



A Brief Summary of the Stark Law and Anti-Kickback Statute Reforms (Final Rules)

Background

On December 2, 2020, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published the final rule, “Revisions to the Safe Harbors Under the Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) Rules Regarding Beneficiary Inducements,” and the Centers for Medicare and Medicaid Services (CMS) published the final rule, “Modernizing and Clarifying the Physician Self-Referral Regulations” in the *Federal Register*.¹ These rules are part of the HHS Regulatory Sprint to Coordinated Care, which examined federal regulations that potentially impede health care providers’ efforts to advance the transition to value-based care and improve the coordination of patient care across care settings in federal health care programs and the commercial sector.

The AMA submitted comments on both the [AKS](#) proposed rule and the [Stark Law](#) proposed rule in December 2019.

Effective Dates: The Stark and AKS final rules give an effective date of January 19, 2021, for most of the provisions, with the exception of certain changes to the definition of a “group practice,” which have an effective date of January 1, 2022, to give physician practices additional time to adjust their compensation methodologies.^{2, 3}

NOTE: There are fundamental differences in the statutory structure, operation, and penalties between the Stark Law and the AKS and, as a result, complete alignment between the exceptions to the Stark Law and safe harbors to the AKS is not feasible. The differences between the two final rules create a dual regulatory environment, where a value-based arrangement could meet the requirements for protection under one law but not the other, which could hinder the transition to a value-based health care delivery and payment system. In the final rule, CMS acknowledged the “dual regulatory environment” and the challenges for stakeholders in ensuring compliance with both. **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.**

¹ The Medicare physician self-referral law (often called the “Stark Law”), has not been significantly updated since it was enacted in 1989. When the Stark Law was enacted in 1989, healthcare was paid for primarily on a fee-for-service basis. Since that time, Medicare and the private market have implemented many value-based healthcare delivery and payment systems to address substantial cost growth in the current volume-based system.

² Note: The Congressional Review Act (CRA) is an oversight tool that Congress may use to overturn rules issued by federal agencies. As of January 9, 2020, the CRA had been used to overturn a total of 17 rules. Sixteen of those rules were overturned in the 115th Congress (2017-2018). Prior to the 115th Congress, one rule was overturned in the 107th Congress (2001-2002). <https://fas.org/sgp/crs/misc/R43992.pdf>

³ The official scheduled publication date of these rules is listed as December 2, 2020, which creates doubt under the CRA about whether the rules can go into effect prior to President-elect Biden’s inauguration on January 20, 2021. Under the CRA, the 60-day clock begins to tick upon the date of publication in the *Federal Register*, not the informal public display of a final rule. New administrations may institute a hold on any regulation that has not gone into effect by inauguration day or shortly thereafter in order to have time to review those regulations. The AMA will continue to monitor this issue.

The Physician Self-Referral Law Changes

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 care provided to Medicare or other patients.

Definitions

Target Patient Population: In the proposed rule, CMS sought public comment on whether it should incorporate a requirement that patients in the target patient population have at least one chronic condition in order to align with OIG's proposals. In the AMA's comment letter, we voiced our opposition to CMS' proposal to limit a target patient population to patients with at least one chronic condition. **Consistent with the AMA's request, CMS is not limiting a target patient population to patients with at least one chronic condition.** As finalized, target patient population means an identified patient population selected by a value-based enterprise (VBE) or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

Designated Health Services: **In alignment with the AMA's comments, CMS revised the definition of designated health services to exclude inpatient services paid for under prospective payment systems if furnishing those services does not increase the amount of Medicare's payment to the hospital.** In the final rule, CMS declined to expand the modified definition to outpatient hospital services.

Physician: CMS finalized the definition of "physician" as proposed. The revised definition aligns the regulatory definition of "physician" at 42 Code of Federal Regulations (CFR) §411.351⁴ with the statutory definition of "physician" in §1861(r) of the Social Security Act⁵ to ensure that there are no inconsistencies between the two. Under the statutory definition, a "physician" includes a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor, but provides for certain limitations on when such doctors are considered "physicians." CMS clarifies in the final rule that it does not believe that the definition of "physician" in the regulations should be either more limited or more expansive than the statutory definition. Therefore, CMS states, that to the extent that the statutory definition of "physician" includes doctors other than doctors of medicine and osteopathy, those practitioners fall within the ambit of the physician self-referral law.

New Compensation Exceptions

Value-Based Care Exceptions: 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 care furnished to people with Medicare or other patients. The new value-based exceptions largely mirror the proposed rules, with some changes favorable to physicians. **Consistent with the AMA's request, in the full financial risk exception CMS has extended the "pre-risk" period from six months as proposed, to 12 months.** With regards to the meaningful downside financial risk exception, the final rule requires the physician be responsible to pay or forego no less than 10 percent, rather than paying 25 percent as proposed, of the value of the remuneration the physician receives under the value-based arrangement.

⁴ Regulatory Definition of Physician, 42 CFR §411.351. "Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart." <https://www.law.cornell.edu/cfr/text/42/411.351>

⁵ Statutory Definition of Physician, 42 U.S. Code §1395x(r), <https://www.law.cornell.edu/uscode/text/42/1395x>.

