Proposed Rule Implementing Section 603 of the Bipartisan Budget Act of 2015 Dashes Hospitals' Hopes

July 20, 2016

On July 6, 2016, the Centers for Medicare & Medicaid Services (CMS) issued its highly anticipated CY 2017 Hospital Outpatient Prospective Payment System Proposed Rule (the Proposed Rule). Among the items addressed in the Proposed Rule is the implementation of Section 603 of the Bipartisan Budget Act of 2015 [1] (Section 603), which amended the Social Security Act to exclude from payment under the hospital outpatient prospective system (OPPS) effective January 1, 2017, applicable items and services furnished at off-campus outpatient provider-based departments (PBDs) that began billing on or after November 2, 2015, except for items and services furnished by a dedicated emergency department. Section 603 provides that these items and services excluded from OPPS will be paid under another applicable payment system such as the Medicare Physician Fee Schedule or the Ambulatory Surgery Payment System.

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Hospitals were hopeful that the Proposed Rule would answer some questions left uncertain by the blunt statutory language of Section 603 and offer relief from its harsh effects, such as the effect on hospitals in the middle of constructing new off-campus PBDs at the time of its enactment. However, if the Proposed Rule is finalized as currently drafted, hospitals will not be able to bill under OPPS for items and services furnished in new off-campus PBDs, nor will they be able to relocate or expand services furnished at off-campus PBDs that existed at the time of the enactment of Section 603 without losing the ability to bill under OPPS. Hospitals and other industry stakeholders can submit comments on the Proposed Rule through September 6, 2016.

Exception for certain outpatient provider-based departments

Section 603 excludes from receiving reimbursement under OPPS items or services furnished at off-campus PBDs that began billing under OPPS on or after November 2, 2015, except for the following:

- Exception for items and services furnished in a dedicated emergency department. Section 603 specifies that for purposes of its exclusion from OPPS reimbursement for off-campus PBDs, "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department. [2] CMS is proposing that all services furnished in a dedicated emergency department, whether or not they are emergency services, be exempt from Section 603's reimbursement limitation. Thus, all services provided in a dedicated emergency department would remain eligible for payment under OPPS.
- Exception for locations within the distance of a remote location. Section 603 defines "off-campus outpatient department of a provider" as a department of a provider that is not located on the campus of the provider or "within the distance from a remote location" of a hospital facility. To implement this part of Section 603, CMS is proposing to use the existing provider-based rule's definitions of "campus" and "remote location". In the Proposed Rule, CMS clarifies that "within the distance of a remote location" of a hospital means within 250 yards of the remote location measured by a straight line from the off-campus PBD to the remote location. [3] CMS is referring to these locations as "excepted PBDs."
- Other exceptions. The reimbursement limitations imposed by Section 603 also do not apply to on-campus PBDs or to a second inpatient campus of a hospital (i.e., remote location), satellite facilities or rural health clinics.

CMS is seeking public comments on the type of information that is needed to identify non-excepted PBDs for purposes of Section 603.

Relocation of excepted off-campus PBDs

Among the questions unanswered by Section 603 is whether excepted locations can

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relocate and keep their excepted status. In the Proposed Rule, CMS clarifies its position that Section 603 applies to off-campus PBDs as they existed at the time of its enactment, and only excepts those items or services furnished and billed by excepted off-campus PBDs as of that date. CMS is concerned that if it permits excepted off-campus PBDs to relocate and still remain excepted, hospitals would be able to relocate the excepted off-campus PBDs to larger facilities and expand the services receiving OPPS rates in those locations. For example, they could purchase additional physician practices and move them into the relocated off-campus PBDs. As a result, CMS is proposing that excepted off-campus PBDs, and the items and services furnished there, would no longer be excepted if an off-campus PBD relocates. CMS is proposing a strict interpretation of this standard, stating that the unit number or suite number would be treated as part of the address, thereby preventing an excepted off-campus PBD from purchasing and expanding into additional units or suites in the same building and receiving OPPS reimbursement for items or services furnished in the new units or suites. Under CMS' proposal, if an excepted off-campus PBD moves from the address on the hospital's enrollment form (even by moving to or expanding into a new unit or suite in the same building), items or services furnished at the new address would not be excepted and would no longer be entitled to payment at OPPS rates.

