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Historical changes to key health care laws present new opportunities in the health care industry

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On December 2, 2020, the Department of Health and Human Services's (HHS's) Office of the Inspector General (OIG) and the Centers for Medicare and Medicaid (CMS) published historic revisions to regulations governing the federal physician self-referral law (Stark Law), Anti-Kickback Statute (AKS), and beneficiary inducement Civil Monetary Penalties (CMP) laws.

The rules

The two highly anticipated final rules are a part of the federal agency's "Regulatory Sprint to Coordinated Care":

- OIG's Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (OIG Final Rule), available from the *Federal Register*;
- CMS's Modernizing and Clarifying the Physician Self-Referral Regulations (CMS Final Rule), available from the *Federal Register*.

The effective date

The OIG Final Rule becomes effective January 19, 2021. Most regulations in the CMS Final Rule will become effective January 19, 2021, but certain provisions relating to group practices will not be effective until January 1, 2022. Notably, the new requirements apply only prospectively. Existing contracts and arrangements entered into prior to January 20, 2021, are subject to current regulations governing Stark Law, AKS, and CMP as they stand today.

New opportunities

The final rules present opportunities in the health care industry for novel arrangements and provide clear guidance on some common compliance concerns impeding innovation. HHS notes that the regulations will facilitate a "range of arrangements to improve the coordination and

management of patient care and the engagement of patients in their treatment." The federal agency notes several permissible new examples:

- Hospital furnishes care coordinators for individually tailored post-acute case management services;
- Specialty physician offers data analytics software and services to primary care practice to help predict follow-up care;
- Medical technology company provides digital health technology to manage discharged inpatients to observe recovery and intervene if necessary;
- Hospital pays providers based on benchmark outcome measures that effectively and efficiently coordinate services throughout care settings;
- Primary care physician distributes a smart tablet or other telecommunications device to patients to facilitate communication and provision of in-home services; and
- Health system provides cybersecurity technology to hospital-aligned physician practices.

How the rules work together

Each of the final rules employs various methods to reform the Stark Law, the AKS, and the CMP. The revisions include new exceptions and safe harbors, and modify or remove existing requirements that are viewed as barriers to coordinated or value-based arrangements. Since relationships between and among stakeholders in the health care industry can often implicate the Stark Law and AKS, CMS and OIG worked together to ensure that exceptions and safe harbors, as well as any clarification or modification under either law, are consistent, further clearing the path to assure regulatory compliance of novel arrangements.

The OIG Final Rule includes new protections for certain patient engagement activities, and to support care coordination activities among providers for shared patients. The CMS Final Rule, which is one of the most-significant updates to the Stark Law since it was enacted in 1989, reflects material reforms to encourage value-based health care. The CMS Final Rule adds permanent exceptions to the Stark Law for value-based arrangements and provides more flexibility on several key requirements that must often be met for physicians and health care providers to comply.

Six key takeaways

1. Creation of new value-based enterprises (VBEs) among providers that encourage risk assumption for shared patients

The final rules provide a framework for value-based arrangements that encourage care coordination, quality of care, and cost containment. New safe harbors and exceptions rely on a set of shared terminology: Two or more entities can create a VBE, with a common governance structure, through which the entities can engage collectively in *value-based arrangements*. This means that separate providers and other organizations may work together with a "value-based purpose" to address a *target patient population*. The coordination and management of care activities under such a VBE could include, for example, predictive analytics, monitoring, diagnostics, and communication related to treatment.

Both the new Stark Law and AKS protections centered around value-based care are anchored by the premise that greater compliance flexibility can be offered to such arrangements where parties are assuming financial risk. Both rules protect arrangements with *full financial risk*. A Stark Law

exception covers *substantial financial risk*, and a new AKS safe harbor protects arrangements with *meaningful financial risk*. Accordingly, the new rules provide far more leeway in structuring relationships among providers proportional to their appetite to collectively assume financial risk. Importantly, the three proposed exceptions do not include any requirement that the arrangements reflect fair market value (FMV) or commercial reasonableness, or that the remuneration exchanged between parties in a VBE not be determined in a manner that takes into account the volume or value of referrals between the parties — all conditions found throughout many of the existing Stark Law exceptions and AKS safe harbors that constitute significant barriers to value-based payment arrangements.

HHS's risk-based approach has raised some concerns from stakeholders. Trade associations, including the American Medical Association, warn of the potential for further consolidation among providers in the health care industry because the new regulations encourage risk assumption.[1] The new value-based safe harbors also do not protect an entity whose predominant or core business is one of the following: pharmaceutical manufacturers, distributors and wholesalers, pharmacy benefit managers, laboratory companies, compounding pharmacies, medical supplies, and durable medical equipment.

