology is used for all the physicians included in their component.

DHS includes, among other items, clinical laboratory services, physical, occupational and speech therapy, certain imaging services, radiation therapy, durable medical equipment, and outpatient prescription drugs.

Ambulatory Surgery Centers

CMS did not change the existing exemptions for Ambulatory Surgery Centers under the Stark Law.

Anti-Kickback Statute

The new regulation finalizes proposals that modify existing safe harbors, creates new safe harbors, and creates a new civil monetary penalty exemption.

Remuneration Safe Harbors

The regulation finalized three new safe harbors that vary in terms of the type of remuneration that can be provided, the level of financial risk the parties assume (full financial risk, substantial downside financial risk, and no or lower risk), and the types of safeguards required to satisfy the safe harbor. Overall, the value-based safe harbors are generally narrower than the Stark exceptions. The safe harbors do not require compliance programs to review patient medical records.

Specific Safe Harbors

OIG finalized a patient engagement and support safe harbor to protect furnishing certain tools and support to patients to improve quality, health outcomes, and efficiency. This safe harbor is only

available for value-based enterprise participants and the requirements for the safe harbor include that the remuneration can be in-kind only and it is limited to an inflation adjusted $500 annual cap.

OIG finalized a safe harbor to protect certain remuneration provided in connection with models sponsored by CMS. This safe harbor only protects certain CMS sponsored models.

OIG finalized a standalone protection for donations of cybersecurity technology and services, including certain cybersecurity hardware donations.

Modifications to Existing Safe Harbors

The OIG modified the existing personal services and management contracts safe harbor which protects payments tied to achieving measurable outcomes that improve patient or population health or appropriately reduce payor costs.

The OIG finalized several proposed changes to the electronic health records and services safe harbor, including modifying the timing of certain required recipient contributions, permitting certain donations of replacement technology and removing the sunset provision.

DISCLAIMER: *The AAO-HNS agrees with the American Medical Association (AMA) recommendation which states, "If upon reviewing this information, a reader wishes to pursue any of the opportunities and/or options described herein, the AMA strongly recommends consultation with health care counsel experienced in the federal Stark Law and the AKS, as well as the applicable state's fraud and abuse laws, prior to taking any actions in reliance on the final rules discussed in this brief summary."*