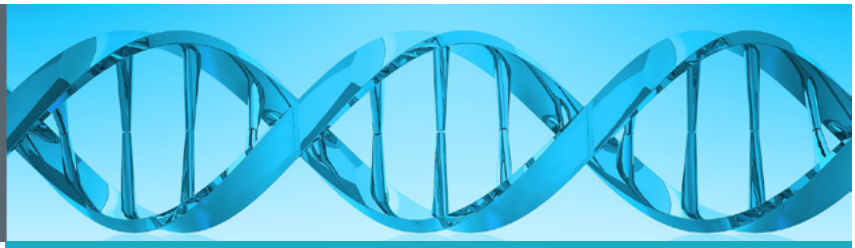
POLSINELLI

in the news

Health Care



November 2016

OPPS Provider-Based Final Rule—A More Practical Approach From CMS

In this Issue:

CMS recently finalized sweeping changes to the way Medicare pays hospitals for services furnished in "new" off-campus provider-based departments (referred to as "off-campus PBDs").

CMS revealed the changes on November 1 with the publication of the CY 2017 OPPS Final Rule (the "Final Rule"), which implements Section 603 of the BBA. Section 603 included revisions to payment for off-campus PBDs developed on or after November 2, 2015. A copy of the Final Rule can be found here. Section 603 is discussed on pages 79699 – 79729.

While rulemaking is constrained by the requirements of Section 603, **CMS seems to have heard the concerns of stakeholders and has reversed course on a number of problematic proposals contained in its Proposed Rule.**

Highlights of the Final Rule include:

- **No Mid-Build/Under Development Grandfathering** - Payment reductions will apply to nonexcepted items and services furnished in departments that did not bill OPPS or provide OPPS billable services prior to November 2, 2015. CMS did not implement a mid-build or under development exception and deferred to pending legislation.

- **Broad Exemption for Dedicated Emergency Departments; On-Campus PBDs** - Payment reductions do not apply to any items or services provided in dedicated emergency departments, on-campus locations (as determined by the CMS Regional Office), or PBDs within 250 yards of remote locations.

- **How to Measure 250 Yards** - CMS reinforced that Regional Offices have discretion to determine what qualifies as on-campus, including the discretion to extend the campus beyond 250 yards. CMS also confirmed 250 yards should be measured from any point on the main hospital/remote location to any point on the provider-based site.

- **Elimination of Clinical Family of Services** - Grandfathered locations may expand services in existing locations and remain grandfathered for all services as CMS eliminated its clinical family of services proposal.

- **Limited Ability to Relocate Grandfathered PBDs** - CMS finalized its proposal to limit the ability of grandfathered sites to relocate, except in circumstances beyond the main provider's control. Otherwise changing a grandfathered site's address or suite number without CMS's prior approval will risk grandfathered status.

- **Institutional Claims and the New PN Modifier** - CMS will not require hospitals to re-enroll off-campus PBDs as a different provider/supplier type and will not require physicians to bill Medicare for hospital services as CMS originally proposed. Rather, CMS issued an interim final rule providing that hospitals will bill nonexcepted items and services on an institutional/UB claim form using a new "PN" modifier—rendering the services reimbursable for cost reporting and 340B eligibility purposes.

- **Medicare Physician Fee Schedule is CMS's Payment System of Choice** - CMS will establish new payment rates for nonexcepted items and services based on the MPFS (i.e., a reduced amount using 50% of the OPPS payment as a benchmark for many services).

The new payment regulations will take effect on January 1, 2017—no delay.

- CMS provided insight as to the timing of its rulemaking implementing Section 603. While CMS acknowledged there is no legislative history or records regarding Section 603, CMS cited the Congressional Budget Office's estimated projection that program savings related to Section 603 could be approximately $9.3 billion over a 10-year period. CMS stated that stakeholders were informed in January 2016 via a notice posted on its website that CMS expected to present its proposal to implement Section 603 in the CY 2017 OPPS/ASC proposed rule and that stakeholders were given a dedicated email address to provide information they believed was relevant in formulating the policies in the proposed rule.

