CMS RELEASES DETAILS ON SITE-NEUTRAL PAYMENT PROVISION UNDER BIPARTISAN BUDGET ACT

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Health Care Alert

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On July 6, the Centers for Medicare and Medicaid Services ("CMS") released the Medicare hospital outpatient prospective payment system ("OPPS") and the Medicare ambulatory surgical center ("ASC") payment system proposed rule for calendar year 2017 (the "Proposed Rule").[1] Among the many items contained in the Proposed Rule, CMS describes its plans for implementing section 603 of the Bipartisan Budget Act of 2015.[2] As discussed in our previous alert, section 603 eliminates OPPS reimbursement for applicable items and services furnished in certain off-campus provider-based outpatient departments ("PBDs") established on or after November 2, 2015 (the date of enactment), starting on January 1, 2017. Instead, these items and services will be reimbursed under the "applicable non-hospital payment system" — in many cases, the Medicare Physician Fee Schedule ("PFS"). The Proposed Rule addresses several issues not specifically discussed in section 603, including the circumstances under which an excepted off-campus PBD (established before the date of enactment) may lose its grandfathered status. Comments on the Proposed Rule are due by September 6, 2016.

SUMMARY OF PROPOSED RULE

CMS included several provisions in the Proposed Rule relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs may be exempt from the payment changes described in section 603. However, the Proposed Rule generally does not provide the level of flexibility sought by providers, despite significant pressure from industry and lawmakers prior to its publication.[3] Instead, CMS developed its proposals "in accordance with our belief that section 603 . . . is intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."[4] In this regard, CMS estimates that section 603 will result in $500 million in savings to the Medicare program in CY 2017.

To implement section 603, CMS proposes to exclude from payment under the OPPS "[e]ffective January 1, 2017, for cost reporting periods beginning on or after January 1, 2017," items and services provided by an off-campus PBD that does not meet the definition of excepted items and services as proposed in § 419.48.[5]

Locations that are Not "Off-Campus PBDs" Will Continue to Receive OPPS Reimbursement

As proposed, the definition of an "off-campus PBD" excludes a department that is located on the hospital's main campus.[6] The term "campus" is defined in accordance with the provider-based rules as follows:

> *Campus* means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.[7]

Also excluded from the term "off-campus PBD" is a provider-based department located within 250 yards of a "remote location" of the hospital. Generally, a remote location of a hospital is a location that provides inpatient hospital services under the name, ownership, and financial and administrative control of the main hospital, in accordance with the provider-based rules, but does not include a "satellite facility" as defined in 42 C.F.R §§ 412.22(h)(1) and 412.25(e)(1).[8] Of note, CMS suggests hospitals "use surveyor reports or other appropriate documentation to ensure their off-campus PBDs are within 250 yards (straight-line) from any point of a remote location for this purpose."[9]

Therefore, items and services furnished in a PBD on the main campus of the hospital or within 250 yards of a remote location can continue to receive OPPS reimbursement as of January 1, 2017.

Excepted Items and Services in Off-Campus PBDs Will Continue to Receive OPPS Reimbursement

CMS proposes to allow certain off-campus PBDs to continue receiving OPPS reimbursement for excepted items and services, including:

- All items and services (whether emergency or nonemergency services) furnished in a "dedicated emergency department," as defined at 42 C.F.R. § 489.24(b).
- Certain items and services furnished by an off-campus PBD that billed for services under the OPPS prior to November 2, 2015.

In the Proposed Rule, CMS addresses one of the most significant issues raised in advance of its publication: how CMS would treat off-campus PBDs that were in place before the date of enactment and therefore excepted (i.e., grandfathered). In particular, there has been intense interest in the issue of when, and how, an excepted off-campus PBD might lose its excepted status. CMS includes several proposals on this issue:

- ***Relocations***: Under the Proposed Rule, excepted off-campus PBDs would lose their excepted status if the PBD moves or relocates from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015. In the case of addresses with multiple units, CMS considers the unit number part of the address, meaning that relocations even within the same building could jeopardize a location's excepted status. CMS is requesting comments on whether to develop "a clearly defined, limited relocation exception process for natural disasters and other extraordinary circumstances."[10] Similarly CMS is soliciting comments on whether there are any other circumstances that are "completely beyond the control of the hospital" but which might necessitate a relocation for which the loss of grandfathered status should not apply.[11]
- ***New or Expanded Service Lines***: Excepted off-campus PBDs would also only be eligible for payment under the OPPS for items and services within the same "clinical families" that the off-campus PBD was

furnishing prior to the date of enactment of section 603. Accordingly, items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would not be reimbursed under the OPPS. The Proposed Rule lists 19 "clinical families" of services that would apply for purposes of this rule.[12] CMS is not proposing to limit the volume of excepted items and services but is soliciting comments as to whether to specify OPPS services had to be billed during a particular timeframe in order to the excepted.[13]

- ***Changes of Ownership***: Finally, during a change of ownership, the excepted status of an off-campus PBD would be transferred to a new owner only when there was a transfer of ownership of the entire hospital and the new owner assumes the existing Medicare provider agreement. In this regard, a hospital could not transfer an excepted off-campus PBD on an individual basis and maintain the PBD's excepted status. As such, the transfer of an off-campus PBD between hospitals (even, apparently, if both are operated by the same legal entity but under separate Medicare provider agreements/CMS Certification Numbers) would result in the loss of excepted status.