2. Technology and gig economy meet health care

A key goal of the regulatory overhaul inherent in the revised regulations is to remove barriers to technological innovation among providers and to support patient care. The new OIG safe harbor regulations, particularly in connection with VBEs, purport to do just that, as follows:

- ***Coordination among providers —*** The AKS is often seen as a barrier for health care providers and stakeholders seeking to engage in care coordination ventures that involve free services or products. In deviating from the proposed rules, the new OIG safe harbors for *care coordination arrangements* are meant to protect in-kind remuneration of *digital health technology* between two or more participants in a value-based arrangement—even without risk assumption. This potentially opens up a number of previously closed doors for providers to share certain non-cash resources, including software and other technology with each other, to facilitate collective goals in connection with patient care. Similar to the EHR donation safe harbor, this safe harbor for care coordination requires that the recipient of the in-kind remuneration pay at least 15% of the costs or fair market value of the item or service. Importantly, manufacturers of devices or medical supplies, and durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) companies are eligible to participate in these care coordination arrangements as *limited technology participants*.
- ***Engagement and support for patients —*** The federal CMP law prohibits items and services of value to be given to a patient if the remuneration is likely to influence the patient's selection of the provider. OIG finalized a new safe harbor for *patient engagement and support* that protects tools furnished to a patient that are valued up to $500 annually. Subject to meeting certain safeguards, this new safe harbor protects items or services furnished to a patient that the patient's licensed provider recommends in connection with safety, disease prevention, and management, or adherence to a treatment plan or drug regimen. The AKS patient engagement safe harbor is available for non-VBE participants.

[1] See Letter re Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, File Code CMS-1720-P (December 20, 2019).

3. Redefining Stark

The amendments and clarifications involving a range of exceptions and technical requirements to the Stark Law promise to reduce administrative burdens for compliance. CMS finalized revisions to the "big three" fundamental terms that apply to numerous Stark exceptions for compensation relationships. A new definition of *commercially reasonable* now provides that arrangements that do not result in profit for one or more parties may nonetheless be commercially reasonable. Separately, CMS clarified in commentary that unit-based compensation (i.e., wRVUs) and productivity bonuses do not take into account *volume or value of referrals*. The final rule revises the definition of *fair market/general market value* to eliminate references to the *volume or value* standard. However, CMS cautions against over-reliance on salary surveys for FMV determinations, recognizing that compensation set forth in a salary survey may not be identical to the worth of a particular physician's services.

4. Flexibilities for imperfect performance under Stark … but more headaches?

The CMS Final Rule encourages parties to identify and remedy administrative or operational errors, including payment discrepancies, that take place during the course of an arrangement involving physicians. For example, new rules expand *temporary noncompliance* with the Stark Law's "writing" requirements, and include a new exception for *limited remuneration to a physician* totaling $5,000 for non-abusive relationships. Certain provisions of the new rules, however, may create additional compliance headaches: The modification of *group practice* definition may require changes to a physician organization's existing compensation methodology. Similarly, a revision to the *isolated transaction* exception establishes that arrangements relying upon the exception cannot include a single payment for multiple or repeated services.

5. Some limited protections for cybersecurity, electronic health records (EHR), and in-home dialysis.

Through identical modifications to the existing EHR donation exceptions in both rules, OIG and CMS finalized new protections for non-monetary donations of *cybersecurity* hardware, technology, and related services. The final rules remove the EHR sunset provision, under which the existing EHR protections under Stark and AKS would have expired at the end of 2021. The regulations also clarify interoperability requirements for EHR donation.

Arguably, these rules did not go far enough. For example, HHS did not remove other stringent requirements under the Stark EHR exception, including the regulation's minimal 15% contribution requirement for recipients of EHR donations. Further, the new rules were not modernized enough to address the often-thorny questions arising from the reality that many EHRs are purchased as subscription services, rather than off-the-shelf products. The OIG Final Rule also codifies a new exception to the CMP law for telehealth technologies furnished *in home-based dialysis* treatment.

6. Other notable AKS and CMP changes

The final rules modify existing safe harbors for personal services and management contracts, warranties, and local transportation. The *personal services and management contracts* safe harbor has been broadened to permit part-time or unpredictable compensation arrangements, and to provide new protection for outcome-based payment arrangements. These include, for example, payments from shared savings, shared losses payments, pay-for-performance, or episodic or bundle payment programs. A modified *warranty* safe harbor permits medical device manufacturers to create a bundled warranty for a collection of items, or items and services together. The *local transportation* safe harbor increases rural area limits to 75 miles. The revisions eliminate distance limitations altogether for patients who are discharged from the hospital.

Conclusion

These final rules aim to provide greater flexibility to providers and certainty to facilitate the coordination of care and support a shift toward a more-affordable, high-quality, value-based health care system. While this is a welcome dose of clarity in certain cases, as always, additional bright lines under Stark, CMP, and AKS create their own compliance challenges — particularly in the area of value-based care, where many providers have already moved forward and created arrangements using best efforts for compliance, unable to wait for additional guidance from HHS.

In addition, it is important to remember that the finalized federal regulations do not affect state law requirements. Several jurisdictions, including California and New York, include separate state statutes that prohibit referrals or kickbacks in ways that differ from the federal restrictions. Although most state schemes incorporate federal exemptions or safe harbors by reference, these rules and regulations add another layer of complexity in structuring arrangements. In addition, state health plan and insurance licensing laws may be triggered by risk assumption activities encouraged by the final rules. Health care providers should review these rules carefully with legal counsel to take full advantage of new opportunities and flexibilities, and be aware potential pitfalls.

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