

# PUBLICATION

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## Stark Law Clarifications in Proposed CY 2019 Physician Fee Schedule

July 2018

The Centers for Medicare and Medicaid Services (CMS) included two Stark Law clarifications in its proposed CY 2019 Physician Fee Schedule (Proposed Rule). The first change is with respect to the special rule for certain arrangements involving temporary noncompliance with signature requirements, and the second relates to CMS's prior "collection of documents" guidance. Each proposal is intended to add clarity to the Stark regulations and assist in aligning the Stark regulations with statutory language included in the Bipartisan Budget Act of 2018 (2018 BBA). Neither proposed change represents a shift in Stark Law policy.

**Comments on the Proposed Rule are due by 5:00 p.m. on September 10, 2018.**

The 2018 BBA added a new "Signature Requirement" provision to the Stark statute. 42 U.S.C. § 1395nn(h)(1)(E). The provision, on its face, appears to have been intended to codify existing regulations on the "special rule for certain arrangements involving temporary noncompliance with signature requirements" (i.e., the 90-day late signature rule). 42 C.F.R. § 411.353(g). However, and of practical import, the statutory language used in the 2018 BBA does not reference the regulatory requirement that the 90-day late signature rule can be used only once every three years for the same physician.

Accordingly, and to align the 2018 BBA 90-day late signature language with that of CMS regulations and eliminate potential inconsistencies, the Proposed Rule would remove the current regulatory language that restricts entities' reliance on the 90-day late signature rule to no more than once every three years for the same physician. Per the Proposed Rule, this change would apply retroactively to February 9, 2018 – the effective date of the 2018 BBA.

### Collection of Documents Guidance

The 2018 BBA also added a new provision to the Stark statute titled, "Written Requirement Clarified." 42 U.S.C. § 1395nn(h)(1)(D). This provision states that the writing requirement for a Stark Law compensation arrangement may be satisfied by a "collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved." The new statutory provision sets forth CMS's previously stated stance on the writing requirement, as detailed in the preamble to the [2016 Physician Fee Schedule final rule](#).

In light of the new statutory provision, the Proposed Rule would add a new regulatory provision that largely mirrors the text in the BBA 2018, and likewise the discussion in the preamble to the 2016 Physician Fee Schedule.

### Baker Donelson Comments

The Proposed Rule seeks to align Stark regulations and the 2018 BBA provisions with respect to both the 90-day late signature rule and the collection of documents guidance. While neither change, if finalized, would represent a shift in Stark Law policy, both would add clarity to the Stark regulations – in particular, confirming that the once-every-three-years limitation to the late signature rule is no longer applicable as of February 9, 2018. To the extent these regulatory clarifications are finalized, providers may wish to update their internal compliance policies and procedures accordingly.