- CMS is not delaying its implementation of Section 603, which will take effect on January 1, 2017. To address commenters' concerns that hospitals would not be able to provide necessary outpatient services if the proposed rule was finalized without modification, CMS is, through an interim final rule, establishing payments rates under the MPFS to be used by hospitals for billing nonexcepted items and services beginning January 1, 2017.

- CMS did not agree that delaying implementation would be required for CMS to collect more appropriate data. CMS intends to use the new modifier "PN" for nonexcepted items and services to collect and analyze claims-based data. CMS will use that information to make payment for nonexcepted items and services under the MPFS and, over time, refine payment for those items and services.

POLSINELLI
real challenges. real answers. SM

- CMS did not make changes to the provider-based criteria set forth in the regulations at 42 C.F.R. § 413.65.

Dedicated Emergency Departments are exempt from Section 603.

- Items and services provided by a dedicated emergency department (ED), as defined by the EMTALA regulations at 42 C.F.R. § 489.24(b), are not subject to Section 603. CMS made no changes to its proposals regarding dedicated EDs. While CMS did not address whether scheduled services provided by a dedicated ED would be exempt from Section 603, CMS finalized its policy that dedicated EDs may furnish both emergency and nonemergency services as long as the requirements under 42 C.F.R. § 489.24(b) are met. CMS also stated that all services furnished in a dedicated ED would be exempt from Section 603. This position offers flexibility relative to the services dedicated EDs can provide, though state law limitations may exist.

- CMS also confirmed that Section 603 does apply to provider-based FQHCs and FQHC look-alikes, but does not apply to off-campus PBDs operated by the Indian Health Service or by a tribe or tribal organization.

PBDs within 250 yards of a remote location of a hospital are exempt from Section 603.

- CMS finalized its proposal, in line with Section 603, to exclude off-campus PBDs that are located at or within 250 yards of a remote location of a hospital facility.

- In measuring the 250 yards, the hospital may measure from any point in the physical facility that serves as the site of services of the remote location to any point in the PBD.

Relocation of currently exempt off-campus PBDs billing prior to November 2, 2015 permitted in narrow circumstances.

- Section 603 states that the term "off-campus outpatient department of a provider" does not include off-campus PBDs that furnished and billed covered outpatient services under the OPPS prior to November 2, 2015. CMS's concern when determining the scope of this exception focused on how relocation of the physical location or expansion of services at the excepted off-campus PBD would affect the excepted status and the items and services furnished by the excepted off-campus PBD.

- CMS proposed that an excepted status would be lost if the off-campus PBD moves or relocates from the physical address (including suite number) that was listed on the provider's hospital enrollment form as of November 1, 2015. Once an excepted off-campus PBD relocated, CMS proposed that both the off-campus PBD itself and the items and services provided at that off-campus PBD would no longer be excepted. CMS solicited comments on whether there should be a clearly defined relocation process and whether CMS should allow off-campus PBDs to maintain excepted status in circumstances when relocation is completely beyond the control of the hospital.

- CMS concluded that excepted off-campus PBDs should not have the flexibility to relocate for any reason the

hospital desires, and finalized a more narrow approach. CMS reasoned that, if excepted off-campus PBDs could be relocated without limitations, hospitals could subvert Section 603's intent by purchasing larger facilities, purchasing additional physician practices and moving the practices into the larger relocated space that would be paid under the OPPS.

- CMS believes that Section 603 applies to PBDs as they existed as of November 2, 2015. CMS declined to permit relocation even if the total number of off-campus PBDs for a hospital did not increase relative to the number prior to the enactment of Section 603. CMS also declined to implement a "substantially similar" test - akin to the critical access hospital (CAH) relocation requirements - to determine if a relocated location is actually "new."

- As finalized, CMS will allow excepted off-campus PBDs to relocate temporarily or permanently, without loss of excepted status, for extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues. This policy will be limited and applied in a rare manner to help ensure this exception does not undermine Section 603's goal of limited growth and expansion of excepted off-campus PBDs. CMS intends to issue sub-regulatory guidance on the technical process to submit a request for a relocation exception. Regional Offices will make the determinations for relocation requests on a case-by-case basis.