In response to hospitals' concerns that there may be circumstances when an excepted off-campus PBD may need to relocate, CMS is seeking comments on whether it should develop a clearly-defined, limited relocation exception only for circumstances beyond the hospital's control, such as a natural disaster or other extraordinary circumstances. CMS is also seeking comments on whether it should consider exceptions for any other circumstances that are completely beyond the control of the hospital.

Expansion of clinical family of services at an excepted off-campus PBD

Another question unanswered by Section 603 is whether an excepted off-campus PBD can add or change the items or services furnished at the location. Reiterating its position that excepted status only applies to the items and services furnished by the excepted off-campus PBD as they were being furnished when Section 603 was enacted, CMS is proposing that an off-campus PBD's ability to bill under OPPS is limited to those items or services it was furnishing prior to November 2, 2015. To implement this, CMS is proposing that any items or services that are not part of a "clinical family" (a new term used in the Proposed Rule) of services furnished and billed under OPPS by the excepted off-campus PBD prior to November 2, 2015, would not be payable under OPPS. CMS identified 19 clinical families and their respective APCs in Table 21 of the Proposed Rule. (See Attachment 1 at the conclusion of this publication.) CMS is not limiting the volume of excepted items and services within a clinical family that an excepted off-campus PBD can furnish, however.

In reaching its proposal, CMS considered how expanding services at an excepted off-campus PBD could affect payment to physicians' offices purchased after November 2, 2015. CMS raised concerns that if excepted off-campus PBDs could expand the types of services provided at the location and also receive OPPS rates for new types of services, hospitals could purchase more physician practices and add those physicians to excepted off-campus PBDs. This would result in new physician practices furnishing services at OPPS rates at an excepted location after Section 603's enactment date, which CMS believes Section 603 was intended to prevent. CMS is seeking comments on whether it should adopt a specific timeframe in which services must have been billed before November 2, 2015, to qualify as an excepted clinical family, such as, for example, CY 2013 through November 1, 2015.

Change of ownership of excepted off-campus PBDs

Under the Proposed Rule, an excepted off-campus PBD would lose its excepted status if there is a change of ownership of the PBD unless the new owner also acquires the main hospital (and not just the PBD) and the new owner agrees to accept the main hospital's existing Medicare provider agreement. This means that:

- individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain their excepted status; and
- if the buyer of the main hospital and associated off-campus PBDs terminates the existing Medicare provider agreement rather than accepting it, the previously-excepted off-campus PBD, and all excepted items and services furnished in the excepted off-campus PBD, will no longer be excepted from Section 603's payment limitations and will not receive OPPS rates.

Payment for applicable items and services furnished in non-excepted off-campus PBDs

Under Section 603, items and services furnished in non-excepted off-campus PBDs will not be covered under OPPS and, as a result, will not be eligible for a facility fee payment [4] under OPPS. Section 603 provides that payment for applicable items and services that are not covered under OPPS shall be made under an applicable payment system under Medicare Part B. The challenge is that Section 603 does not designate a specific "applicable payment system," and CMS says it cannot at this time propose an alternate mechanism for an off-campus PBD to bill and receive payment for applicable items and services furnished on or after January 1, 2017. Instead, CMS is proposing that the applicable payment system be the MPFS, which is not available to hospitals. CMS offered two temporary options for hospitals to bill for non-excepted items and services in 2017.

