CMS Stark Law Revisions Propose 2 Key Exceptions

By **Patricia Markus and Hannah Cross** (December 11, 2019)

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The Centers for Medicare & Medicaid Services recently issued a notice of proposed rulemaking to amend current regulations interpreting the Medicare physician self-referral law, the Stark Law.[1]

The proposed rule and companion proposed regulations to amend the Anti-Kickback Statute published by the Office of Inspector General together aim to foster greater coordination of health care and improved, more secure information sharing to better coordinate and reduce the cost of such care. At over 330 pages, the proposed rule is the first stand-alone amendment to the Stark law in more than 10 years. Two proposed exceptions in particular, if adopted, would create much-needed flexibility for stakeholders engaging in nonabusive business practices.

Limited Remuneration to a Physician Exception

Recognizing that the Stark law is meant to protect Medicare beneficiaries and the Medicare program from overutilization and other harms, CMS has proposed a new exception at Section 411.357(z) to protect arrangements involving limited remuneration to a physician that typically would not involve such harms. The limited remuneration to a physician proposed exception would protect remuneration, in an amount not to exceed $3,500 in the aggregate per calendar year,[2] from an entity to a physician for the physician's provision of items or services, if the following conditions are met:

1. The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

2. The compensation does not exceed the fair market value of the items or services.

3. The arrangement is commercially reasonable.

4. Compensation for the lease of office space or equipment is not determined using a formula based on:

> (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or
>
> (B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

5. Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on:

> (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel,

items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.[3]

This exception aims to protect common arrangements in which physicians provide items or services on a short-term or infrequent basis to entities to which the physicians refer patients for designated health services, but where such arrangements would not otherwise fit within an exception — often because the arrangements are not reduced to writing.

The exception evolved from various self-referral disclosure protocol submissions describing arrangements that CMS determined did not pose a risk of program or patient abuse but nonetheless did not fit within an existing exception. CMS found that a number of legitimate arrangements were excluded from exceptions like the employment exception[4] and the fair market value exception[5] due to technical requirements, such as the requirements for an existing employment relationship or written documentation of the arrangement.

In response, CMS has proposed this "limited remuneration to a physician" exception from which it intentionally excluded certain common requirements found in other exceptions, such as compensation being set in advance, to reflect the low likelihood of abuse posed by a limited relationship in which a physician is compensated for items or services under the $3,500 annual limit.

Because CMS remains concerned that leases of office space or equipment that use a percentage-based or per-unit of service compensation formula may incentivize overutilization and patient steering, CMS would exclude these payment formulas from the proposed exception. CMS also states that if it were to retain compliance with the AKS as a requirement for certain Stark law exceptions, it also would add that requirement to the proposed exception if finalized.[6]

Although the exception would protect a number of legitimate arrangements with physicians, CMS did not extend the exception to items or services provided by, or payments made to, a physician's family members.[7]

Practically speaking, compensation paid by an entity to a physician that implicates the Stark law and fits within another exception would not be included in the $3,500 annual limit. Moreover, CMS points out that $3,500 is the annual aggregate, not the per arrangement, limit. This means that if an entity had multiple arrangements with a physician that it hoped to protect using this exception, the sum of payments for all such arrangements could not exceed $3,500 in total compensation for the year for the parties to utilize this exception.

If annual compensation would exceed the limit, however, CMS also notes that the parties could rely on a combination of exceptions. For instance, this proposed exception could be used for the first payments of an ongoing arrangement, up to $3,500, and the parties then could rely on the personal services exception[8] once the requirements of that exception (including the fair market value and in writing requirements) have been satisfied.

Last, CMS clarifies that parties would not be required to include arrangements relying on this new exception in a master list of contracts (as required by the personal services exception), and that use of this exception would not violate the prohibition on entering into a contract for the same or similar items or services during a calendar year (as specified in

the fair market value compensation exception).[9]

Comments

Overall, this proposed new exception — depending on how it is finalized — could prove very useful for physicians and health systems. It will give providers some much-needed flexibility, particularly in situations where physician services are needed on an unexpected and urgent basis. Nonetheless, this provision would not be a cure-all.

