

Stark Law Reform a Focus of Recent Regulatory and Legislative Initiatives; 2018 DHS Code List and CPI-U Updates

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by Ross C. D'Emanuele and Laura B. Morgan

Stark Law Reform Initiatives

The Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma recently identified federal physician self-referral law (or “Stark Law”) reform as a top policy priority and reported that an inter-agency group is being formed to review the law. Specifically, in a January 17 American Hospital Association Town Hall webcast focused on regulatory relief for hospitals and health systems (excerpt available [here](#)), Verma reported that CMS will be looking to modernize the Stark Law to reflect the move from fee-for-service to value-based payments under Medicare. According to Verma, the Stark Law was one of the top responses from providers to a CMS request asking providers to identify the most burdensome regulations. Because the Stark Law is not completely in CMS’s jurisdiction, an inter-agency group is being formed to look at Stark Law reform initiatives that will include CMS, the Department of Health and Human Services (HHS) Office of Inspector General, the HHS General Counsel, and the Department of Justice. Verma also indicated that then-acting Secretary of HHS Eric Hargan was interested in the issue. Lastly, Verma specified that Congressional intervention may be required.

While not mentioned by Verma in the recent webcast, a bill that addresses modernizing the Stark Law in light of the shift to value-based payment under Medicare, titled the “Medicare Care Coordination Improvement Act of 2017,” was introduced in both the U.S. House of Representatives ([H.R. 4206](#)) and the Senate ([S. 2051](#)) on November 1, 2017. The bill is still under consideration in both the House and the Senate. If enacted, this bill would give HHS authority to grant waivers to fraud and abuse-related statutes for participants in the Medicare Shared Savings Program, i.e., accountable care organizations. Such waiver authority would be extended to “covered APM entities” such as entities participating in alternative payment models (or “APMs,” as defined by MACRA) and similar entities. Additionally, the bill would expand the authority of HHS to promulgate ownership and compensation exceptions to the Stark Law to promote care coordination, by expanding the HHS Secretary’s authority to provide exceptions for financial relationships not posing a “*significant* risk of program or patient abuse, including

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those that would promote care coordination, quality improvement, or resource conservation by physician practices under [Medicare] part B” (emphasis added), rather than the current standard for exceptions, which requires that excepted arrangements not pose a “risk of program or patient abuse.” It would also limit the Secretary from imposing requirements that could adversely affect care coordination or participation in APMs. Finally, it would establish a new statutory exception to the Stark Law for services furnished pursuant to an arrangement entered into for the purpose of developing or operating an APM, provided the arrangement meets certain requirements including that it is in writing, that services are furnished at fair market value and that semi-annual reports are submitted to the Secretary on the progress of the APM (among other requirements).

Further, while not addressing modernizing the Stark Law in light of the shift to value-based payment under Medicare, two additional bills that would amend the Stark Law are currently pending. First, H.R. 3726, the “Stark Administrative Simplification Act of 2017,” was introduced in the House on September 11, 2017. This bill proposes an alternative protocol to the Stark self-referral disclosure protocol (SRDP) for inadvertent technical noncompliance (including, for example, compensation arrangements with an inadvertent missing signature) with the Stark Law and reduced civil monetary penalties for disclosures made pursuant to this alternative protocol. This bill is still under consideration in the House. Second, H.R. 3178, titled the “Medicare Part B Improvement Act of 2017,” was passed in the House in July 2017 and is currently pending in the Senate. Among non-Stark Law-related provisions, if enacted, this bill would codify in the Stark Law certain regulatory changes that went into effect on January 1, 2016 (and corresponding clarifications via preamble by CMS) regarding the writing requirement of the Stark Law compensation exceptions, temporary non-compliance with the signature requirement of the Stark Law compensation exceptions, and the indefinite holdover provision for the lease of office space or equipment and personal services arrangements exceptions.

It remains to be seen where the above-described legislation will lead, and what additional legislative and/or regulatory initiatives will be pursued given the stated focus on Stark Law reform by CMS Administrator Verma, the inter-agency group formed to review Stark Law changes, and the new HHS Secretary Alex Azar.

2018 DHS Code List and CPI-U Updates

The 2018 Medicare Physician Fee Schedule (PFS) final rule, which took effect on January 1, included the annual update to the list of CPT/HCPCS codes used to identify certain categories of Stark designated health services (DHS) (the Code List). As we explained in our post on the 2017 PFS, the Stark Law regulations at 42 C.F.R. § 411.351 specify that the following four categories of DHS are defined by reference to the Code List: (1) clinical laboratory services; (2) physical therapy, occupational therapy, and outpatient speech-language pathology services; (3) radiology and certain other imaging services; and (4) radiation therapy services and supplies. (The other categories of DHS—which are (1) durable medical equipment and supplies; (2) parenteral and enteral nutrients, equipment and supplies; (3) prosthetics, orthotics, and prosthetic devices and supplies; (4) home health services; (5) outpatient prescription drugs; and (6) inpatient

and outpatient hospital services—are defined at 42 C.F.R. § 411.351 without reference to the Code List.) The Code List is updated annually to reflect changes in the most recent CPT and HCPCS Level II publications and to account for changes in Medicare coverage and payment policies.

Further, items and services that may qualify for either of two Stark Law exceptions—the exception for preventive screening tests, immunizations and vaccines at 42 C.F.R. § 411.355(h) and the exception for EPO and other dialysis-related drugs at 42 C.F.R. § 411.355(g)—are identified by reference to the Code List. The Code List included the annual updates to the codes eligible for the preventive screening tests, immunizations and vaccines exception. However, as in previous years, the Code List does not include any codes eligible for the EPO and other dialysis-related drugs exception (for reasons explained by CMS in the rule).

The PFS rule includes tables showing the additions and deletions to the Code List. As per usual, the complete list was posted to the CMS website dedicated to the Code List, found [here](#).

Finally, per the [CPI-U Updates page of the CMS Stark website](#), CMS updated the compensation limits for the nonmonetary compensation exception (at 42 C.F.R. § 411.357(k)) and medical staff incidental benefits exception (at 42 C.F.R. § 411.357(m)), which are both updated annually for inflation. For calendar year 2018, the non-monetary compensation limit is \$407 and medical staff incidental benefits must be less than \$34 per occurrence. (CMS also noted in a footnote on this page that, “From November 9, 2016, through November 16, 2017, the CY 2015 nonmonetary compensation limit was inadvertently listed on this website as \$395 instead of \$392.”)