CMS ANNOUNCES FINAL RULE IMPLEMENTING SITE-NEUTRAL PAYMENT RULE FOR CERTAIN OFF-CAMPUS HOSPITAL OUTPATIENT PROVIDER-BASED DEPARTMENTS

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Health Care Alert

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On November 1, 2016, the Centers for Medicare & Medicaid Service ("CMS") released the pre-publication form of its much-anticipated Hospital Outpatient Prospective Payment System ("OPPS") CY 2017 final rule with comment period and interim final rule with comment period (the "Final Rule")[1], which, among other things, implements Section 603 of the Bipartisan Budget Act ("Section 603").[2] Section 603 generally eliminates OPPS reimbursement for items and services furnished in off-campus hospital outpatient provider-based departments ("PBDs") established on or after November 2, 2015.

In response to the CY 2017 OPPS proposed rule (the "Proposed Rule")[3] (see our previous Alert), many commenters urged CMS to delay implementation in order to take the time necessary to formulate policies that would avoid undue burdens on CMS and hospitals. In the Final Rule, CMS declined to delay implementation of the site-neutral payment rule, reaffirming that it will be effective January 1, 2017.[4] CMS did, however, modify a number of key provisions in the Proposed Rule and additionally issued an interim final rule with comment period to establish new payment rates under the Medicare Physician Fee Schedule ("MPFS") enabling hospitals to bill and be reimbursed directly for services provided at nonexcepted off-campus PBDs.[5]

OVERVIEW OF SECTION 603

On November 2, 2015, President Barack Obama signed the Bipartisan Budget Act, which significantly changed how Medicare pays for outpatient services furnished at certain hospital locations. Specifically, Section 603 imposes a "site-neutral" payment policy for new off-campus PBD locations established on or after November 2, 2015. This provision represents the latest effort of policy makers to move toward eliminating differential payments for services based on the location where the service is delivered. Whereas Medicare has historically reimbursed services provided at off-campus PBDs at a higher rate as a result of the ability to bill for a facility fee reimbursed under the OPPS in addition to professional services reimbursed under the MPFS, Section 603 works to neutralize this additional reimbursement for new off-campus PBDs, excluding dedicated emergency departments. In the Proposed Rule, CMS proposed regulations and explained its plans for implementing Section 603 in a number of areas, including reimbursement of nonexcepted items and services, prohibition on expansion of services and relocation of excepted off-campus PBDs, and changes of ownership. The Final Rule responds to significant comment from industry stakeholders and addresses CMS's finalized plans in each of these areas.

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PAYMENT FOR NONEXCEPTED OFF-CAMPUS PBDS

In the Final Rule, CMS reiterates its position from the Proposed Rule that locations subject to Section 603 nevertheless remain part of the hospital.[6] Nonetheless, beginning January 1, 2017, CMS will reimburse hospitals directly for items and services provided at nonexcepted off-campus PBDs according to new MPFS payment rates. [7]

This is in sharp contrast to the Proposed Rule, which had suggested a one-year transition period for CY 2017 during which generally only physicians/practitioners would be able to bill for nonexcepted items and services and payment would be made under the MPFS at the nonfacility rate.[8] In this context, CMS assumed that the hospital and physician would then divide the single MPFS payment between them.[9] Alternatively, CMS indicated that if the hospital could meet applicable requirements, the hospital could enroll the location providing nonexcepted items and services as a freestanding supplier (e.g., group practice, ASC) and bill for the services as that supplier type.[10] Many hospitals argued that not directly reimbursing hospitals for the facility component of services could require hospitals and physicians to establish financial relationships that implicate the Stark Law and Anti-Kickback Statute.[11] Hospitals noted in comments to CMS that entering into such arrangements would not be permitted in some instances and would be difficult to accomplish by January 1, 2017.[12]

