SQUIRE PATTON BOGGS

CMS Releases Final Rule Implementing Site Neutral Payment Rule

Earlier this month, Centers for Medicare and Medicaid Services (CMS) released final rules implementing Section 603 of the Bipartisan Balanced Budget Act of 2015 (the Final Rule). Section 603 effectively reduces Medicare compensation paid to certain off-campus hospital outpatient departments (HOPDs) beginning January 1, 2017 by eliminating HOPD eligibility for compensation under Medicare's Hospital Outpatient Prospective Payment System (OPPS). HOPDs that are not otherwise excepted will generally be compensated under the Medicare Physician Fee Schedule at rates that are roughly 50% of the OPPS rate for 2017.

Notably, the Section 603 payment provisions do not apply to HOPDs located on the campus of a hospital or a "remote location" of a hospital (as defined under 42 C.F.R. § 413.65) (On-Campus HOPDs). These On-Campus HOPDs will continue to be reimbursed for services under the OPPS. To be considered an On-Campus HOPD, the department must meet the following locational criteria:

- With respect to the main hospital facility, be within 250 yards of the hospital's main buildings or any other areas determined on an individual case-by-case basis by the regional office; or
- Be within 250 yards of a remote location of the hospital.

The Final Rule generally adopts most of the provisions contained in the proposed rules (the Proposed Rule) released earlier this year, with a few significant exceptions discussed below. The Final Rule also includes an Interim Final Rule establishing a mechanism for HOPDs to continue to bill directly for services. This is significant since CMS's Proposed Rule suggested that no such mechanism would be in place for 2017. This caused considerable concern among hospitals as it was unclear how they would be reimbursed for services performed.

Importantly, the 21st Century Cures Act (the Act), discussed in more detail below, may alter some of the provisions of Section 603 and, consequently, the Final Rule. The House passed the legislation this week, and the Senate is expected to follow suit next week.

Some of the Final Rule's significant provisions are as follows:

Grandfathered HOPDs and Emergency Departments – Under the Final Rule, HOPDs that *furnished and billed covered* services prior to November 2, 2015 (Grandfathered HOPDs) remain eligible for compensation under the OPPS after January 1, 2017 and are excepted from the "site neutral" payment limits implemented by Section 603. The Final Rule clarifies that a HOPD that first provided covered services before November 2, 2015, but did not bill for such services until on or after November 2, 2015, will be considered a Grandfathered HOPD, provided that the bills were submitted in accordance with timely filing limits and also provided the claims have been paid.

The Final Rule also provides a categorical exception from the site neutral payment limits implemented by Section 603 for dedicated emergency departments. All services provided at a dedicated emergency department, as defined under 42 C.F.R. 489.24(b), whether emergency or non-emergency, will continue to be eligible for payment under the OPPS.

Relocation of Grandfathered HOPDs – Relocating a Grandfathered HOPD will generally result in the loss of excepted status for the Grandfathered HOPD, precluding it from continuing to bill under the OPPS after the relocation. The Final Rule does provide limited exceptions to the relocation prohibition for reasons such as natural disasters, seismic building code requirements and safety issues. Rather than provide clearly defined exceptions, the Final Rule states that each claim for a relocation exception is to be evaluated on a case-by-case basis by the relevant CMS Regional Office.

Under the Final Rule, CMS adopted a broad view of what constitutes "relocation" for purposes of determining whether a Grandfathered HOPD may lose its grandfathered status. In CMS's view, Section 603 applies of HOPDs "as they existed at the time the law was enacted." Thus, any change in address of an HOPD as reported to Medicare on November 2, 2015 would likely be considered a "relocation." This includes moving into adjacent units in a multi-unit structure. CMS rejected proposals to permit relocation so long as the total number of HOPDs operated by a hospital remained the same or to adopt permissible relocation criteria similar to that applied to critical access hospitals. Instead, CMS adopted a policy of limited exceptions, noting that the granting of such exceptions should be "limited and rare" so as to not undermine the goal of "limiting the growth and expansion of [Grandfathered HOPDs]."

Expansion of Services at Grandfathered HOPDs – CMS will not implement its proposed restriction on service line expansion at Grandfathered HOPDs, at least for the time being. In the Proposed Rule, CMS discussed implementing a system of "clinical families" to determine whether new services provided at a Grandfathered HOPD would be eligible for reimbursement under the OPPS. In the Final Rule, CMS did not finalize this provision, but cautioned that it will monitor service line growth at Grandfathered HOPDs, and may propose a limitation in the future, including limitations on increases in service volume.

Change of Ownership (CHOW) of a Grandfathered HOPD – The Final Rule adopts the Proposed Rule's provisions regarding change of ownership transactions. Specifically, a Grandfathered HOPD will retain its excepted status in a CHOW transaction only if (i) ownership in the main hospital location is also transferred to the new owner and (ii) the new owner accepts the hospital's existing Medicare provider agreement. A sale of the Grandfathered HOPD alone will result in the loss of the Grandfathered HOPD's excepted status.

Payment for Non-Excepted Items and Services – Under the Proposed Rule, CMS suggested that it would not have a system in place by 2017 for HOPDs to bill under the Medicare Physician Fee Schedule. The Final Rule (through an Interim Final Rule) addresses this issue by implementing a payment system for HOPDs that will permit them to continue billing Medicare directly for 2017. Under the Interim Final Rule, for 2017 non-excepted HOPDs will be able to bill for services directly, receiving payments at MPFS rates that are roughly half of the current OPPS rates. Although payments will be made at MPFS rates, CMS will still apply the same packaging rules as under the OPPS.

CMS anticipates updating the rates for 2018, and will explore other payment methods for implementation in 2019. Under this system, services provided at non-excepted HOPDs will continue to be reported on the hospital's cost report, which should mitigate concerns regarding whether non-excepted HOPDs would still be considered "child sites" for 340B purposes.

HOPDs Under Development – The Final Rule does not contain any provision providing exceptions for HOPDs that were mid-build or under development (and thus, not furnishing services) as of November 2, 2015. Absent a legislative remedy (such as through the 21st Century Cures Act discussed below), these HOPDs will not be eligible for reimbursement under the OPPS.

Although the Final Rule does not provide any exception for mid-build or under development HOPDs, sections 160001 and 160002 of the 21st Century Cures Act may provide some relief if passed. Under the Act, HOPDs that (i) are the subject of a binding written agreement for construction, prior to November 2, 2015, with an outside unrelated party; and (ii) submit a provider-based attestation within 60 days of the Act's enactment, will be considered Grandfathered HOPDs, and will be eligible for compensation under the OPPS. The Act also contains certain exceptions for cancer hospitals. The House passed the legislation this week, and the Senate is expected to act on it in December.

While the Final Rule addresses many issues regarding implementation of Section 603, other questions remain. For example, given CMS's insistence that Section 603 applies to outpatient departments as they existed at the time of Section 603's enactment, what is the impact of the expansion of a Grandfathered HOPD's footprint without a change in address? While CMS's language suggests this could be problematic to maintaining grandfathered status, the Final Rule appears to contain no provisions that would prohibit this. Additionally, the Final Rule does not address the impact on "under arrangements" agreements between hospitals and service providers.

CMS is soliciting comments regarding the Final Rule concerning the payment system, limitations on increases service volume among Grandfathered HOPDs and other issues. Parties interested in submitting comments to CMS regarding the Final Rule's provisions will have until December 31, 2016 to submit such comments.

If you would like to discuss the implications of the Final Rule for your business, please speak to one of the individuals listed in this publication or your firm contact.

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