New Exception for Limited Remuneration to a Physician: **The AMA is pleased that CMS finalized a new exception to protect compensation not exceeding an aggregate of \$5,000 per calendar year (increased from \$3,500 as proposed), adjusted for inflation, to a physician for the provision of items and services without the need for a signed writing and compensation that is set in advance if certain conditions are met.** The rule also permits the physician to provide the items or services in question through employees the physician hired for the purpose of performing the services, a wholly owned entity or locum tenens physicians.

Other: The AMA, along with several other public commenters, urged CMS to create an exception for value-based arrangements that is exclusively available to rural providers and small physician practices. In the final rule CMS acknowledged the challenges faced by rural providers and small physician practices but declined to create the requested exception.

New Exception for Cybersecurity Technology and Related Services: **New Exception for Cybersecurity Technology and Related Services: CMS finalized a new exception to protect arrangements involving the donation of certain cybersecurity technology and related services, including certain cybersecurity hardware donations.** Note, that this is separate from the electronic health records exception clarification by CMS, which in the final rule expressly permits donations of cybersecurity software and services that protect electronic health records under the EHR exception. **In response to AMA advocacy, 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

Clarifications to "Group Practice" Requirements: 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. As noted above, CMS delayed the effective date for this portion of the rule to January 1, 2022, to give physician practices additional time to adjust their compensation methodologies.

Clarification for Electronic Health Records (EHR) Items and Services Exception: The AMA voiced support for the concept of updating the exception to recognize the significant updates regarding information blocking but raised questions and voiced concerns regarding how such a provision would work in the EHR exception. CMS finalized many proposed changes to this exception however, CMS did not finalize its proposal to modify the provision addressing the concept of information blocking and instead removed that provision from the exception due to the significant questions raised by commenters.

The AKS Changes

The AKS final rule finalizes many of OIG's proposals that modify existing AKS safe harbors, create new AKS safe harbors, and create a new CMP law exception.

New AKS Safe Harbors

Value-Based Arrangements: The OIG finalized three new safe harbors to protect certain payments among individuals and entities in a value-based arrangement. The three new safe harbors 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 OIG has stated that entities ineligible to use the value-based safe harbors are: pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers (PBMs); laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices or medical supplies; entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and medical device distributors and wholesalers. However, the OIG carved out a separate, limited pathway for certain medical device manufacturers and durable medical equipment companies to participate in protected care coordination arrangements that involve digital health technology, provided that certain requirements are met.

The AMA voiced our opposition to the proposal requiring that a VBE have a compliance program, requiring that all VBE participants affirmatively recognize the oversight role, having more specific responsibilities on the accountable body or responsible person, implementing reporting requirements or mechanisms for obtaining access to participant data, and imposing a standard requiring either independence or a duty of loyalty. The AMA voiced our understanding for the need for accountability and for compliance programs but argued that the proposals unnecessarily create additional burden without substantially reducing the risk of program fraud and abuse. **Consistent with the AMA's comments, the OIG decided that for purposes of these safe harbors in the final rule, the OIG will not require the VBE or its accountable body or responsible person to have a compliance program or to review patient medical records periodically.** The OIG will also not be requiring an attestation or other agreements from each VBE participant that it has a compliance program and conducts annual compliance reviews.

Patient Engagement and Support: OIG finalized a safe harbor to protect furnishing certain tools and support to patients in order to improve quality, health outcomes and efficiency. Importantly, this safe harbor is only available for value-based enterprise participants. The remuneration can be in-kind only and is limited to a \$500 annual cap, adjusted for inflation, along with many other requirements.

CMS-Sponsored Models: OIG finalized a safe harbor to protect certain remuneration provided in connection with certain models sponsored by CMS, thereby reducing the need for HHS to issue individualized fraud and abuse waivers for each model.

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

Modifications to Existing AKS Safe Harbors

Personal Services and Management Contracts Safe Harbor: The OIG finalized a new provision to 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.

Local Transportation: The OIG finalized its proposal to expand and modify mileage limits applicable to patient transportation in rural areas (expanded from 50 to 75 miles) and patient transportation from inpatient facilities post-discharge (removed all mileage limits). The OIG did not extend safe harbor protection to transportation of patients to any location of their choice or for nonmedical purposes.

Electronic Health Records Items and Services Safe Harbor: Like CMS, the OIG finalized several proposed changes to this safe harbor, including modifying the timing of certain required recipient contributions, permitting certain donations of replacement technology and removing the sunset provision. The OIG also did not finalize its proposal to modify the provision addressing the concept of information blocking, and instead removed that provision from the safe harbor entirely.

Warranties: OIG finalized its proposal to expand the warranty safe harbor to protect warranties covering a bundle of one or more items and related services.

Accountable Care Organization (ACO) Beneficiary Incentive Programs: The OIG amended the civil monetary penalty (CMP) rules by codifying a revision to the definition of “remuneration” added by the Bipartisan Budget Act of 2018.

New CMP Exception

Telehealth for In-Home Dialysis: The OIG finalized its proposal to interpret and incorporate the Bipartisan Budget Act of 2018 statutory exception for furnishing telehealth technologies to certain in-home dialysis patients.

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