



CMS Issues Final Rule on Off-Campus Hospital Department Reimbursement

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UPDATE: Since this alert was drafted, President Obama signed into law the 21st Century Cures Act (H.R. 34). Beginning in 2018, the 21st Century Cures Act establishes an exception to Section 603's elimination of OPPS reimbursement for certain off-campus PBDs for facilities that were "mid-build" prior to November 2, 2015. To qualify for the exception, a provider (i) must have had a binding written agreement with an outside party for the construction of the facility prior to November 2, 2015; (ii) must submit, by December 31, 2016 or within 60 days after the enactment of the "mid-build" exception, a provider-based attestation for the facility; (iii) must submit, within 60 days after the enactment of the "mid-build" exception, written certification from the hospital's chief executive officer or chief operating officer that the facility was "mid-build" prior to November 2, 2015; and (iv) must include the facility as part of the provider on its enrollment form. Facilities that comply with the "mid-build" exception will be eligible for OPPS reimbursement effective January 1, 2018. In addition, effective January 1, 2017, the 21st Century Cures Act establishes an exception for PBDs of cancer hospitals that meet certain requirements.

As of January 1, 2017, hospitals will receive lower Medicare reimbursement for items and services provided at certain off-campus provider-based facilities. This Alert provides an overview of the new reimbursement framework for those off-campus facilities, as recently finalized by the Centers for Medicare and Medicaid Services (?CMS?).

Introduction

For a year, hospitals have been awaiting clarification on a key Medicare reimbursement issue: how will CMS reimburse certain hospital-operated outpatient facilities outside of the four walls of the hospital, known as provider-based departments ("PBDs")?

Historically, the services furnished by PBDs have been reimbursed under the Medicare Hospital Outpatient Prospective Payment System ("OPPS"). Although the Medicare regulations governing PBDs

distinguish between PBDs located on and off the hospital campus, both categories of PBDs have been eligible thus far for OPPS payment, as long as they comply with the relevant regulatory requirements[1]

Last fall, a new law was passed which significantly changed Medicare reimbursement of PBDs. Specifically, beginning in 2017, Section 603 of the Bipartisan Budget Act of 2015 (Section 603) prohibits OPPS payments for items and services furnished by certain off-campus PBDs[2] CMS has now issued its final rule (Final Rule)[3] and an accompanying interim final rule with comment period (Interim Rule,[4] and, together with the Final Rule, the Rule) outlining CMS's framework for implementing Section 603. The Rule, released November 1, 2016, and published in the Federal Register on November 14, 2016, specifies when and how much Medicare will pay for items and services provided at off-campus PBDs beginning in 2017. Section 603 and the key provisions of the Rule are summarized below.

The Rule is likely to have a significant impact on hospital campus development as hospitals attempt to maximize provider-based space in which OPPS-reimbursable services may be provided. New development will move closer to the hospital and existing on-campus parking areas, open spaces, and buildings housing non-hospital services may become particularly attractive for hospitals. Moreover, in close cases of buildings that do not meet the regulatory definition of "on campus" but are operated and held out as part of the hospital's campus development, hospitals may consider seeking a fact-specific determination from their regional CMS office as to whether CMS would consider a particular building to be located on the campus of the hospital. At the same time, hospitals will have to adjust to lower Medicare reimbursement for services furnished at their non-grandfathered off-campus PBDs.

Section 603 Summary

Section 603 excludes from OPPS coverage items and services furnished at certain off-campus PBDs effective January 1, 2017. Excluded from the legislation's reach are dedicated emergency departments, PBDs located on the campus of the hospital, and PBDs located within 250 yards from a remote location of a hospital facility. In addition, Section 603 establishes a grandfathering exception for off-campus PBDs that were furnishing OPPS-reimbursed items and services prior to November 2, 2015. Those PBDs may continue to bill for covered outpatient services under the OPPS if they meet certain requirements related to their location and ownership.

Rule Summary

Effective January 1, 2017, the Rule excludes from OPPS coverage all items and services that do not meet the definition of excepted items and services. Excepted items and services include those items and services furnished in:

1. an emergency department;
2. an on-campus PBD[5]
3. a PBD located within 250 yards from a remote location of a hospital facility; or
4. an off-campus PBD that was billing for covered OPPS services furnished prior to November 2, 2015, provided that the excepted off-campus PBD does not relocate impermissibly and does not experience an impermissible change of ownership.