In deciding not to adopt the proposal that physicians/practitioners bill for the nonexcepted items and services, CMS acknowledged these concerns.[13] Instead, effective January 1, 2017, CMS established a mechanism by which hospitals will still be permitted to submit claims for nonexcepted items and services on the institutional claim form as they currently do.[14] In order to be reimbursed at the reduced rate, however, the hospital must append a new "PN" modifier to line items for the nonexcepted items and services.[15] In this manner, while billed on an institutional claims form, these items and services will be paid at an MPFS rate.[16] For CY 2017, CMS has generally established that rate as 50 percent of the OPPS rate with certain exceptions.[17] Similarly, physicians and nonphysician practitioner claims for professional services provided at nonexcepted locations will be billed and reimbursed at the existing MPFS facility rate, consistent with current practice.[18] CMS indicated that claims including nonexcepted items and services will continue to pass through the Outpatient Code Editor and into the OPPS PRICER to be paid.[19] In addition, CMS indicated it would apply the same hospital wage index to nonexcepted items and services that would otherwise apply.[20] Additionally, hospitals must continue to follow the supervision requirements applicable to hospital outpatient services, regardless of whether the services are excepted or nonexcepted.[21]

However, several other OPPS payment adjustments will not apply to nonexcepted items and service, including, but not limited to, outlier payments, the rural sole community hospital (SCH) adjustment, the cancer hospital adjustments, transitional outpatient payments, the hospital outpatient quality reporting payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service.[22]

CMS published these payment changes as an interim final rule with comment period, noting that it expected to apply the same process and rates to CY 2018 while requesting comments and working on operational changes to institute a longer-term approach to setting these rates under the MPFS.[23]

While explaining this payment mechanism, CMS reiterated its view that Section 603 is intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices and convert them to off-campus PBDs in order to leverage higher reimbursement, stating its goal to ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible.[24] For CY 2019 and

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beyond, CMS is considering adopting a payment methodology similar to that initially proposed for CY 2017.[25] Alternatively, CMS indicates it could continue an approach like the one finalized in the Final Rule.[26]

340B CHILD SITE ELIGIBILITY

Apart from the obvious benefit of hospitals receiving direct, albeit limited, reimbursement for nonexcepted items and services, another important consequence of the modifications to the Final Rule is that nonexcepted off-campus PBDs should be eligible to enroll as child sites of covered entity hospitals under the Health Resources and Services Administration ("HRSA") 340B Drug Pricing Program. While the 340B Drug Pricing Program was not directly addressed in the Proposed Rule, the lack of direct billing by and reimbursement to the hospital for nonexcepted items or services provided at an off-campus PBD caused many commenters to question whether nonexcepted off-campus PBDs would be adequately represented on the hospital's Medicare cost report, consistent with HRSA requirements for child site eligibility.[27] Although deferring to HRSA for questions regarding 340B eligibility, CMS indicated that hospital outpatient services billed with the PN modifier will be included on Provider Statistical and Reimbursement reports and be reported on the hospital cost report with Medicare facility charges and reimbursement.[28] CMS indicated that if cost report changes were needed as a result of the payment process under the Final Rule, CMS would issue subregulatory guidance.[29]

EXPANSION OF SERVICES AT EXCEPTED PBDS

CMS did not ultimately adopt its proposal to limit the scope of excepted items and services to those that are within the same "clinical family of services" as those items and services furnished by that off-campus PBD prior to November 2, 2015.[30]

The Proposed Rule would have prohibited hospitals from receiving OPPS reimbursement for additional types of services provided even within existing excepted PBD locations.[31] CMS proposed to accomplish this by requiring hospitals to identify the CPT codes billed prior to November 2, 2015, for each off-campus PBD and then mapping them to corresponding ambulatory payment classifications, which were then grouped into clinical families in the Proposed Rule.[32] Any items or services outside these clinical families subsequently provided at an excepted PBD location would have then been subject to the site-neutral payment reduction, while only items and services within the same clinical family would continue to enjoy the benefits of excepted status.[33] Many hospitals noted that identifying and tracking these clinical families would be administratively burdensome.[34] Moreover, given the rapid and changing nature of healthcare services and technology, limiting OPPS reimbursement to existing clinical families of services could have impeded their adoption in off-campus PBDs.[35]

