

Part B Insider (Multispecialty) Coding Alert

Compliance: Stark Update Offers Providers a Sleigh Full of Surprises

Hint: New exceptions and definitions clear up confusion.

Since the onslaught of the pandemic, the feds have been forced to pause several policy rollouts and focus on COVID-19 instead. But, in a recent turnaround, the feds changed course, fast-tracking a final rule a year earlier than promised. Read on for the details.

Backtrack: In October 2019, the Centers for Medicare & Medicaid Services (CMS) proposed long-awaited updates to the Physician Self-Referral Law - Stark Law for short - modernizing many of the policies to address technology, value-based care, and compensation. The revamp also aimed to nix outdated administrative regulations and align Stark with CMS' signature program, Patients Over Paperwork.

Originally, after years of industry anticipation, the agency promised the final rule in August 2020. However, on Aug. 27, CMS released an extension in the Federal Register that delayed the final rule until 2021 (see Part B Insider Vol. 21, No. 11).

Now: On Nov. 20, CMS released the Stark Law final rule, which is chock full of burden-reducing arrangements and cost-cutting revisions. The rule was published in the Federal Register on Dec. 2.

"When we kicked off our Patients Over Paperwork initiative in 2017, we heard repeatedly from front-line providers that our outdated Stark regulations saddled them with costly administrative burden and hindered value-based payment arrangements," said CMS Administrator **Seema Verma** in a release. "That sound you hear is the mingled cheers and exclamations of relief from doctors and other healthcare professionals across the country as we lift the weight of our punishing bureaucracy from their backs."



Pocket These 5 Takeaways

The Stark update follows through on many of CMS' 2019 proposals, offering a plethora of care coordination goodies that focus on giving patients more control of their healthcare decision-making. Check out five final rule factors to know:

1. Definitions: CMS clarifies guidance on several Stark-related terms and arrangements with either new or revised definitions. Many of the changes fall under the umbrella of "value-based definitions" that address commenters' requests for more in-depth descriptions of value-based activity, value-based arrangement, value-based enterprise (VBE), value-based participant, and value-based purpose. However, the agency also puts a new spin on terms "such as designated health services, physician, referral, remuneration, and transaction, some importantly narrowing the Stark Law's scope," relate attorneys **Michael Paddock, Erica Kraus, and Theresa Thompson** with Sheppard Mullin in a blog post.

2. Exceptions: The final rule lays out three new Stark Law exceptions for value-based arrangements with varying levels of risk and reward. They include the following:

- **Full financial risk:** The VBE takes on the risk and "is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of such patient care items and services," notes the final rule.
- **Meaningful downside financial risk to a physician:** Commenters "opined" that value-based care is in its infancy and urged CMS to not lay all the responsibility on physicians. According to the final rule, alternative payment model participation quashes that theory, insisting that a little downside risk is necessary to move value-based care forward. This exception builds on those principles and protects "remuneration paid under a value-

based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value based purpose(s) of the value-based enterprise," explains the rule.

- **Value-based arrangements regardless of risk:** "The most onerous exception for value-based arrangements," this "exception potentially applies to arrangements where neither party has assumed any financial risk," explain attorneys **Karen S. Lovitch** and **Rachel E. Yount** with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. in online legal analysis. However, unlike the other two exceptions, CMS does include some safety nets for this exception "to guard against patient and program abuse," Lovitch and Yount point out.



3. Compliance requirements: CMS outlines the "big three" - fair market value, commercially reasonable, and volume or value standard - in great detail. The final rule clarifies and defines each under the Stark Law while setting parameters for the separate but intertwined requirements related to financial arrangements.

4. EHRs and interoperability: Due to overwhelming public commentary and recent 21st Century Cures Act developments, CMS updated its Stark-related EHR exceptions, expanding on current EHR donation rules and adding new cybersecurity exceptions. "CMS added protections for financial arrangements related to cybersecurity technology, to update and remove interoperability requirements and to remove the electronic health records exception's sunset date," note attorneys **Gretchen Heinze Townshend** and **Timothy J. Fry** with McGuireWoods in online analysis.

5. Limited remunerations: After reviewing extensive public dialogue on payment limits under Stark, CMS decided to add a limited remuneration to a physician exception. Now, "arrangements where a physician receives remuneration limited to no more than \$5,000 per calendar year (up from \$3,500 as proposed), adjusted annually for inflation, is a fair market value exchange for items or services actually provided by the physician," Heinze Townshend and Fry acknowledge.

Timeline: The majority of the final rule changes are effective Jan. 19, 2021. A group practice-related amendment won't go into effect until Jan. 1, 2022.

Resource: Review the Stark final rule at <https://public-inspection.federalregister.gov/2020-26140.pdf>.