Under CMS's finalized policy, excepted PBDs will be permitted to continue to bill for excepted items and services under the OPSS. Items and services furnished in non-excepted PBDs will no longer be eligible for payment under the OPSS. Instead, as set forth in the Interim Rule, those items and services will be reimbursed at newly established rates under the Medicare Physician Fee Schedule (MPFS).

Excepted On-Campus PBDs

Section 603 does not apply to on-campus PBDs. However, the distinction under Section 603 and the Rule between on-campus and off-campus makes the definition of what qualifies as "on-campus" more important than ever.

When is a PBD located on-campus??

Under existing regulations governing PBDs, the definition of "campus" includes "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."^[6] Although CMS received numerous comments during the rulemaking process requesting changes to the "campus" definition, it did not implement any such changes. Instead, the Final Rule emphasizes that the existing framework for determining when a PBD is located on campus, including the ability of regional CMS offices to exercise discretion in assessing a building's location, allows a "flexible and realistic approach to the configurations a hospital may adopt."^[7]

How are distances between buildings measured for purposes of on-campus location?

Historically, the ways in which regional CMS offices have measured the distance between the main building and the purported PBD have varied. Recent informal CMS guidance suggested that regional CMS offices were adopting a uniform wall-to-wall measurement policy whereby the starting point for the 250-yard measurement was a brick-and-mortar wall of the hospital building behind which billable inpatient services were furnished. The Final Rule suggests more flexibility for hospitals in measuring relevant distances, providing that measurements can be made from "any point of the physical facility that serves as the site of services."^[8] Although CMS discusses this approach only in the context of departments of remote locations of hospitals, the Final Rule does not impose more rigid measurement requirements on purported on-campus PBDs, instead simply deferring to the regional CMS offices' discretion. In addition, representatives of some CMS regional offices previously have suggested that they likely would apply any applicable measurement methodology consistently in both settings "i.e., in the context of both on-campus PBDs and PBDs of remote locations of hospitals. In short, if adopted by the regional offices, the "from any point" measurement methodology may be decisive in close cases, qualifying as "on-campus" certain PBDs that, under the wall-to-wall measurement approach, would be considered off-campus.

Can an on-campus PBD relocate off-campus and continue billing under the OPSS?

No. While an on-campus PBD will be treated as excepted, the PBD's subsequent relocation to an off-campus site would result in the PBD no longer being paid under the OPSS. The Rule does not

establish any exceptions to this categorical relocation bar.

Grandfathered Off-Campus PBDs

When is an off-campus PBD eligible for grandfathering?

In the proposed rule (Proposed Rule),^[9] CMS proposed to grandfather off-campus PBDs that furnished and billed for OPSS-covered items and services prior to November 2, 2015. The Final Rule broadens the scope of the grandfathering exception somewhat. Specifically, grandfathered status is available to PBDs that furnished OPSS-covered items and services prior to November 2, 2015, and billed for those services under the OPSS in a timely manner, even if after November 1, 2015.

What services can be provided in a grandfathered off-campus PBD and billed under the OPSS?

The Final Rule provides that a grandfathered off-campus PBD will receive payments under the OPSS for all billed items and services, regardless of whether it furnished such items and services prior to [November 2, 2015], as long as the excepted off-campus PBD remains excepted; that is, it meets the relocation and change of ownership requirements adopted in the Final Rule and discussed further below.^[10] The Final Rule is potentially more flexible than the Proposed Rule in defining the scope of services that can be provided and billed under the OPSS at a grandfathered off-campus PBD because the Proposed Rule's clinical families limitation was not incorporated into the Final Rule.