Health care providers taking advantage of the finalized exception would be wise to maintain records of those instances in which this exception is used to avoid the possibility of inadvertently exceeding the annual aggregate remuneration for a particular physician.

Cybersecurity Technology and Related Services Exception

CMS also has proposed a new Stark law exception permitting donations of cybersecurity technology and related services, based upon substantial industry feedback and requests for such an exception.

To fit within the proposed new exception, donated technology and related services must be necessary and used predominantly to implement, maintain or reestablish cybersecurity. CMS seeks comment on whether it should deem certain arrangements (for example, those that conform with widely recognized cybersecurity standards) to satisfy this necessary requirement.[10]

Additionally, the eligibility of a physician for, and the amount or nature of, the technology or services cannot be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Although the arrangement must be documented in writing, CMS specifies that a signed contract would not be required.[11] Finally, neither the physician nor his or her practice or any practice workforce member is permitted to make the amount or nature of the technology or services a condition of doing business with the donor.[12]

CMS further proposes to define cybersecurity as "the process of protecting information by preventing, detecting, and responding to cyberattacks"[13] and technology as "any software or other type of information technology other than hardware."[14] CMS seeks comments as to whether a narrower definition of cybersecurity tailored to the health care industry would be preferable.[15]

It also explains that hardware is not included within the definition of technology due to its multifunctionality and, accordingly, the possibility that the donation of cybersecurity technology that is hardware, such as a laptop, could be used other than predominantly to implement, maintain or reestablish effective cybersecurity.[16]

Nonetheless, the agency seeks public comment as to whether certain types of hardware should be protected. In this vein, CMS has proposed for consideration two alternatives that would permit donations of certain cybersecurity hardware:

1. Hardware that is necessary for cybersecurity that is stand-alone technology and serves only cybersecurity purposes (such as a two-factor authentication dongle);[17] and

2. Cybersecurity hardware that has been determined reasonably necessary to respond to

particular cybersecurity risks identified in a donor's and a potential recipient's cybersecurity risk assessment.[18]

Protected Cybersecurity Technology and Services

The broad range of cybersecurity technology the new exception would protect includes cybersecurity software providing malware prevention; software security measures to protect endpoints that permit network access control; business continuity software; data protection and encryption; and e-mail traffic filtering.

The exception also would protect cybersecurity services associated with developing, installing and updating cybersecurity software; cybersecurity training services; cybersecurity services for business continuity and data recovery services; cybersecurity-as-a-service models; cybersecurity risk assessments or risk or vulnerability analyses; sharing information about known cyberthreats; and assisting recipients responding to attacks on or threats to their systems.

CMS emphasized that donations may not be in cash, and any donated cybersecurity and services must be for items and services that are not used in the normal course of the recipient's business (e.g., general help desk services).[19]

CMS repeatedly has been advised that requiring potential recipients to share in the cost of cybersecurity technology could serve as a barrier to the adoption of such technologies and therefore undermine the security of the health care data ecosystem. Due to this concern, CMS would not require recipients of cybersecurity technology and services to contribute to the cost of the technology and services, although it will permit donors to charge for the solutions.[20]

Related Tweaks to the Exception Permitting Donation of EHR Items and Services

Elsewhere in the proposed rule, CMS suggests changes to the exception for donations of electronic health record software and related training services. The proposals include eliminating the sunset provisions, thereby enabling such donations to continue after Dec. 31, 2021; confirming that cybersecurity software and services are protected as part of an EHR items or services donation; and offering alternative options regarding recipient cost-sharing for such donations.[21]

On the cost-sharing point, CMS alternatively proposes to:

1. Eliminate or reduce the percentage contribution requirement for small or rural practices;

2. Eliminate or reduce the 15% contribution requirements for all recipients; or

3. Modify or eliminate the contribution requirement for donations of updates to EHR software or technology that was previously donated.[22]

