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CMS clarifies the process for correcting mistakes under the Stark Law

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On October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) published [proposed changes](#) to the regulations interpreting the Physician Self-Referral Law (Stark Law). The proposed rule contains several new exceptions and clarifications of existing regulations and guidance. One of the most useful clarifications addresses whether mistaken payments of excess or insufficient compensation that differ from the amount indicated in the written agreement result in Stark Law noncompliance. The proposed rule also clarifies how certain administrative and operational errors can be resolved.

In the proposed rule, CMS explains that it was “never our intent” for administrative errors that inadvertently result in payment of excess or insufficient compensation to trigger liability under the Stark Law. For example, charging the wrong amount of rent or paying above what the contract states for personal services due to a typo or other error does not automatically result in a violation. However, “the failure to remedy such operational inconsistencies could result in a distinct basis for noncompliance with the physician self-referral law.”

The proposed rule also explains how parties can fix these administrative errors when they occur during the course of an arrangement. CMS clarifies that, if a discrepancy is

unintended – due to an administrative or other operational error – the parties can correct the error during the term of the arrangement by collecting the overage or making up the underpayment. But, if the parties fail to identify the error during the term of the arrangement (what CMS calls a “live” or ongoing arrangement), CMS emphasizes that the parties cannot simply “unring the bell” by correcting it at some date after the termination or expiration of the arrangement. In that case, the failure to identify and rectify the compensation problem during the term of the arrangement would expose the parties to the referral and billing prohibitions during the entirety of the arrangement.

Some additional comments from the proposed rule include:

- Parties cannot turn back the clock and cure noncompliance retroactively once an arrangement has ended.
- If the parties detect and correct administrative or operational errors or discrepancies during the course of the arrangement, they are not necessarily turning back the clock to cure past noncompliance; rather, they are addressing a current problem.
- It is a normal business practice and a key element of an effective compliance program to actively monitor ongoing “live” financial relationships and to correct problems that the monitoring uncovers.
- Once a financial relationship has ended, the parties cannot retroactively cure previous noncompliance by recovering or repaying problematic compensation.
- Once a noncompliant financial relationship ends, the period of disallowance also ends.

CMS provides additional commentary to assist parties that discover a noncompliant financial relationship too late to correct it while the arrangement is still ongoing. In particular, CMS notes that if that occurs, the parties should analyze the situation carefully in order to properly characterize the potential noncompliance and then look for other possible ways to “save” some or all of the arrangement from noncompliance by satisfying an available Stark Law exception. For example, if the actual amount paid in an arrangement is more than the amount indicated in the written agreement, CMS advises that so long as the actual amount paid is consistent with fair market value, the arrangement can be treated as a failure to document the actual arrangement, rather than payment of the incorrect amount of compensation. To remedy that situation, CMS clarifies that the parties should look for other available ways to protect the arrangement by complying with an available exception, such as relying on the 90-day grace period for reducing arrangements to writing, or the proposed new exception for limited remuneration to a physician.

The proposed changes will likely generate many public comments regarding how these proposals will impact real-life arrangements. [Public comments](#) are due by December 31, 2019. As a result, CMS will not finalize the proposed Stark Law changes

until 2020.

This publication is part of a series of updates regarding CMS and OIG's proposed fraud and abuse law changes. Bricker & Eckler's health care attorneys will continue to publish analyses of the proposed rule.