NON-STARK LAW PROPOSED CHANGES TO POLICIES AND PAYMENTS UNDER THE PHYSICIAN FEE SCHEDULE FOR CY 2016

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Health Care Alert

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On July 15, 2015, the Centers for Medicare and Medicaid Services ("CMS") published proposed regulations governing policies and payments made under the Physician Fee Schedule ("PFS") for calendar year 2016 (the "Proposed Rule").[1] The Proposed Rule includes proposed clarifying guidance and significant amendments to the federal physician self-referral law, or "Stark Law," including two new exceptions and revisions to regulatory definitions. Click here for our alert addressing the proposed Stark Law changes. This alert focuses on other changes in the Proposed Rule that may be of interest to providers, including changes to the incident to rules, the development of appropriate use criteria for advanced diagnostic imaging services, payment reductions for certain computed tomography services, changes related to telehealth, and automatic renewal of opt-out affidavits. CMS is accepting public comments on the Proposed Rule until September 8, 2015.

PROPOSED CHANGES TO THE "INCIDENT TO" RULES

The Proposed Rule includes proposed changes to the regulation at 42 C.F.R. § 410.26 governing reimbursement under Medicare Part B for services and supplies provided incident to the service of a physician or non-physician practitioner. These rules are commonly referred to as the "incident to" rules and when they are met, services and supplies furnished by auxiliary personnel will be reimbursed as if personally performed by the physician or practitioner.

One requirement of the incident to rules is that, with certain specified exceptions, the services and supplies must be furnished under the direct supervision of the physician (or other practitioner). CMS notes its guidance from commentary in the CY 2002 PFS final rule that the physician billing number used on the claim for an incident to service should be the number of the physician who provided the direct supervision, not that of the ordering physician if they are not the same.[2] In that same rule, however, CMS amended the regulation[3] to state, as it currently does, that the physician/practitioner providing the supervision does not need not be the same physician/practitioner upon whose professional service the incident to service is based.[4] In the Proposed Rule, CMS proposes to change the regulation to delete that sentence and to explicitly state in the regulation that the direct supervision must be provided by the billing physician/practitioner.[5] If finalized as proposed, operational changes to physician practices may be needed to ensure the requirement is met.[6]

In addition to changes to the direct supervision requirement, CMS also proposes changes to the definition of auxiliary personnel to explicitly state that auxiliary personnel furnishing the incident to service must not have been

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excluded from Medicare or have had his/her Medicare enrollment revoked.[7] While noting that providers are responsible for compliance, CMS is also soliciting comments on methods to facilitate oversight of the incident to rules, such as by establishing new enrollment categories or a registration mechanism; submission of information on claims through, for instance, the use of modifiers; or post-payment audits, investigations, and recoupments by CMS contractors, such as Recovery Auditors or Program Integrity Contractors.[8]

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

Section 218(b) of the Protecting Access to Medicare Act of 2014 ("PAMA")[9] establishes a short implementation timeline for CMS to develop a new Medicare program requiring physicians and practitioners to consult certain appropriate use criteria ("AUC") when ordering advanced diagnostic imaging services in certain settings.[10] The services covered by this program include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (include positron emission tomography), and other diagnostic imaging services specified by CMS in consultation with the medical community and stakeholders, but excluding x-ray, ultrasound, and fluoroscopy services.[11] According to CMS, the statutory goal of the AUC program is to promote evidence-based care and to reduce inappropriate imaging.[12] CMS notes the tremendous magnitude of this program: "The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. . . . and could have a particular impact on primary care physicians since their scope of practice can be quite vast."[13]

The four major components of the AUC program are:

- Specification of applicable AUC—through rulemaking in consultation with physicians, practitioners, and other stakeholders—by November 15, 2015;
- Identification of an initial list of clinical decision support ("CDS") mechanisms for ordering physicians to access AUC, by April 1, 2016, with annual updates to the list thereafter;
- AUC consultation by professionals ordering advanced diagnostic imaging services and reporting by professionals furnishing the service of certain information related to the AUC consulted by the ordering professional, by January 1, 2017; and
- Annual identification of outlier ordering professionals, by January 1, 2017, with the establishment of a prior authorization requirement for such professionals by January 1, 2020.[14]

The Proposed Rule focuses primarily on the first component of the AUC program. By statute, AUC may only be developed or endorsed by national professional medical specialty societies or other provider-led entities.[15] CMS has proposed to codify the new requirements at 42 C.F.R. § 414.94,[16] including defining key terms in § 414.94(b).[17] CMS is particularly interested in stakeholder comment on its proposed definition of and process for qualification as a provider-led entity, as only qualified provider-led entities will have the opportunity to develop, modify or endorse AUC.[18] The Proposed Rule also introduces the concept of clinical priority areas, which will be used to identify outlier professionals, and proposes to develop a process to identify and discuss non-evidence-based AUC.[19]