In the Final Rule, CMS ultimately agreed with commenters that its proposal to limit excepted items and services to those within the same clinical families could be complex and burdensome.[36] However, CMS did note that it intended to monitor service line growth and that it may propose a limitation on the expansion of services or service lines in future rulemaking.[37] Importantly, CMS noted that it believes that it has the statutory authority to limit not only the types, but also the volume of services furnished to the level furnished prior to November 2, 2015.[38] While it did not propose to do so at this time, CMS is seeking feedback from stakeholders regarding potential policies limiting service lines or the volume of services. [39] Further, CMS stated its intention to monitor shifts in services from nonexcepted PBDs to excepted off-campus or on-campus PBDs.[40]

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RELOCATION OF EXCEPTED PBDS

In the Final Rule, CMS largely adopted its proposal to significantly limit an excepted off-campus PBD's ability to relocate or expand and preserve its excepted status.[41] Under the Final Rule, CMS indicated that off-campus PBDs will generally lose their excepted status if they relocate from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015.[42] CMS specifically noted that, in the case of addresses with multiple units, such as medical office buildings with multiple suites, the unit or suite number will be considered part of the address.[43] Importantly, CMS noted that it plans to instruct its Medicare contractors to update their systems using enrollment data that will identify each off-campus PBD by physical address and by the date it was added to the hospital's enrollment.[44]

Many commenters objected to this provision, noting that in many instances hospitals are required to temporarily or permanently relocate a PBD for reasons beyond the control of the hospital. CMS noted this concern and in the Final Rule provided the potential for requesting an exception where relocation is necessary as a result of circumstances outside the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues.[45] Under the Final Rule, such exceptions will only be granted on a case-by-case basis as determined by the relevant CMS Regional Office.[46] CMS indicated that it would provide additional subregulatory guidance on the specific process and requirements for hospitals to request CMS to issue such an exception.[47]

CHANGES OF OWNERSHIP

In the Final Rule, CMS also adopted its proposal that excepted PBDs would lose their excepted status if they undergo a change of ownership, unless the new owner acquires the entire hospital and assumes the existing Medicare provider agreement.[48] Under relevant commentary in the Proposed Rule, CMS appeared to take the position that this would be the result even when a change of ownership did not occur, but the PBD was simply moved from one Medicare number to another within the same legal entity (e.g., when a single legal entity owns and operates more than one separately enrolled hospital).[49]

In response to comments, CMS argued that excepted off-campus PBDs have excepted status by virtue of their relationship to the main hospital and that they are not an asset that can be transferred individually.[50] CMS specifically noted as an example that the combination of two certified hospitals under one Medicare provider agreement with one CMS Certification Number would result in the loss of excepted status for an off-campus PBDs not enrolled as provider-based to the surviving, consolidated hospital and billing under OPPS for covered items and services furnished prior to November 2, 2015.[51]

NEW PBDS MID-BUILD AS NOVEMBER 2, 2015

Many commenters argued that CMS should provide excepted status for projects that were under development on November 2, 2015.[52] CMS declined to create an excepted status for such "mid-build" off-campus PBDs, noting that such an exception was not contemplated in Section 603.[53]

CMS's position in this regard is contrary to the flexibility requested by both House and Senate letters signed by 235 representatives and 51 senators to CMS, urging it to include flexibility in implementing Section 603 to enable hospitals to continue to serve patients in off-campus PBDs.[54] In this regard, proposed legislation may provide relief for such mid-build off-campus PBDs.[55] Under that bill, new off-campus PBDs would be considered

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excepted if they qualified as "mid-build," which is described as having a binding agreement with an outside unrelated party for the actual construction of the new off-campus PBD before November 2, 2015.[56]

THE PATH FORWARD

Given the rapid growth in outpatient services provided by hospitals, understanding the Final Rule is of critical importance. The Final Rule implements changes to the billing (with the addition of a new PN modifier) and reimbursement of existing PBDs that lose their excepted status and new off-campus PBDs. More importantly, all off-campus PBDs are now at risk of losing their excepted status if undertaking what might appear to be routine actions related to expansion/relocation or reorganization of departments among otherwise related hospitals within a system. As such, hospitals should take a number of key actions in response to the Final Rule.