- CMS expanded the definition of excepted off-campus PBDs to include off-campus PBDs that billed under the OPPS prior to November 2, 2015 and off-campus PBDs that furnished provider-based services prior to November 2, 2015 even if the services were not billed under the OPPS until after November 2, 2015 assuming the PBD meets timely filing limits.

CMS will permit excepted off-campus PBDs to expand the services they provide.

- CMS proposed to limit excepted off-campus PBDs to the same "clinical family of services" as were provided as of November 2, 2015. Under the proposal, CMS outlined 19 clinical families of services. An excepted PBD could expand the services offered within the same clinical family, but any new items or services offered (i.e., any services not within the same clinical family) would not be paid under the OPPS. CMS based this proposal on the understanding that Section 603 addressed not only the PBD itself, but also the items and services being provided as of November 2, 2015. Otherwise, in CMS's view, hospitals could buy physician practices and just add them to existing excepted PBDs – a practice CMS believes Congress intended to prevent.

- Based on feedback to the proposed rule, CMS did not finalize this proposal. As such, an excepted off-campus PBD will continue to receive OPPS payment for all items and services provided in the excepted PBD, regardless of whether those same items or services were provided prior to the enactment of Section 603. The PBD, however, must continue to meet the relocation and change of ownership rules, discussed elsewhere in this E-Alert.

- Despite not adopting its proposals with respect to clinical family of services, CMS indicated that it was within its authority to do so and that it intends to monitor the potential for shifting what were previously physician practice services to excepted off-campus PBDs or on-campus PBDs. To that end, CMS seeks feedback on: (1) how either a limitation on volume of services or a limitation on lines of service would work in practice; (2) what data is

currently available or could be collected that would allow for implementation on a service expansion limitation; and (3) suggestions for changing the clinical family of services outlined in Table 21 of the proposed rule.

CMS finalized its policy that excepted status for an off-campus PBD transfers to new ownership only if ownership of the main provider, as well as its provider agreement, are also transferred.

- CMS finalized its change of ownership proposals without modification, reiterating that provider-based status is defined as the relationship between a facility and a main provider, and not an asset that can be transferred from one provider to another.

- CMS clarified that it has the authority and is permitted to address change of ownership as part of its implementation of Section 603, and that the rationale for its change of ownership proposal is modeled after longstanding payment policy in which assets/liabilities are transferred to the new owner only if the new owner accepts the existing provider agreement.

- CMS stated that if a hospital is sold to or merges with another hospital, an outpatient department's provider-based status generally transfers to the new ownership as long as the transfer doesn't result in any material change of provider-based status.

- CMS explained that hospital owners that decide to combine two certified hospitals under one Medicare provider agreement with one Medicare certification number will lose excepted status if the off-campus PBD was not enrolled as a provider-based department of the resulting combined hospital and billing under the OPPS for covered items and services prior to November 2, 2015.

CMS will not require hospitals to modify their enrollment data to separately identify their off-campus PBDs.

- CMS solicited comments regarding whether hospitals should be required to separately identify all off-campus PBDs, the date that the PBD began billing, and the clinical families of services provided by the PBD prior to November 2, 2015. Commenters encouraged CMS not to require modifications to existing enrollments, or new attestation forms, as these would significant administrative costs to both the Medicare program and to enrolled hospitals.

- CMS will not require hospitals to modify their enrollment data to more specifically address off-campus PBD information. Rather, it intends to use existing program integrity protocols to monitor and enforce billing for nonexcepted items and services. Hospitals are expected to maintain documentation to prove that an off-campus PBD was billing under the OPPS prior to November 2, 2015. CMS also intends to direct Medicare contractors to update their systems using enrollment data that identifies off-campus PBDs by physical address and the date the PBD was added to the hospital's enrollment.

CMS is adopting the MPFS as the "applicable payment system" required under Section 603 for nonexcepted items and services.