One option is for physicians to bill and be paid at the non-facility rate for providing non-excepted items and services in an off-campus PBD. However, under this option, there will be no accompanying Medicare facility payment for hospitals to bill for non-excepted items and services furnished in those locations, because there will be no

payment system available for billing non-excepted off-campus PBD services under the MPFS as of January 1, 2017. Rather, for hospitals to receive payment in 2017 for any non-excepted items and services furnished in off-campus PBDs, hospitals must enter into Stark-compliant arrangements with the physicians who will be billing under the MPFS at the non-facility rate, which includes payment for the practice expense. Hospitals will need to develop a formula to receive a share of the non-facility payment the physicians will receive. Hospitals will have only a few months to negotiate these arrangements with the physicians furnishing services in their off-campus PBDs, which may be challenging, particularly for arrangements involving independent physicians.

The second temporary option CMS is suggesting is that an off-campus PBD could enroll as a freestanding facility or supplier, such as an Ambulatory Surgery Center (ASC) or physician group practice, which could bill and be paid under the payment system for that type of entity. As with the first option, hospitals may not have enough time to become certified as an ASC before January 1, 2017. Given the tight timeline to determine the best option for 2017 and to take the necessary steps to implement the option, many hospitals may find they are without any way to bill for non-excepted items and services in 2017.

340B Program implications

The Proposed Rule is silent regarding Section 603's impact on 340B Program child site eligibility for off-campus PBDs. Under the 340B Program, child sites must report Medicare-reimbursable outpatient costs and charges on the hospital's Medicare cost report, which requires the location to meet the provider-based requirements. Hospitals are concerned that items or services furnished in non-excepted locations may no longer meet the 340B Program eligibility criteria because they will not be paid under OPPS in 2017, and, as a result, they may not be included in the hospital's cost report. It remains unclear, however, whether the Health Resources and Services Administration Office of Pharmacy Affairs, which administers the 340B Program, may change its child site and/or patient eligibility criteria in light of Section 603's impact.

Attachment 1

CMS-1656-P

TABLE 21.—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical Families	APCs
Advanced Imaging	5523-25, 5571-73, 5593-4
Airway Endoscopy	5151-55
Blood Product Exchange	5241-44

Cardiac/Pulmonary Rehabilitation	5771, 5791
Clinical Oncology	5691-94
Diagnostic tests	5721-24, 5731-35, 5741-43
Ear, Nose, Throat (ENT)	5161-66
General Surgery	5051-55, 5061, 5071-73, 5091-94, 5361-62
Gastrointestinal (GI)	5301-03, 5311-13, 5331, 5341
Gynecology	5411-16
Minor Imaging	5521-22, 5591-2
Musculoskeletal Surgery	5111-16, 5101-02
Nervous System Procedures	5431-32, 5441-43, 5461-64, 5471
Ophthalmology	5481, 5491-95, 5501-04
Pathology	5671-74
Radiation Oncology	5611-13, 5621-27, 5661
Urology	5371-77
Vascular/Endovascular/Cardiovascular	5181-83, 5191-94, 5211-13, 5221-24, 5231-32
Visits and Related Services	5012, 5021-25, 5031-35, 5041, 5045, 5821-22, 5841

[1] Pub. L. 114-74. Section 603

[2] A "dedicated emergency department" is defined in the existing Emergency Medical Treatment and Active Labor Act regulations.

[3] Any facility that is not located on the main campus, whether it provides only outpatient services or outpatient and inpatient services, is considered "off-campus" under the provider-based rule. Thus, while Section 603 excepts off campus PBDs that are located within 250 yards of a remote location of a hospital from the definition of "off-campus outpatient department of a provider" for purposes of OPPS reimbursement, these excepted PBDs are still "off-campus" for purposes of complying with the provider-based rule.

[4] Under existing Medicare policy, Medicare makes two types of payments for most items and services furnished in an off-campus PBD: (1) payment for the items or services furnished by the facility where the services is performed to cover things like the surgical supplies, equipment and nursing services provided by the facility (the

"facility fee"), and (2) payment for the physician's professional services (the "professional fee"). The facility fee is paid under OPPS, and the professional fee is paid under the Medicare Physician Fee Schedule (MPFS) at the facility rate to reflect that a payment was also made to the facility.