Significantly, CMS also proposes to reverse its prior prohibition on donation of equivalent or replacement EHR technology. CMS acknowledges that due to the rapid, ongoing advancement of technology, including EHR-related products, replacement technology may be appropriate, but industry stakeholders note that such technology may be prohibitively expensive. In suggesting this reversal, CMS seeks to prevent physician practices from being locked in to a certain EHR vendor due to cost considerations, even if the practices are dissatisfied with the technology.[23]

Comments

CMS's areas of emphasis in outlining these cost-sharing alternatives are somewhat surprising. First, the agency seeks comment regarding whether donors should charge recipients for updates to previously-donated EHR software or technology. However, technology vendors typically do not charge for updates (or patches) to software, as updates are usually minor enhancements that either are automatically implemented or easy to install. Accordingly, it would not make sense for a donor to charge a recipient of EHR software for updates for which the donor does not have to pay.

In contrast, software upgrades typically involve substantial improvements that can significantly affect performance or functionality of the software, and vendors typically do charge software licensees for upgrades. If an upgrade that a donor elects to implement requires additional payment, under those circumstances the donor may wish to pass along a proportion of the cost of the upgrade to recipients of the donated software (and upgrade).

Given that this proposed regulation is intended to reduce administrative burden, it also is puzzling that CMS did not seek comment on whether the 15% cost-sharing requirement imposes undue burden on donors of EHR items and services. Many EHR systems used by health systems actually are bundles of different vendors' software applications, each of which has its own sublicensing requirements and costs.

Because of the various ways technology vendors charge for additional users (and types of users), and because most EHR donors also provide implementation assistance and first level help desk services to recipients of the donated software, determining the incremental costs of sublicensing or adding additional licenses and related services for the current EHR software bundles can be a particularly complex and time-consuming process for donors.

CMS continues to request public input on numerous details of and assumptions underlying the various proposals. Comments on this proposed rule must be submitted by 5 p.m. on Dec. 31.

Unless and until CMS issues a final rule incorporating these two additional exceptions to the Stark law regulations, providers will not be able to use them to protect arrangements, and the associated commentary will be of limited use for entities and physicians.

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[1] The proposed rule was published in the Federal Register on October 17, 2019 and is available at https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22028.pdf.

[2] The annual remuneration limit of $3,500 would be adjusted in accordance with the Consumer Price Index-Urban All Items (CPI-U) as published after September 30 each year.

[3] 84 Fed. Reg. 55766, 55846 (Oct. 17, 2019).

[4] 42 C.F.R. § 411.357(c).

[5] 42 C.F.R. § 411.357(l).

[6] Previously in the proposed rule, CMS indicated that it proposes to decouple the AKS from the Stark law by removing compliance with AKS as a requirement for meeting certain Stark law exceptions. That said, those involved in arrangements that implicate AKS would still need to be mindful of compliance; however, such compliance would not be a requirement for an arrangement to comply with a Stark law exception.

[7] 84 Fed. Reg. at 55828.

[8] 42 C.F.R. § 411.357(d).

[9] See 84 Fed. Reg. at 55830.

[10] 84 Fed Reg. at 55832.

[11] Id. at 55834. In the OIG's companion proposed safe harbor for cybersecurity technology and services, the OIG stated it would require that the parties sign a written agreement and that the donor would not be permitted to shift the donation costs to federal health care programs (e.g., through a cost report). See Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55694, 55765 (Oct. 17, 2019). Accordingly, obtaining a signed contract may be the most practical approach to compliance.

[12] 84 Fed. Reg. at 55847.

[13]84 Fed. Reg. at 55847.

[14] Id. at 55840.

[15] Id. at 55831.

[16] Id.

[17] Id.

[18] Id. at 55834.

[19] Id. at 55832.

[20] Id. at 55833.

[21] Id. at 55823-55825.

[22] Id. at 55825.

[23] Id. at 55826.