

ALERTS

Client Alert: CMS open door forum on new Stark regulations

12.2020

On December 2, 2020, the Centers for Medicare & Medicaid Services (“CMS”) held a Special Open Door Forum to discuss a new final rule amending the regulations that interpret the federal physician self-referral law (the “Stark Law”). CMS released the final rule on November 20, 2020, the same day that the Office of Inspector General (“OIG”) of the Department of Health and Human Services released a new final rule amending the regulations under the Medicare antikickback statute (“AKS”). The two final rules generally take effect January 19, 2021, and are, according to HHS, intended to reduce regulatory barriers to care coordination and accelerate the transformation of the healthcare system into one that pays for value.

At the outset of the Forum, CMS representatives acknowledged that when the Stark Law was enacted in 1989 it addressed concerns that arose in Medicare’s volume-based reimbursement system, and that the new final rule aims to encourage and advance the transition to value-based care. Recognizing that many compensation arrangements between parties participating in value-based payment models and other novel financial arrangements implicate both the Stark Law and the AKS, CMS and OIG coordinated development of the two final rules. Given the differences in the statutory structures and penalties of the Stark Law and the AKS, however, CMS and OIG maintained in the two final rules differences in restrictions for certain arrangements. OIG will use the AKS, which is an intent-based criminal law, as “backstop” protection to pursue abusive arrangements that satisfy an exception to the strict liability Stark Law.

HIGHLIGHTS OF THE FORUM

- There are three new exceptions to the Stark Law for value-based compensation arrangements: (i) the full financial risk exception, (ii) the meaningful downside financial risk exception, and (iii) the value-based arrangement exception. CMS introduced and defined several terms in connection with these exceptions, including value-based activity, value-based arrangement, value-based enterprise, value-based purpose, VBE participant and target patient population. Services must meet the definition of value-based activity, for example, to qualify for the value-based arrangement exception. These new exceptions do not require, however, that compensation to the physician be set in advance, consistent with fair market value or determined in a manner that does not take into account the volume or value of the physician’s referrals or other business generated by the physician.

CLIENT ALERT: CMS OPEN DOOR FORUM ON NEW STARK REGULATIONS

- The final rule clarifies several terms and provisions of the Stark Law, including (i) defining the previously undefined term “commercially reasonable” to mean that “the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty”; (ii) revising the special rule on compensation to permit satisfaction of the “set in advance” requirement even if compensation is modified during the course of a compensation arrangement so long as certain conditions are met; and (iii) introducing a new special rule on writing and signature requirements allowing parties to obtain required writings or signatures within 90 days following the date on which the writings or signatures were required.
- The final rule removes the sunset provision for and revises the exception for electronic health records items and services and adds a new exception for nonmonetary remuneration in the form of cybersecurity technology and related services.

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