Payments to Nonexcepted Off-Campus PBDs

The Proposed Rule also addresses how nonexcepted off-campus PBDs would be reimbursed. CMS acknowledges it has no means to implement the changes needed to make the payment adjustments required by section 603 to off-campus PBDs under OPPS prior to January 1, 2017. As a result, for CY 2017, it is proposing a one-year transition period in which: (1) physicians/practitioners could bill for the nonexcepted items and services and receive payment under the PFS nonfacility rate; or (2) provided it could meet applicable requirements, the hospital could enroll the location providing nonexcepted items and services as a freestanding facility/supplier (e.g., group practice, ASC) and bill for the services as that supplier type.[14]

CMS also notes that to the extent physicians and hospitals were otherwise operating under a joint billing model (e.g., where the hospital billed the technical fee and the physician billed the professional fee), the hospital may need to enter into new compensation arrangements with such physicians to split what will now be a single revenue stream.[15]

As such, the Proposed Rule may require a hospital to either seek new CMS enrollments/billing numbers (and implement changes to billing systems) to insure it can bill under an alternative billing method or negotiate and execute new agreements with physicians — in order to continue receiving even reduced reimbursement.

CMS is also requesting comments as to changes needed to items such as enrollment forms and claim forms to develop a new payment and billing policy beginning January 1, 2018, to permit a PBD to receive payment for nonexcepted items and services at a nonhospital rate but in a manner that recognizes the location is still part of the hospital for other purposes (e.g., conditions of participation, provider-based rules).[16] CMS is specifically soliciting comments as to the cost reporting implications of their proposals but did not definitively state that these clinics, in 2017 or in the future, could be included on a reimbursable line of the hospital's cost report. This is particularly noteworthy, as currently only locations identified on a reimbursable line of a hospital cost report may be registered as eligible child sites under the 340B Drug Pricing Program.

Required Data Collection

Section 603 requires hospitals to report information to identify locations subject to the new exclusion from the OPPS. As a means of implementing this requirement, CMS is considering whether to require hospitals to separately identify all excepted off-campus PBD locations, the date that each excepted off-campus PBD began billing under the OPPS, and the clinical families of services that were provided by the excepted off-campus PBD prior to the date of enactment of section 603. CMS indicates it would expect to collect this information through a newly developed form.[17]

THE PATH FORWARD

Although the Proposed Rule answers some of the key questions regarding CMS's plan to implement section 603, it leaves many other issues unaddressed and raises a host of new questions and concerns. These include the manner of billing and reporting nonexcepted items and services after the transition year in 2017, the interaction of section 603 with the 340B Program (and the potential it will freeze the enrollment of new off-campus PBDs as 340B child sites), and the practical impact of the Proposed Rule on routine hospital reorganizations, service expansions, and relocations — all of which will now be fraught with the risk that they will result in a loss of OPPS reimbursement. Finally, as noted above, hospitals must assess as to each nonexcepted location that is currently billing under the OPPS how it will seek reimbursement in 2017 and consider the enrollment or contracting arrangements that are needed to facilitate that reimbursement.

Moreover, CMS's interpretation of the statute, particularly as it concerns the excepted status of off-campus PBDs in place prior to the date of enactment, is expected to generate significant interest from providers and lawmakers, who urged CMS earlier this year to interpret section 603 in a manner that provides flexibility to providers.[18] As noted above, comments on the Proposed Rule are due by September 6, 2016. The OPPS final rule is typically release around November. Accordingly, health care providers may wish to comment on the Proposed Rule and should otherwise monitor the implementation of section 603 closely.

Notes:

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; etc., 81 Fed. Reg. 45,604 (proposed July 14, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-07-14/pdf/2016-16098.pdf. Fact sheet from CMS: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-06.html.

[2] Pub. L. No. 114-74.

[3] Letter to CMS Acting Administrator Andy Slavitt from Members of United States House of Representatives, May 24, 2016, http://f.datasrvr.com/fr1/816/63094/house_letter_to_CMS_Regarding_Flexibility_of_HOPD_Status.pdf; Letter to CMS Acting Administrator Andy Slavitt from Members of United States Senate, May 19, 2016, http://www.aha.org/advocacy-issues/letter/2016/160519-senate-hopd-dearcolleague.pdf.

[4] 81 Fed. Reg. 45,684.

[5] *Id.* at 45,774 (to be codified at 42 C.F.R. § 419.22). The language "for cost reporting periods beginning on or after January 1, 2017" in the operative regulation could be read to suggest OPPS reimbursement is not lost until the start of a provider's cost reporting period after January 1, 2017; however, CMS does not address this language in commentary, instead repeatedly indicating that these changes are effective January 1, 2017.

[6] *Id.* at 45,775 (to be codified at 42 C.F.R. § 419.48(b)).

[7] 42 C.F.R. § 413.65(a)(2).

[8] *Id.*

[9] 81 Fed. Reg. 45,684.

[10] *Id.* at 45,684.

[11] *Id.*

[12] The proposed clinical families are published in Table 21 and include advanced imaging, airway endoscopy, blood product exchange, cardiac/pulmonary rehabilitation, clinical oncology, diagnostic tests, ENT, general surgery, gastrointestinal, gynecology, minor imaging, musculoskeletal surgery, nervous system procedures, ophthalmology, pathology, radiation oncology, urology, vascular/endovascular/cardiovascular, and visits and related services. *Id.* at 45,685-86.

[13] *Id.* at 45,685.

[14] *Id.* at 45,688-89.

[15] *Id.* at 45,689.

[16] *Id.* at 45,690.

[17] *Id.* at 45,686.

[18] See footnote 3 above.

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