DHHS's Regulatory Sprint to Coordinated Care Gains Traction in Changes to Stark Regulations

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As noted in our previous Client Alert, on October 9, 2019, the Federal Department of Health and Human Services ("HHS") issued two separate Proposed Rules under the *Regulatory Sprint to Coordinated Care* ("RSCC"), as part of efforts to overhaul the regulatory burdens imposed upon healthcare providers and beneficiaries while maintaining strong safeguards to protect patients and federal healthcare programs from fraud and abuse. Our prior Alert addressed two statutes that are enforced under the authority of the HHS Office of Inspector General ("OIG") —the Anti-kickback Statute ("AKS") and the Beneficiary Inducements Civil Monetary Penalty Law ("CMP Law"). This alert follows with a summary of the changes to regulations under the Physician Self-Referral Law (aka the "Stark Law").

In addition to the AKS changes, also proposed are changes to the Stark Law regulations and to the degree they overlap, they have been coordinated and are largely consistent. The focus has recognized that since the original Stark Law was passed there have been significant changes in health care delivery to encourage coordination of care and a further recognition that aspects of the Stark Law and its regulations may impede the efforts at coordination of care.

The proposed rules create new permanent exceptions to Stark for value-based amendments. These new rules would apply whether the arrangement relates to care furnished to people with Medicare or other patients. The regulations will continue to provide safeguards against overutilization.

The proposed rules also solicit comments on the role of pure transparency and whether to require cost-of-care information at the point of referrals for an item or service.

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The proposed rule would also provide guidance on how to determine if compensation meets the fair market value requirement. The new rule also proposed guidance on certain arrangements such as the donation of cybersecurity technology that safeguards the integrity of the healthcare system irrespective of value-based or fee for service payment system.

Some of the changes proposed to the Stark regulations are:

1. New exceptions for compensation arrangements including ones that take into account financial risk in a value-based enterprise. Some of the changes impact the prior approach requiring the setting of compensation in advance, fair market value and not taking into account the value or volume of referrals. An example of a proposed change would have the methodology for determining remuneration set in advance, but not necessarily the amount. These exceptions would apply specifically to Value-Based Arrangements.
2. A full financial risk that would apply to value-based arrangements between Value-Based Enterprise participants that have assumed full financial risk for the cost of patient care is proposed. An example of full financial risk would be capitated arrangements or global budget payment. The rule would also protect patients from a reduction in care.
3. There is a proposed definition of "commercially reasonable".
4. The proposed regulations take a fresh look at the definition of "Fair Market Value". The proposed definition eliminates connecting the definition to the volume or value of referrals.
5. The interpretation of when compensation will be considered to take into account the volume or value of referrals or other business generated would be codified.
6. The proposed rule would no longer include requirements pertaining to compliance with the anti-kickback statute and Federal and State laws or regulations governing billing or claims submission as requirements of the exceptions to the physician self-referral law.
7. Modifications are proposed to the meaning of Designated Health Services.
8. Modifications to the definition of "remuneration" by deleting the carve-out to the exception for "surgical devices".
9. The proposed regulations propose a definition of "isolated financial transaction" at Section 411.351. Corresponding changes would be made to Section 411.357(f).
10. Proposing elimination of Section 411.353(c)(1) on the period of disallowance. The current Rule did not provide the "bright line" intended.
11. Proposing to extend the concept of titular ownership or investment interests to rules governing ownership or investment interests at Section 411.354(b). Ownership and investment interests would not include titular ownership of investment interests.
12. Proposing that participation in an "ESOP" be removed from the definition of "ownership or investment interest" qualified under IRS Section 401(a) as it does not pose a risk of program or patient abuse.

13. Proposing new Rule 411.354(e)(3) where the writing requirement would be satisfied if (a) the compensation arrangement satisfies all requirements of an applicable exception other than writing or signature requirements and (b) the parties obtain the writing or signature within 90 consecutive calendar days after the date on which the arrangement failed to satisfy the requirements of the applicable exception to the compensation arrangement rule. The compensation formula must be set in advance.
14. Proposing a regulation to clarify that remuneration from a hospital to a physician does not relate to a provision of a designated health service if the remuneration is for items or services that are not related to patient care services provided the remuneration is not determined in a manner that takes into account the volume or value of physician referrals. Proposed Section 411.357(g).
15. A new update for provisions of electronic health records is proposed pertaining to interoperability 411.357(w)(2) and data lock-in 411.357(w)(3). The changes seek to clarify that donations of certain cybersecurity software and services are permitted under the EHR exception. The rule proposes removal of the sunset provision and modification of the definitions of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act. Also proposed is a modification to the 15% physician contribution requirement and to permit certain donations of replacement technology.

Like with the Anti-Kickback proposed rule changes, comments are due to the secretary by December 31, 2019.

Although the above is not an exhaustive list of the proposed changes the explanations are illustrative of many of the proposed changes. Should you have a specific question or comment, do not hesitate to contact us.

For more information about this alert or other issues in healthcare, please contact the authors of this alert, any member of Butzel Long's Healthcare Industry Group, or your regular Butzel Long attorney.

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