KING & SPALDING

Client Alert

Healthcare Practice Group

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CMS Finalizes Policies on Off-Campus Provider-Based Status

CMS Will Pay Non-Excepted PBDs in 2017, But Adopts Nearly All Other Proposals

On November 1, 2016, the Centers for Medicare & Medicaid Services (CMS) issued its CY 2017 Outpatient Prospective Payment System (OPPS) Final Rule, which includes the agency's final policies implementing legislative changes to treatment of off-campus provider-based departments (PBDs). These changes are the result of Congress's passage of Section 603 of the Bipartisan Budget Act of 2015, which directs CMS to no longer pay hospitals the OPPS rate for services furnished in off-campus PBDs beginning January 1, 2017 – unless such PBD is a dedicated emergency department, is located within 250 yards of a remote inpatient hospital campus, or had been billing under the OPPS prior to November 2, 2015.

Many commenters had urged CMS to delay implementation of Section 603 until it could better operationalize its proposals. The agency declined to delay implementation but made two significant changes from the Proposed Rule to address hospital concerns. (King & Spalding's *Health Headline* summarizing the Proposed Rule is available here.)

First, CMS will make payment in CY 2017 to hospitals that furnish services at "non-excepted" (non-grandfathered) off-campus PBDs at half of the OPPS rate. The agency first proposed that it would not make *any* payment to non-excepted PBDs in CY 2017 due to systems difficulties and would instead only pay treating physicians for their professional services. The final policy will enable the agency to comply with its statutory directive to pay non-excepted off-campus PBDs according to an "applicable payment system" and, in turn, will permit hospitals to record reimbursable Medicare outpatient charges on their cost reports. Recording these charges is essential to maintaining "child site" eligibility under the 340B Drug Pricing Program.

Second, CMS elected to not adopt its proposal to limit changes in service mix at excepted (grandfathered) off-campus PBDs to only those "clinical families of services" that the off-campus PBD had billed prior to November 2, 2015. CMS stated that it was persuaded by commenter feedback that billing for excepted services at the OPPS rate and non-excepted services at the Medicare Physician Fee Schedule (MPFS) rate at the same location –

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and even in the same patient encounter – would prove overly burdensome to hospitals and confusing to beneficiaries.

However, CMS adopted its proposals to significantly limit the ability of an excepted off-campus PBD to retain its excepted status in the event of a relocation or a change in ownership. CMS Regional Offices will only permit a relocated off-campus PBD to retain its excepted status in "extraordinary" circumstances such as natural disasters or major patient safety issues – and not in any other circumstances that may be beyond a hospital's control such as a loss of a lease. An off-campus PBD that changes owners will retain its excepted status only if the entire hospital to which the PBD is provider-based is acquired by the same entity and its Medicare provider agreement is accepted by the new owner. An individual off-campus PBD that is bought by a new owner will not retain its excepted status.

Payment for Non-Excepted Off-Campus PBDs in CY 2017 and Beyond

CMS will pay hospitals for services furnished in non-excepted off-campus PBDs beginning January 1, 2017 at half the OPPS rate for such services. In the Proposed Rule, CMS stated that it did not have the systems capabilities to pay hospitals under the MPFS for services billed on institutional claims. As a result, CMS proposed to not make payments to hospitals at all during CY 2017 while it reorganized its claims processing systems. CMS proposed to make payment only to the treating physician for professional services at the non-facility rate.

This proposal was contrary to the plain language of Section 603, which states that CMS "shall" make payment to hospitals for services at a non-excepted PBD according to an "applicable payment system." Even if CMS could no longer make OPPS payments, Congress still required CMS to pay hospitals pursuant to another payment system in CY 2017.

In addition to the financial challenges posed by a year of no hospital payment, the proposal also presented legal and operational concerns. If only physicians could bill for their professional services – and at the non-facility rate – physicians would be receiving payment for overhead expenses that the hospital was incurring. Hospitals and physicians would therefore be required to enter into new financial relationships by January 1, 2017 to ensure that the physician would remit some portion of his/her payment to compensate the hospital for the overhead expenses it was incurring. Failure to do so would have implicated the Federal Stark Law and Anti-Kickback Statute. To complicate matters more, such a transfer may run afoul of State laws that prohibit fee splitting.

CMS agreed in the Final Rule that these legal and operational challenges imposed an undue burden on hospitals and therefore adopted a new subset of payment rates for non-excepted PBD services within the MPFS equal to 50 percent of the corresponding OPPS payment rate. Hospitals will bill these services on the UB-04 claim form using the claims modifier "PN" for each such service. These services will technically be payable under the MPFS, but will incorporate OPPS packaging and other payment policies. Physicians will continue to bill for their professional services at the facility rate. Payment rates for other hospital outpatient services that are already paid at MPFS rates, such as therapy and preventative services and separately payable Part B drugs, will remain the same and will not be reduced by 50 percent.

Commenters expressed concern that if hospitals would not be able to bill and receive payment for services furnished in non-excepted PBDs, these locations would be ineligible to qualify as "child sites" that may administer discounted drugs purchased through the 340B Drug Pricing Program. While deferring generally to the Health Resources and Services Administration (HRSA) that administers the 340B Program, CMS stated that its new payment policy for 2017 will enable hospitals to record reimbursable Medicare outpatient charges on the cost report – which is how HRSA determines whether a PBD qualifies as a "child site."