- As detailed in the Interim Final Rule (discussed below), CMS finalized its proposal that the MPFS is the appropriate "applicable payment system" for items and services that will no longer be paid at OPPS rates. In the Final Rule, CMS reiterated that many off-campus PBDs were initially enrolled

as freestanding physician practices, which, according to CMS, makes the MPFS the appropriate payment system. Further, preliminary data from use of the "PO" modifier in 2016* indicates that most items and services furnished in off-campus PBDs are types commonly furnished in the physician office setting (the most common being E/M, followed by diagnostic and imaging services, drugs or biological and drug administration). CMS rejected proposals to use the ASC payment system, a combination of the ASC payment system and MPFS, or a new system based on the ASC payment system, MPFS, and OPPS.

*In 2015, CMS adopted a voluntary "PO" claim modifier to identify items and services furnished in off-campus PBDs, and use of this modifier became mandatory for CY 2016.

For CY 2017, CMS published an Interim Final Rule permitting hospitals to bill for nonexcepted items and services on the institutional claim form using the line modifier "PN".

- CMS acknowledged that a nonexcepted off-campus PBD is still considered to be part of the hospital: "The Amendments made by section 603 of Pub. L. 114-74 did not change the status of these [nonexcepted off-campus] PBDs; only the status of and payment mechanisms for the services they furnished changed." Final Rule, page 79717.

- However, CMS reiterated its position that Medicare payment processing systems are not currently designed to allow a hospital to bill for the services of an off-campus PBD under a payment system other than the OPPS. Rather, a hospital includes its PBDs in its Medicare enrollment and may only submit institutional claims for outpatient department services. Accordingly, hospitals will continue to use institutional claim forms for nonexcepted items and services, identifying such nonexcepted items and services with modifier "PN."

- In addition, hospitals with nonexcepted off-campus PBDs may continue to include the cost of nonexcepted items and services on their cost reports. CMS specifically addressed this issue to alleviate commenters' concerns that 340B participation would be jeopardized for nonexcepted PBDs. If final payment policies require hospital cost reporting change, CMS will issue sub-regulatory guidance.

The Interim Final Rule creates a payment framework to reimburse hospitals directly for nonexcepted items and services, on an institutional claim, at rates based on the MPFS.

- For CY 2017, CMS will establish new MPFS rates for nonexcepted items and services. The rates will be site-of-service specific and based on the technical component of the MPFS facility rate, and will use OPPS concepts, including C-APCs and packaging logic. In developing the rates, CMS compared off-campus PBD payment data from 2016 to MPFS rates at the code level. As a result, CMS will use a rate for nonexcepted items and services that is 50% of the OPPS rate.

- CMS is not adopting its proposal to pay the physician or practitioner at the MPFS nonfacility rate in lieu of paying the hospital for the hospital's services. CMS acknowledged commenters' fraud and abuse concerns where physicians or other practitioners would bill and receive payment based on the MPFS nonfacility rate for what are actually hospital services (e.g., the nursing, laboratory, imaging, chemotherapy, surgical services, and other services provided by the hospital outpatient department). CMS agreed with commenters that its proposal could have implicated the Stark Law and Anti-Kickback Statute and required hospitals

and physicians to enter into financial arrangements by January 1, 2017.

- Items and services that are currently paid based on other fee schedules or based on rates from other fee schedules (e.g., certain clinical laboratory tests, ambulance services, and separately payable drugs and biologicals) will continue to be paid accordingly and are not subject to the Interim Final Rule. All exceptions and adjustments are displayed in Table X.B.2.

- Beneficiary cost-sharing for nonexcepted items and services will generally be equal to their cost-sharing where the items and services are provided at a freestanding facility (i.e., 20% of the new rate, which is intended to be similar to the MPFS nonfacility rate).
- The hospital outpatient supervision rules under 42 C.F.R. § 410.27 will continue to apply to nonexcepted off-campus PBDs. CMS again noted that while Section 603 changed the payment mechanism for nonexcepted off-campus PBDs, it did not change their status as being PBDs of a hospital.

The Interim Final Rule applies to payment in CY 2017 and likely to CY 2018; changes may be in store for CY 2019.

