MAJOR CHANGES ANNOUNCED IN NOVEMBER 2020 REGULATIONS UNDER THE STARK PHYSICIAN SELF-REFERRAL ACT

November 24, 2020

On November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) published final regulations that make significant modifications to the federal physician self-referral law frequently known as the Stark law.

Hancock Daniel will be issuing a separate client advisory regarding value-based entities and initiatives addressed under the November 2020 Stark regulations; this client advisory focuses on other major developments under these regulations. A copy of the 600+ pages of new regulations and comments may be found here. Except as otherwise stated in this client advisory, the final regulations take effect on January 19, 2021.

NEW EXCEPTIONS UNDER STARK

Cybersecurity Technology

The Stark regulations include a new exception for cybersecurity technology and related services. The new exception covers non-monetary benefits consisting of technology and services that are necessary and used predominantly to implement, maintain, or re-establish cybersecurity. In order to meet the new exception, physician eligibility and benefits may not be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Neither the physician nor the physician's practice may make receipt of the technology or services a condition of doing business with the donor and the arrangement must be documented in writing. This new exception can include both software, hardware, and other types of information technology.

Limited Renumeration Without Documentation

The new regulations include a new exception for aggregate compensation of up to $5,000 per calendar year (adjusted for inflation) paid to a physician for the provision of items or services. Unlike most exceptions under Stark, this special new limited exception is available even where the parties fail to document the arrangement in a contemporaneous writing. The exception requires that the compensation not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician, the compensation may not exceed the fair market value of the items or services provided by the physician, and the arrangement must be commercially reasonable. This new exception is available for lease of office space and equipment and other arrangements meeting the relevant standards. Significantly, the $5,000 aggregate limit applies to all arrangements in the calendar year where the parties rely upon this exception. For example, if a physician in a hospital relies upon this exception to cover a $1,000 payment, the parties could not rely upon this exception for more than $4,000 in additional payments for the remainder of the calendar year. Further, unless payments can be attributed to an

individual physician and are passed directly through to that physician, payments under this exception to a group practice would be allocated and count against the annual aggregate limit for each physician owner within the group practice. For example, depending upon the circumstances, a $1,000 payment to a group practice could be treated as a $1,000 payment to each of the physician owners of the group practice for purposes of the aggregate limit.

SIGNIFICANT MODIFICATIONS AND GUIDANCE REGARDING EXISTING EXCEPTIONS

Commercial Reasonableness

The regulations include a new definition of "commercial reasonableness." CMS indicates that commercial reasonableness is based upon a determination whether the particular arrangement furthers a legitimate business purpose of the parties and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. CMS also indicates that the determination of commercial reasonableness is not necessarily dependent upon "whether the arrangement is profitable; compensation arrangements that do not result in profit for one or more parties may nonetheless be commercially reasonable." CMS further states, "We acknowledge that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the agreement," citing examples including community need, timely access to health care services, licensure and regulatory obligations, charity care obligations, and quality measures.

Takes into Account the Volume or Value of Referrals or Other Business

The regulations provided further guidance regarding determinations of whether compensation is treated as varying with the volume or value of referrals or other business generated. Under the guidance and regulatory changes, the "volume or value" standard is based upon whether the relevant formula "includes the physician's referrals [or other business generated by the physician] to the entity as a variable" resulting in a correlation between compensation and referrals or other business generated by the physician.

Directed Referrals

CMS indicates that, to the extent that the exceptions under Stark allow directed referrals, the conditions prohibit the DHS entity from tying compensation arrangements to the number or value of the physician's referrals to a particular provider, practitioner, or supplier. CMS further indicates, however, that the directed referral provisions would not "categorically prohibit" an arrangement under which a physician is paid different stipulated percentages of a bonus pool depending on the percentage of the physician's referrals that are "in network."