CMS anticipates paying the 50-percent rate for CYs 2017 and 2018 and will use data reported with the PN modifier to gradually set hospital payment rates under the MPFS to equal the technical or practice expense payments made to physicians in non-facility settings.

Payment Policies for Excepted Off-Campus PBDs

CMS elected to not adopt its proposal to limit the payment of OPPS rates to those "clinical families of services" that an off-campus PBD had previously billed prior to November 2, 2015. Instead, CMS announced that it will make full OPPS payment for all services furnished in an otherwise excepted PBD. CMS acknowledged the arguments that commenters made that Section 603 did not limit grandfathered or excepted status to particular services, but only to facilities. (Indeed, CMS's longstanding policy had been that the provider-based regulation only applied to facilities and not to the individual services those facilities provide.) While CMS still believes that it has the authority to limit both the type and volume of services furnished in off-campus PBDs, the agency backed off of its original proposal after recognizing the operational difficulties associated with tracking and properly billing services furnished in the same encounter under different payment systems. CMS said it will monitor services billed with the "PO" modifier (off-campus PBD) to determine whether hospitals are, in the agency's view, attempting to evade Section 603 by purchasing additional physician practices and relocating them to excepted off-campus PBDs.

Contrary to widespread concern expressed by hospitals, CMS adopted its proposals regarding relocation and changes in ownership of excepted off-campus PBDs. An off-campus PBD may relocate and retain its excepted status only if the relocation – whether permanent or temporary – is due to "extraordinary" circumstances such as natural disasters, significant seismic building code issues, or significant public health and safety concerns. CMS stated that Regional Offices will approve these relocations on a case-by-case basis and that approval will be exceedingly rare. CMS will continue to define a location by the address – including unit number – that was listed on the hospital's enrollment form as of November 1, 2015. The agency acknowledged that hospitals urged CMS to expand the exception process to include many other circumstances beyond a hospital's control such as the loss of a lease in a medical office building, but CMS declined to do so out of concern that hospitals may use these relocations as opportunities to move into larger facilities that include additional purchased physician practices. In addition, CMS will only permit an excepted off-campus PBD to retain its status after a change in ownership if the entire hospital to which the PBD is provider-based is purchased by the same new owner who also accepts assignment of the acquired hospital's Medicare provider agreement.

Other Notable Provisions

The Final Rule also includes these other notable policies:

- An off-campus PBD will be considered excepted if it furnished any covered OPPS service prior to November 2, 2015 – even if such service was billed after November 2. The service, however, must have been paid in order to be considered "covered."

- All services furnished by a dedicated emergency department – whether emergent or not – will continue to receive OPPS payment. CMS reiterated that an off-campus PBD can qualify as a dedicated emergency department if it meets any of the definitions set out in the EMTALA regulations at 42 C.F.R. § 489.24(b):

    - The department is licensed by the State in which it is located under applicable law as a dedicated emergency department;

  - The department is held out to the public as a place that provides emergency medical care on an unscheduled basis; or

  - During the previous calendar year, at least one-third of the department's outpatient visits were for emergency medical conditions.

- CMS again declined to add any specificity to its definition of a hospital's "main campus." Specifically, commenters asked CMS to further define what qualifies as a hospital "main building" from which the campus's 250-yard radius may be measured. The agency instead will defer to CMS Regional Offices to make case-by-case determinations of what constitutes a main campus. CMS stated that this degree of flexibility is necessary to reflect the differences in hospital campus composition.

  - However, CMS did provide some insight as to how it will measure the 250-yard radius. In discussing how a hospital may determine whether an off-campus PBD located near a remote inpatient campus is excepted under the 250-yard rule, CMS stated that any such PBD located within a straight-line distance of 250 yards from "any point of the physical facility that serves as the site of services of the remote location to any point in the PBD" will be excepted. This confirms CMS's longstanding practice of measuring from any exterior point and not necessarily the front door of a hospital facility. While this discussion occurred in the context of measuring the radius around a remote location, presumably the same logic would apply to mapping out the borders of a hospital's main campus – even if CMS did not define what exactly constitutes a "main building" from where that measurement would begin.

- CMS stated that it did not have the authority to except those off-campus PBDs that were "mid-build" (*i.e.*, under construction) prior to November 2, 2015. Commenters urged CMS to delay implementation of Section 603 until Congress passed the Helping Hospitals Improve Patient Care Act (H.R. 5273), which is pending in the U.S. Senate. CMS said that it did not have the authority to delay or to create an exception for mid-build departments.

The King & Spalding Government Advocacy and Public Policy practice group understands that the Senate Finance Committee is analyzing the impact of the Final Rule before taking up H.R. 5273. There is a possibility that this legislation is addressed after the November 8 election during the "lame duck" congressional session. Hospitals are strongly encouraged to work with their congressional delegations to move this legislation forward and to potentially include other provisions that address challenges created by CMS's policies in the Final Rule regarding relocations and changes in ownership.

King & Spalding will continue to monitor these legislative and regulatory developments as they unfold.