

December 31, 2019

Office of Inspector General
U.S. Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521
Cohen Building
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Washington, DC 20201

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically via <http://www.regulations.gov>.

The American Dental Association (ADA) appreciates the opportunity to comment on the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) concerning proposed changes to the Anti-Kickback Statute (AKS) safe harbors and the Physician Self-Referral (Stark) Law exceptions.

Simplification and coordination. The ADA generally urges OIG and CMS to simplify and coordinate the final rules to the greatest extent possible in order to reduce uncertainty and compliance burdens on stakeholders. The ADA urges OIG and CMS to consider in particular, when developing final rules, the potential burdens and benefits of the rules to providers that are small businesses or located in rural and medically underserved areas, and their patients.

DMEPOS suppliers. The ADA urges OIG and CMS to exempt dentists from any prohibition on a Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) supplier acting as a donor or recipient. Dentists may, as part of their dental practice, supply oral sleep apnea devices as DMEPOS suppliers. Dentists supplying oral sleep apnea devices have direct patient contact and relationships with their patients, in some cases as both a provider and a supplier, that distinguishes them from DMEPOS suppliers generally.

Cybersecurity technology and services. The ADA supports OIG and CMS's efforts to help address the growing threat of cyberattacks by proposing a safe harbor and an exception to help protect donations of certain cybersecurity technology and related services provided certain safeguards are met. ADA supports amending the AKS safe harbors and Stark Law exceptions to permit healthcare organizations to assist doctors in the acquisition of cybersecurity technology and services such as anti-virus software and incident response

and training services to help improve the cybersecurity posture of the health care industry, protect patient information from attack, and to protect recipients from liability for fines, ransom, and litigation risk. The ADA urges OIG and CMS to permit, with appropriate safeguards, both nonmonetary and monetary remuneration for the purchase of cybersecurity technologies and services. Permitting monetary remuneration in appropriate situations could, for example, help alleviate unintended adverse effects of the final rule on competition, such as in a situation where a donor wished to supply cybersecurity technology to two competing small providers and one of the small providers had already purchased the technology but the other had not: permitting monetary reimbursement of the first provider and an in-kind donation to the second provider would be more fair than permitting the donor to benefit one competitor and not the other. The ADA urges OIG and CMS to extend the AKS safe harbor and the Stark Law exception to include cybersecurity hardware without the requirement of a cybersecurity risk assessment; while donors should be free to require and even donate a cybersecurity risk assessment, adopting such a requirement could slow the provision of cybersecurity technology. The ADA urges OIG and CMS not to adopt a contribution requirement, although donors would be free to require recipients to contribute to the cost of donated cybersecurity technology. Omitting a contribution requirement would help permit providers with limited resources to receive protected cybersecurity donations. If adopted, any contribution requirement should at a minimum exempt rural and small practices as well as those in medically underserved areas and federally qualified health centers.

Electronic health records. ADA urges OIG and CMS to adopt the proposed changes to existing rules concerning the donation of interoperable electronic health records software or information technology and training services and to insure as much consistency as possible between the final rules. ADA urges OIG and CMS not to impose a contribution requirement, or in the alternative to exempt small and rural practices, and practices in medically underserved areas.

Personal services and management contracts. ADA supports OIG's proposal to modify the existing safe harbor for personal services and management contracts. ADA believes the proposed changes will enhance flexibility and ease compliance burdens.

Warranties. ADA supports OIG's proposal to update the existing safe harbor for warranties to protect warranties for one or more items and related services upon certain conditions (bundled warranties), exclude beneficiaries from the reporting requirements applicable to buyers, and define warranty directly and not by reference. ADA urges OIG not to require that all federally reimbursable items and services subject to the bundled warranty be reimbursed by the same Federal health care program and in the same payment because such a requirement might inhibit warranties pertaining to items used across a patient population that are not reimbursed in the same payment. ADA urges OIG not to cap the remuneration a manufacturer or supplier may pay to an individual or entity to the cost of the items and services subject to the warranty.