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OTHER PROPOSED CHANGES

- *Payment Reductions for Certain Computed Tomography ("CT") Services.* Section 218(a) of PAMA requires payment reductions beginning January 1, 2016 for certain CT services furnished using equipment that does not meet each element of the National Electrical Manufacturers Association ("NEMA") Standard XR-29-2013, "Standard Attributes on CT Equipment Related to Dose Optimization and Management."[20] Consistent with the statute, payments for the technical component ("TC") of the PFS service—including the TC of the global fee—and the hospital OPPS payment will be reduced by 5 percent in 2016 and by 15 percent in 2017 and subsequent years for specified CT services[22] that are provided using equipment that does not meet the standard.[21] CMS plans to create a new modifier, "CT," that will be required on claims for services provided by non-compliant equipment beginning on January 1, 2016, which will result in the applicable payment reduction for that service.

- *Telehealth Services.* CMS has proposed expanding the list of CPT codes for covered Medicare telehealth services beginning in CY 2016 to include certain prolonged service and ESRD–related service CPT codes. CMS also proposes to add Certified Registered Nurse Anesthetists ("CRNAs") as authorized telehealth practitioners. CMS did not previously include CRNAs on the list of permitted distant site practitioners because it did not believe CRNAs provided any Medicare telehealth services. However, CMS recognizes in the Proposed Rule that CRNAs are licensed in some states to provide such services, and therefore has now proposed the addition of CRNAs to the list of Medicare telehealth distant site practitioners.[23]

- *Physician and Practitioner Opt-Out from Medicare.* The Proposed Rule also will allow for the automatic renewal of Medicare opt-out affidavits.Prior to the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[24] a physician or practitioner was required to file an affidavit every two years renewing his/her agreement to opt-out of Medicare. The Proposed Rule includes regulations implementing Section 106(a) of MACRA so that an opt-out affidavit filed on or after June 16, 2015 shall automatically renew for additional two-year terms.[25]A physician or practitioner may rescind the affidavit by providing notification at least 30 days prior to the start of the next term.[26]

NOTES:

[1] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 41,686 (proposed July 15, 2015) (to be codified at 42 C.F.R. pts. 405, 410, 411, 414, *et al.*) [hereinafter Proposed Rule].

[2] *See id.* at 41,785 (citing to 66 FR 55267).

[3] *See* Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2016, 66 Fed. Reg. 55,246, 55,329 (Nov. 1, 2001).

[4] *See* 42 C.F.R. § 410.26(b)(5).

[5] *See* Proposed Rule, 80 Fed. Reg. at 41,785.

[6] The proposed regulatory text also states that the billing physician/practitioner must be enrolled in Medicare Part B at the time the services are furnished. *See id.* at 41,953 (to be codified at 42 C.F.R. § 410.26(b)(5)).

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[7] *See id.* at 41,952 (to be codified at 42 C.F.R. § 410.26(a)(1)).

[8] *See id.* at 41,786.

[9] Pub. L. No. 113-93, § 218(b), 128 Stat. 1040, 1065 (2014).

[10] *See* 42 U.S.C. § 1395m(q). The statute provides for limited exceptions to the AUC consulting and reporting requirements for certain emergency services, for inpatient services under Part A, and for ordering professionals who obtain a hardship exemption. The consultation and reporting requirements otherwise apply to services reimbursed under the PFS, hospital outpatient prospective payment system, and ambulatory surgical center payment system and provided in a physician office, hospital outpatient department, or ambulatory surgical center. 80 Fed. Reg. at 41,805.

[11] 80 Fed. Reg. at 41,803.

[12] *Id*. at 41,802.

[13] *Id.* at 41,807.

[14] *Id.* at 41,803–04.

[15] Pub. L. No. 113-93, § 218(b), 128 Stat. 1065.

[16] 80 Fed. Reg. at 41,960.

[17] *Id.* at 41,805.

[18] CMS has proposed to define provider-led entity as "a national professional medical specialty society, or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare." *Id*. at 41,961.

[19] *Id.* at 41,806–07.

[20] Pub. L. No. 113-93, § 218(a), 128 Stat 1040, 1063 (amending Section 1834 of the Social Security Act, codified at 42 U.S.C. § 1395m(p)).

[21] Impacted CPT codes include 70450–70498,71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574, and their successor codes.

[22] Proposed Rule, 80 Fed. Reg. at 41,716.

[23] *Id.* at 41,783-84 (to be codified at 42 C.F.R. § 410.78(b)(2)(ix)).

[24] Pub. L. No. 114-10.

[25] Proposed Rule, 80 Fed. Reg. at 41,930 (to be codified in 42 C.F.R. pt. 405, subpt. D).

[26] *Id.*

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