

Stark Law Updates in 2017 Medicare Physician Fee Schedule Final Rule

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On November 2, the Centers for Medicare & Medicaid Services (CMS) finalized the 2017 Medicare Physician Fee Schedule (PFS) rule. This rule, which takes effect on January 1, 2017, updates payment policies and rates for services furnished under the PFS. A CMS fact sheet summarizing the major components of the rule is available [here](#). The rule included several updates to and clarifications regarding the federal physician self-referral law (or “Stark Law”), including: (1) unit-based compensation in arrangements for the rental of office space or equipment; (2) a technical correction; and (3) the annual update to CPT/HCPCS codes used to identify certain categories of Stark designated health services (or “DHS”). These updates and clarifications are either routine or, in the case of unit-based compensation, ultimately resulted in no changes to the Stark regulations as currently implemented.

Unit-Based Compensation. First, the PFS rule included a lengthy discussion of unit-based compensation in arrangements for the rental of office space or equipment (so-called “per-click” arrangements). This discussion stemmed from an opinion issued by the D.C. Circuit on June 12, 2015 in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (available [here](#)). In this opinion, the D.C. Circuit concluded that CMS’s discussion of a 1993 House of Representatives conference report in the 2009 Inpatient Prospective Payment System (IPPS) final rule, which finalized regulations prohibiting certain per-unit of service compensation formulas in the rental of office space and equipment *regulatory* exceptions (found at 42 C.F.R. § 411.357(a)(5)(ii)(B) and (b)(4)(ii)(B), respectively), “contained an unreasonable interpretation of the conferees’ statements” concerning the rental of office space and rental of equipment *statutory* exceptions (found at 42 U.S.C. § 1395(e)(1)(A) and (e)(1)(B), respectively), and remanded the case to CMS “to permit a fuller consideration of the legislative history.”

CMS responded to this directive in the final PFS rule. In the proposed 2017 PFS rule (available [here](#)), CMS used the same language in the existing exceptions for office space and equipment and proposed to include in each exception a requirement that, as previously implemented, rental charges for the lease of office space or equipment are not

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determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. CMS also used the opportunity to re-propose the same language, as was previously implemented, banning per-click lease arrangements in the exceptions for fair market value compensation and indirect compensation arrangements (at 42 C.F.R. § 411.357(l)((3)(ii)) and (p)(1)(ii)(B), respectively). In the final rule, CMS finalized these requirements without modification. The net result is that the language in all four exceptions (for office space, equipment, fair market value compensation and indirect compensation arrangements) has remained unchanged. Note that the relatively new exception for timeshare arrangements (at 42 C.F.R. § 411.357(y)(6)(ii)(B)), which was effective on January 1, 2016, includes a parallel ban on per-unit of service fees, with CMS using the same rationale for including it there.

CMS rejected the position of the Council for Urological Interests that it lacked authority to impose a ban on per-click leases, and asserted that its reasoning in this final rule fully addressed the court's concerns. As the D.C. Circuit stated, CMS emphasized that the Stark Law "does not unambiguously forbid the Secretary from banning per-click leases as she evaluates the needs of the Medicare system and its patients." CMS pointed out that the Stark Law gives it the authority to add requirements as needed to protect against program or patient abuse, explicitly permits it to impose additional conditions on arrangements for the rental of office space or equipment, and does not state that per-click rates must always be permitted. CMS stated its belief, as first stated in the 2009 IPPS rule, that such a ban is necessary because per-click lease arrangements (where the lessor makes referrals to the lessee that generate payments to the lessor) create improper incentives for physicians to over-utilize services (by ordering unnecessary services that would not have been ordered absent a profit motive), may narrow the choice of treatment options of a patient and may increase costs to the Medicare program.

Further, citing language from the opinion, CMS stated that "Congress knew how to cabin the Secretary's authority to impose 'other' requirements" and "knew how to further clarify what it meant by compensation that does not take into account the volume of business generated between the parties" (as it did in the employment exception). Additionally, Congress knew how to permit per-click payments explicitly (as it did in the exception for continuation of certain group practice arrangements with a hospital). The fact that Congress did not explicitly prohibit or permit per-click arrangements in the context of the exceptions for office space and equipment leases supports the position that the Stark Law is silent regarding the permissibility of per-click for equipment rentals. Therefore, CMS has the authority to impose such a prohibition in order to protect against program or patient abuse.

CMS emphasized that it does not absolutely prohibit rental charges based on units of service furnished. This is only prohibited "*where the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rented equipment.*" For this reason, per-unit of service rental charges

are permitted, as long as the referral for those services did not come *from the lessor*.

Technical Correction. Second, the rule included a technical correction regarding instructions for submitting a request for an advisory opinion related to physician referrals at 42 C.F.R. § 411.372(a). This rule now provides that parties must submit such requests to CMS according to instructions specified on the CMS website. Previously, this regulation specified that parties must submit such requests to CMS in writing. However, the CMS website regarding advisory opinions (available [here](#)) has not been updated since March 2016 and does not include instructions for submitting an advisory opinion. These instructions will likely be posted to this website in the near future.

Code List Updates. Third, the rule included the annual update to the list of CPT/HCPCS codes used to identify certain categories of DHS (the “Code List”). As specified in the Stark Law regulations at 42 C.F.R. § 411.351, 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 Code List is updated annually to reflect changes in the most recent CPT and HCPCS Level II publications. 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. We expect that, as per usual, the complete list will be posted before the end of the year to the CMS website dedicated to the Code List, found [here](#).

The advanced copy of the PFS rule is available [here](#). The official version of the rule is scheduled for publication in the Federal Register on November 15, 2016.