Overall Profits of a Group Practice

The new regulations include delayed provisions modifying terms relating to division of profits within a group practice. Effective January 1, 2022, among other modifications, the references to Medicaid in the definition of overall profits within a group practice would be eliminated. CMS established delays in the effective date for certain changes to allow group practices to limit the changes over the next year to address the new standards. The regulations and comments clarify that group practice need not treat all components of at least five physicians the same with respect to the distribution of shares of overall profits from designated health services and note that nothing in the regulations prohibits the use of eligibility standards (e.g., some physicians in the group are eligible to participate in the profit

share while others are not) provided that the eligibility standards do not result in the payment of a profit share that is directly related to the volume or value of a physician's referrals. CMS also indicates that group practices (or components) may not distribute the profits from designated health services on a service-by-service basis. The regulations further provide that different components consisting of at least five physicians (each within a group practice) are not required to use the same methodology for distributing the profits of the different components. However, a group practice component must utilize the same methodology for distributing overall profits for every physician in the component.

Fair Market Value Exception

In a major change, the fair market value exception has been modified to allow leases of office space and equipment to qualify under this exception.

Designated Health Services (DHS)

The definition of designated health services has been modified to exclude services furnished to inpatients by hospital if the furnishing of the services does not increase the amount of Medicare's payment to the hospital under acute care hospital inpatient PPS, inpatient rehabilitation facility PPS, inpatient psychiatric facility PPS, or long-term care hospital PPS. The comments indicate that these new rules would apply where no additional payment is available for additional hospital services ordered after patient's admission by a physician who is not responsible for the patient's initial admission. Outpatient services would remain DHS under the regulations.

Isolated Financial Transactions

The regulations include a new definition of "isolated financial transactions." CMS indicates that the exception for isolated financial transactions would be available for settlements of a bona fide legal dispute, but states the exception would not be available for a single payment covering a financial arrangement involving multiple or repeated services over a period of time.

Period of Disallowance

New regulations remove prior provisions offering guidance on the period of disallowance following a prohibited transaction under Stark. CMS notes, however, that the agency continues to believe "that one way to establish that the period of disallowance has ended is to recover any excess compensation and bring the financial relationship back into compliance."

Errors or Mistakes in Written Documentation/Reconciling Compensation

CMS notes that unintended payment discrepancies that are corrected in a timely manner do not necessarily cause the compensation arrangement to fail to satisfy the requirements of an exception. CMS also notes that not "every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of an exception" and that not "every error or mistake must be corrected in order to maintain compliance." As an example, CMS indicates that if a DHS entity paid $150 per hour for services in error rather than an agreed upon $140 per hour rate if the $150 rate was nonetheless within the range of fair market value for the services actually provided, the error might not result in violation. CMS also indicates, however, that not all remuneration creates a financial relationship, noting that tenant's

use of additional space that is unknown to a landlord or similar circumstances may not be treated as creating a financial relationship at all. In regard to correction of errors/payment reconciliations, CMS establishes new provisions allowing a DHS entity to continue to bill and submit claims for DHS notwithstanding a payment discrepancy if the parties reconcile the discrepancies during the term of the compensation arrangement or within 90 days thereafter.

Documenting Compensation Formulas

CMS notes that several exceptions require that the formula for calculating compensation under an arrangement be set in advance and documented before the furnishing of items or services. CMS notes, however, that the documentation stating the formula for calculating compensation may take many forms and could be spread over several documents. CMS states "for example, depending on the facts and circumstances, informal communications by email or text, internal notes file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents reporting similar payments to or from other similarly situated physicians for similar items or services, may be sufficient to establish the amount of or formula for calculating the compensation was set in advance."

Electronic Health Record Exception

The new regulations make permanent the exception for electronic health records, which was previously slated to sunset on December 31, 2021. The regulations retain the standard for EHR donations to require donees to pay at least 15% of the cost prior to the initial donation or a replacement, but allow the 15% charge for updates thereafter to be paid at reasonable intervals. CMS also notes that where a donation is structured to comply with an exception under the value-based provisions, the 15% payment standard may not apply. Significantly, the regulations also eliminate the prior standards restricting EHR donations to cases in which the recipient does not already have equivalent technology.

We will be providing additional Client Advisories with further information on these important regulatory developments in the coming days. In the meantime, if you have any questions or need further guidance regarding these new regulations and their potential impact upon existing and future arrangements, please contact a member of Hancock Daniel's Fraud & Abuse team.

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