Local transportation. ADA supports OIG's proposal to modify the existing safe harbor for local transportation to expand the distance which residents of rural areas may be transported from 50 miles to 75 miles; however, ADA urges OIG to permit transportation up to 50 miles for all patients, and up to 100 miles if a patient lives in a rural area to promote access to care and support patient choice of provider. ADA urges OIG not to add a requirement to demonstrate financial, medical, or transportation need on the part of the patient, in order to simplify requirements and reduce compliance burden, or to provide an exception for small and rural providers and those in medically underserved areas. ADA agrees that use of ride-sharing services should be permitted under the safe harbor. ADA urges OIG not to make providers responsible for knowing or controlling the advertising practices of taxi companies, ride sharing services, or other transportation providers.

Stark Law: Providing flexibility for limited reimbursement to a physician. The ADA urges CMS to adopt the proposed provision protecting limited remuneration to a physician provided certain conditions are met, whether or not the remuneration violates the AKS or other federal or state law, and the ADA agrees that such remuneration is unlikely to cause overutilization or similar harms. However, the ADA believes the \$3,500 limit is too low and urges CMS to adopt a limit of \$5,000. Moreover, ADA urges CMS to extend the protection to items and services provided under the doctor's supervision or direction, and not to restrict the protection to items and services provided by the doctor. ADA further urges CMS to adopt the proposed 90-day period to comply with the writing and signature requirements in 411.355(e).

Stark Law clarification: Fundamental terminology and requirements. ADA appreciates CMS's intention to reduce the burden of compliance with the Stark law and to provide clarification where possible, and to provide clear, bright-line rules, and the guidance and clarification provided in the preamble to the proposed rule. In particular, ADA appreciates the clarification that the determination that an arrangement is commercially reasonable does not turn on whether the arrangement is profitable; ADA supports CMS's proposal to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Stark Law: Recalibrating the scope and application of the regulations. The ADA supports CMS's proposal to remove from the regulatory exceptions the requirement that the arrangement not violate the AKS or any federal or state law governing billing or claims submission wherever such requirements appear. The ADA agrees that such requirement resulted in a compliance burden and could make it unreasonably difficult for entities to meet their burden of proof under the Stark Law.

The ADA also supports CMS's proposal to deem the writing or the signature requirement of an applicable compensation arrangement exception to be satisfied if the compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement(s) and the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to

satisfy the requirement(s) of the applicable exception. The ADA believes this proposed change will help ease compliance burdens on providers. The ADA appreciates CMS's guidance that a single formal written contract is not necessary to satisfy the writing requirement, and that depending on the facts and circumstances the writing requirement may be satisfied by a collection of documents, as well as CMS's clarification that an electronic signature that is legally valid under federal or state law is sufficient to satisfy the signature requirement of various exceptions, and that the collection of documents can include both hard copy and electronic documents. The ADA urges CMS to include specific regulation text to reflect CMS's policy on electronic signatures and documents.

The ADA supports CMS's proposal to modify the regulations concerning the rental of office space and rental of equipment to clarify that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment.

With respect to the exception for physician recruitment, the ADA supports CMS's proposal to eliminate the signature requirement for a physician practice that is not receiving a financial benefit from the recruitment arrangement.

In addition, ADA supports CMS's proposal to modify certain exceptions with respect to payments by a physician, CMS's intention to modify the regulations to broaden the regulations concerning remuneration unrelated to the provision of designated health services, and CMS's clarification of the application of the exception for fair market value compensation to the rental of office space.

Thank you again for the opportunity to comment on the Anti-Kickback and Stark rules. The ADA looks forward to continuing to work with you. Should you have any questions, please do not hesitate to contact Ms. Roxanne Yaghoubi in the ADA's Washington office at (202) 789-5179 or yaghoubir@ada.org.

Sincerely,



Chad P. Gehani, D.D.S.
President



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