In the Proposed Rule, CMS proposed to establish certain clinical families of services and limit a grandfathered PBD's OPSS reimbursement to only those services within the clinical families of services that the PBD provided as of November 1, 2015. Services in a new clinical family of services would be ineligible for OPSS reimbursement. The concern underpinning CMS's proposal was that, absent a limitation on service line expansion, hospitals would be able to purchase additional physician practices and add those physician practices to existing excepted off-campus PBDs.^[11]

Recognizing that the proposed policy could be complex operationally and could pose an administrative burden on hospitals, CMS, and contractors in identifying, tracking, and monitoring billing for clinical services, CMS did not finalize the clinical families proposal. However, CMS intends to monitor service line growth at grandfathered PBDs and may propose limitations on the expansion of services or service lines in future rulemaking. CMS has requested public commentary on how potential approaches to such a limitation might work.

May a grandfathered off-campus PBD relocate and continue billing under the OPSS?

In general, no, unless CMS determines that relocation is necessary due to extraordinary circumstances.

Under CMS's interpretation of Section 603, PBDs (defined by the regulations as including both the specific physical facility and the personnel and equipment needed to furnish services at the facility) located off-campus are grandfathered only as they existed at the time [Section 603] was enacted.^[12] Accordingly, CMS believes that allowing unlimited relocation of a grandfathered off-campus PBD would result potentially in relocation to larger facilities with different equipment and staff and unbridled expansion of service lines, yielding an off-campus PBD that is remarkably different than it was prior to

November 2, 2015. In short, items and services must continue to be furnished and billed at the same physical address of the grandfathered off-campus PBD as was used as of November 2, 2015, in order for the off-campus PBD to be considered grandfathered.

Notably, in extraordinary circumstances outside of the hospital's control (such as natural disasters, significant seismic building code requirements, or significant public health or public safety issues), the Final Rule allows grandfathered off-campus PBDs to relocate without the loss of grandfathered status. The regional CMS offices will evaluate exceptions to the prohibition on relocation on a case-by-case basis. CMS anticipates such exceptions to be both limited and rare and intends to issue additional subregulatory guidance in the future.

May a grandfathered off-campus PBD expand its physical facilities?

Depending on the circumstances, yes. Although the Final Rule does not discuss expansion directly, CMS's commentary related to the relocation of grandfathered off-campus PBDs suggests that the PBD's physical expansion will not jeopardize the PBD's grandfathered status if that expansion does not change the grandfathered PBD's address (including suite number). Conversely, relocation to another suite number within the same building resulting in a new suite address for the PBD likely would be viewed as a prohibited relocation, thus jeopardizing the PBD's grandfathered status. On an industry stakeholder call following issuance of the Rule, CMS encouraged providers to direct specific questions related to space and suite expansion to the regional CMS offices.

Does grandfathered status survive a change of ownership?

In certain circumstances, yes. Grandfathered status will transfer to new ownership only if (i) ownership of the main provider also transfers and (ii) the Medicare provider agreement is accepted by the new owner. If the provider agreement is terminated, all grandfathered off-campus PBDs lose their grandfathered status.

Does a break in service affect an off-campus PBD's grandfathered status?

Most likely, no. CMS does not specifically address whether a break in operations by a grandfathered off-campus PBD affects the PBD's grandfathered status. While regional CMS offices may develop different approaches to address suspension of services, nothing in the Final Rule suggests that a break in service affects grandfathering.

How will non-excepted items and services be paid?

Section 603 provides that payment for non-excepted items and services furnished by off-campus PBDs shall be made "under the applicable payment system." In the Proposed Rule, CMS proposed to specify that "the applicable payment system" is the MPFS. Under that system, CMS would reimburse physicians furnishing services in non-grandfathered off-campus PBDs at the non-facility MPFS rate. CMS proposed not to reimburse hospitals at all, citing operational and logistical billing issues.

CMS did not finalize its MPFS reimbursement proposal. Instead, CMS issued the Interim Rule establishing new, site-specific rates under the MPFS for the technical component of all non-excepted

items and services to be paid directly to hospitals for non-excepted items and services furnished by non-excepted PBDs. The interim MPFS rates will be set at 50% of the OPPS rate for each non-excepted item and service, subject to the OPPS packaging rules and some exceptions (largely based on the OPPS payment policies for therapy, preventive services, and separately payable Part B drugs). Hospitals will bill for such items and services on the institutional claim form utilizing a new claim line modifier ? PN ? to indicate that an item or service is non-excepted while physicians will continue to bill separately for their professional services. Under the Interim Rule, CMS is seeking public comment on the new payment mechanism and will make adjustments as necessary.

