

STARK REGULATIONS PROPOSED TO ENHANCE CONSISTENCY AND FLEXIBILITY

On July 12, 2018, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule pertaining to payment policies under the Physician Fee Schedule for CY 2019 ("Proposed Rule"). In addition to changes to the Physician Fee Schedule and other Medicare Part B payment policies, the Proposed Rule also addressed modifications to various Stark Law regulations.

This article is intended to summarize the proposed changes that affect arrangements impacted by the Stark Law. Hall Render will soon be publishing additional analyses of other modifications addressed by the Proposed Rule.

PROPOSED REVISIONS

The Proposed Rule proposes regulations that mirror the Stark Law statutory language passed by Congress as a part of the Bipartisan Budget Act of 2018 ("Budget Act"). The Budget Act modified the Stark Law statute to implement previous guidance from CMS with a few minor modifications. One of the statutory changes enacted as a part of the Budget Act codified into statute regulations issued by CMS in the CY 2016 PFS Final Rule ("2016 Final Rule").

Indefinite Holdover Provisions

CMS acknowledged that the indefinite holdover language passed as a part of the Budget Act mirrors what was enacted as a part of the 2016 Final Rule and notes that no additional changes to the regulations are needed. Thus, prior regulatory guidance from CMS regarding the allowance of indefinite holdovers of arrangements that otherwise comply with the Rental of Office Space, Rental of Equipment and Personal Service Arrangement exceptions that continue on the same terms and conditions as the original arrangement will remain unchanged.

Writing Requirement

CMS noted in the Proposed Rule that additional regulatory changes will be needed in order to mirror the statutory changes to the writing requirement language set forth in the Budget Act. CMS has proposed a new Special Rule on Compensation (to be set forth as a new 42 C.F.R. §411.354(e)), which will mirror the 'compilation of documents' interpretation set forth in the Budget Act. This guidance establishes that the writing requirement for an "arrangement" can be satisfied by a compilation of documents, including contemporaneous documents evidencing the course of conduct between the parties.

Although the language passed via the Budget Act legislation mirrored CMS guidance from the 2016 Final Rule, this guidance was set forth only in the preamble to the 2016 Final Rule and was not prescribed in the regulations. CMS does not interpret preamble commentary as regulations; therefore, CMS has proposed to mirror this language in the regulation so that the Stark Law regulations are consistent with the statute.

Temporary Noncompliance with Signature Requirements

In the Proposed Rule, CMS has also proposed modifications to the regulations regarding Temporary Noncompliance with Signature Requirements (42 C.F.R. §411.353(g)). The Budget Act codified CMS's regulatory revision that parties have 90 days to obtain signatures, regardless of whether the reason for the late signature was advertent or inadvertent.

However, the Budget Act language did not include the requirement that this Special Rule for Temporary Noncompliance with Signature Requirements can only be utilized for the same physician/physician group once every three years. As such, CMS has now proposed to mirror this statutory language in the regulation, eliminating any confusion about potential restrictions on the frequency for which this special rule regarding temporary noncompliance with signature requirements can be utilized. This proposal means that providers will no longer be limited to utilizing the Special Rule for Temporary Noncompliance with Signature Requirements once every three years for a particular physician/physician group. In addition to removing this limitation on the use of the Special Rule for Temporary Noncompliance with Signature Requirements, CMS has stated that this aspect of the Proposed Rule will be retroactively effective to February 9, 2018 in order to coincide with the effective date of the change established by the Budget Act.

PRACTICAL TAKEAWAYS

The Stark Law regulatory modifications set forth in the Proposed Rule demonstrate a desire from CMS to remain consistent across the Stark Law statute and regulations. In addition, the modification to the Special Rule for Temporary Noncompliance with Signature Requirements may allow providers additional flexibility in compliance analyses for physician contracting arrangements where multiple arrangements with the same physician(s) were executed properly but after the arrangement's effective date.

Although CMS is not specifically seeking comments on the Stark Law components of the Proposed Rule, if you would like to submit a comment, comments on the Proposed Rule must be received by CMS no later than 5:00 PM on September 10, 2018. If you are interested in submitting a comment or would like additional information about this topic, please contact:

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