- Hospitals that have not already done so as a result of the Proposed Rule should identify each of their off-campus PBDs and determine whether they are excepted from, or subject to, the site-neutral payment rule.
  - This determination should include evaluation of how PBDs are listed on enrollment forms and how services were reimbursed prior to November 2, 2015.
  - Hospitals should ensure that they are able to produce adequate documentation to demonstrate that each of their excepted off-campus PBDs was billing under OPPS for services furnished prior to November 2, 2015.
- For each nonexcepted off-campus PBD, hospitals should take steps to ensure that it is able to appropriately submit claims with the "PN" modifier beginning January 1, 2017 and assess the reimbursement impact of the new 50 percent reimbursement reduction.
- Hospitals should develop processes for identifying facility changes that may trigger a loss of excepted status (e.g., relocation/expansion or change of ownership/provider number) so that those issues can be reviewed in advance by planning and legal staff.
- Hospitals should consider responding to CMS's requests for comments on various aspects of the Final Rule and interim final rule. Comments are due by December 31, 2016.

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; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital (to be published Nov. 14, 2016)(hereinafter cited as "Final Rule"), *available at* https://www.federalregister.gov/documents/2016/11/14/2016-26515/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

[2] Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603.

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[3] 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.

[4] Final Rule at 574.

[5] *Id.* at 639.

[6] *Id.* at 570.

[7] *Id.* at 639.

[8] 81 Fed. Reg. at 45,688–89.

[9] *Id.*

[10] *Id.*

[11] Final Rule at 635–37.

[12] *Id.*

[13] *Id.* at 637.

[14] *Id.* at 665.

[15] *Id.* at 680.

[16] *Id.*

[17] *Id.* at 678.

[18] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements (to be published Nov. 15, 2016) *available at* https://www.federalregister.gov/documents/2016/11/15/2016-26668/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

[19] Final Ruleat 665–66.

[20] *Id.* at 666.

[21] *Id.* at 687–88.

[22] *Id.* at 685.

[23] *Id.* at 688–89.

[24] *Id.* at 689.

[25] *Id.* at689–92.

[26] *Id.*

[27] *Id.* at 648.

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[28] *Id*. at 648-49.

[29] *Id.* at 649.

[30] *Id.* at 602–04.

[31] 81 Fed. Reg. at 45,685–86.

[32] *Id.*

[33] *Id.*

[34] Final Rule at 600–02.

[35] *Id.*

[36] *Id.* at 602–03.

[37] *Id.* at 603.

[38] *Id.* at 602.

[39] *Id.*

[40] *Id.* at 602–04.

[41] *Id.* at 588–96.

[42] *Id.* at 592–93.

[43] *Id.*

[44] *Id.* at 615.

[45] *Id.* at 594–95.

[46] *Id.*

[47] *Id.*

[48] *Id.* at 608–11.

[49] 81. Fed. Reg. at 45,686.

[50] Final Rule at 611.

[51] *Id.*

[52] *Id.* at 606.

[53] *Id.* at 607.

[54] See Letter from 51 U.S. Senators to CMS Acting Administrator Andy Slavitt, May 19, 2016, http://www.aha.org/advocacy-issues/letter/2016/160519-senate-hopd-dearcolleague.pdf (the "Senate letter"); Letter from 235 U.S. Representatives to CMS Acting Administrator Andy Slavitt, May 24, 2016, http://www.aha.org/content/16/160524-cms-congress-sec603hopd.pdf (the "House letter").

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[55] Helping Hospitals Improve Patient Care Act of 2016, H.R. 5273, 114th Cong. (as passed by House, June 7, 2016) (this bill was referred to the Senate Finance Committee where it has remained since passing its House vote).

[56] *Id.*

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