While the Interim Final Rule is specific to CY 2017, CMS anticipates that it will use the same method for determining MPFS payment rates for nonexcepted items and services for CY 2018.

For CY 2019 and beyond, CMS intends to pay hospitals for nonexcepted items and services at a MPFS rate that would more directly equalize payment rates between nonexcepted off-campus PBDs and physician offices.

Rather than scaling payments to 50% of OPPS rates, for most services CMS would use a MPFS-based rate equal to the difference between the nonfacility and facility rates for the item or service in question. For a service that does not have separate MPFS payment when paid under the OPPS, the MPFS-based rate would equal the MPFS facility rate, or for some services, the technical component rate under the MPFS. For outpatient services not billable under the MPFS, CMS would consider the relative resources required and anticipates using a rate similar to that paid to ASCs.

CMS acknowledges that this new payment approach would require hospitals to bill for nonexcepted items and services on the CMS-1500 claim form and that it would require substantial system changes. Alternatively, CMS is considering whether to continue with a methodology similar to what it will use for CYs 2017 and 2018 based on a percentage of OPPS rates. CMS acknowledges the benefit of allowing hospitals to continue billing through an institutional claim form. However, it is concerned that if the scaled payments for certain items and services are higher than the payments that would be made for the same service in a physician office, hospitals will have an incentive to acquire certain types of physician practices. CMS is seeking public comment on its payment system proposals for CY 2019 and beyond.

For More Information

For questions regarding this information, please contact the author below, a member of Polsinelli's Health Care practice, or your Polsinelli attorney.

Colleen M. Faddick
303.583.8201
cfaddick@polsinelli.com

To contact a member of our Health Care team, click here or visit our website at www.polsinelli.com > Services > Health Care Services > Related Professionals.

To learn more about our Health Care practice, click here or visit our website at www.polsinelli.com > Services > Health Care Services.

POLSINELLI
real challenges. real answers. SM

About Polsinelli's Health Care Practice

The Polsinelli Health Care practice represents one of the largest concentrations of health care attorneys and professionals in the nation. From the strength of its national platform, the firm advises clients on the full range of hospital-physician lifecycle and business issues confronting health care providers across the United States. Recognized as a leader in health care law, Polsinelli is ranked as "Law Firm of the Year" in Health Care by *U.S. News & World Report* (November 2014), no. 1 by *Modern Healthcare* (June 2015) and nationally ranked by *Chambers USA* (May 2015). Polsinelli's attorneys work as a fully integrated practice to seamlessly partner with clients on the full gamut of issues. The firm's diverse mix of attorneys enables our team to provide counsel that aligns legal strategies with our clients' unique business objectives.
One of the fastest-growing health care practices in the nation, Polsinelli has established a team that includes former in-house counsel of national health care institutions, the Office of Inspector General (OIG), and former Assistant U.S. Attorneys with direct experience in health care fraud investigations. Our group also includes current and former leaders in organizations such as the American Hospital Association. Our strong Washington, D.C., presence allows us to keep the pulse of health care policy and regulatory matters. The team's vast experience in the business and delivery of health care allows our firm to provide clients a broad spectrum of health care law services.

About Polsinelli

real challenges. real answers.[SM]

Polsinelli is an Am Law 100 firm with more than 800 attorneys in 20 offices, serving corporations, institutions, and entrepreneurs nationally. Ranked in the top five percent of law firms for client service*, the firm has risen more than 50 spots over the past five years in the Am Law 100 annual law firm ranking. Polsinelli attorneys provide practical legal counsel infused with business insight, and focus on health care, financial services, real estate, intellectual property, mid-market corporate, labor and employment, and business litigation. Polsinelli attorneys have depth of experience in 100 service areas and 70 industries. The firm can be found online at www.polsinelli.com. Polsinelli PC. In California, Polsinelli LLP.

**2016 BTI Client Service A-Team Report*

About this Publication

Polsinelli provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. The choice of a lawyer is an important decision and should not be based solely upon advertisements.
Polsinelli PC. In California, Polsinelli LLP.