Other Issues

Dedicated Emergency Departments: The Final Rule clarifies that all items and services furnished by dedicated emergency departments ? including emergency and non-emergency services ? remain reimbursable under the OPPS.

Mid-Build PBDs: In June 2016, the United States House of Representatives passed a bill that would reverse Section 603's imposition of site-neutral payments for off-campus PBDs that were ?mid-build? by November 2, 2015, and that meet certain requirements (such as a binding written agreement with an outside, unrelated party before November 2, 2015 for the actual construction of such PBD)[13] The bill was sent to the United States Senate and referred to the Committee on Finance on June 8, 2016. The future of the bill is uncertain. Despite commenters' requests, the Final Rule does not provide for an exception for off-campus PBDs that were mid-build as of November 2, 2015.

Impact On Participation In 340B Drug Pricing Program The Final Rule does not offer insights regarding whether non-excepted off-campus PBDs would be eligible as ?child sites? under the 340B drug program. In response to comments, however, CMS noted that services provided at such PBDs will continue to be reported on the hospital cost report.

Impact On Medicaid Reimbursement Despite commenters' requests, the Final Rule does not clarify the impact of Section 603 on Medicaid reimbursement. Instead, CMS referred commenters to the relevant state Medicaid agencies.

Provider-Based Status: In the Final Rule, CMS reiterates that non-excepted off-campus PBDs still are departments of a hospital, despite loss of reimbursement under the OPPS for non-excepted items and services. Thus, the hospital as a whole still is required to meet all applicable conditions of participation and regulations governing the PBD's provider-based status. Similarly, the supervision rules that apply to hospitals will continue to apply to non-excepted off-campus PBDs.

Data Collection: Hospitals are expected to maintain documentation sufficient to prove that an off-campus PBD is grandfathered. CMS warns providers that Medicare billing data alone may not be sufficient.

Note: This article contains a general, condensed summary of statutes, regulations, and opinions for information purposes. It is not meant to constitute, and should not be construed as, legal advice. For more information or if you have specific questions, please contact the authors.

[1] 42 C.F.R. §413.65 (2009).

[2] Bipartisan Budget Act of 2015, Pub. L. No. 114-74, Sec. 603., 129 Stat. 584, 597 *et seq.*

[3] Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital, 81 Fed. Reg. 79562, 79720 *et seq.* (Nov. 14, 2016).

[4] Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital, 81 Fed. Reg. 79562, 79699 *et seq.* (Nov. 14, 2016).

[5] The new regulatory definition of an excepted PBD, as reflected in the Rule, contains an error. Specifically, the definition seemingly excludes from Section 603's reach only those on-campus PBDs that were on campus as of November 2, 2015:

“excepted off-campus provider-based department” means a “department of a provider” (as defined at 42 C.F.R. §413.65(a)(2) of this chapter) that *as of November 2, 2015 was located on the campus* (as defined in §413.65(a)(2) of this chapter) or within the distance described in such definition from a “remote location of a hospital” (as defined in §413.65(a)(2) of this chapter) that meets the requirements for provider-based status under §413.65 of this chapter. This definition also includes a department of a provider that was billing under the OPPOS with respect to covered [outpatient department] services furnished prior to November 2, 2015.

Final Rule at 79880 (to be codified at 42 C.F.R. §419.48(b)) (emphasis supplied). As the Rule's drafters have confirmed, and as

reflected in CMS's commentary throughout the Rule, consistent with Section 603's language, all on-campus PBDs ? whether or not located on campus as of November 2, 2015 ? are excepted. CMS is working on revising the regulatory language accordingly.

[6] 42 C.F.R. §413.65(a)(2).

[7] Final Rule at 79702-79703.

[8] Id. at 79703.

[9] Payment to Certain Off-Campus Outpatient Departments of a Provider, 81 Fed. Reg. 45604, 45681 *et seq.* (July 14, 2016).

[10] Final Rule at 79707.

[11] Id. at 79706.

[12] Id. at 79704.

[13] Helping Hospitals Improve Patient Care Act of 2016, H.R. 5273, 114th Cong. (2016).

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