PUBLICATION

CMS Adopts Important "Site-Neutral" Changes to Payment Rules

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CMS took another step in its campaign to impose "site neutrality" on hospital outpatient payments with its recently published final Medicare hospital Outpatient Prospective Payment System (OPPS) rule for CY 2019. The final rule reduces payments for "clinic visits" furnished in excepted off-campus locations and for 340B-acquired drugs and biologicals furnished in non-excepted, off-campus hospital departments. Notably, however, CMS did not adopt its proposed policy that would have applied the site neutrality reductions to new services – that is, services that were not part of the same clinical family of services furnished in excepted off-campus locations in 2015.

These adopted changes will have a significant impact on hospitals' finances starting January 1, 2019. According to CMS estimates, the clinic visit policy change alone will eventually reduce Medicare OPPS payments to hospitals by 1.2 percent, with that impact being greater for some hospitals. Hospitals, therefore, should give the new rule their close attention.

Background

Hospitals have long tried to expand their footprints by developing, or in many instances acquiring, physician practices, and other medical operations to furnish hospital outpatient services beyond the immediate vicinity of the hospital's campus. The hospitals have seen many advantages in doing this, including expanding the hospital's name recognition with existing and potential patients, providing "hospital-level" services across a wider geographic area, cementing relationships with a broader network of physicians, and, of course, obtaining "hospital-level" reimbursement with a facility fee on top of the professional fee.

These expansion efforts have come under increased criticism, and in late 2015, Congress enacted § 603 of the BBA 2015 that changed the payment rules applicable to "new" off-campus, provider-based locations so that the payment for those hospital outpatient services are more "site-neutral," meaning closer to parity with freestanding sites of service. Section 603 specified that off-campus sites that had not furnished services and submitted "provider-based" billings to Medicare prior to November 2, 2015, would be considered "new" and, effective January 1, 2017, would no longer be paid by Medicare at OPPS rates. Rather, those hospital outpatient locations would be paid under the "applicable payment system" associated with a corresponding free-standing operation. Congress, however, excluded from this payment reduction items and services furnished by dedicated emergency departments as defined in 42 C.F.R. § 489.24(b) and provided an exception for off-campus locations that were billing Medicare under the OPPS system prior to November 2, 2015, that is, that were "grandfathered."

The provisions of § 603 required implementing regulations, and in the summer of 2016, CMS published its proposed rules implementing that section. Among the proposals was one to expand § 603 payment reductions to include not just "new" off-campus locations, but also "new" services furnished in grandfathered or excepted locations. More specifically, CMS proposed that if an excepted off-campus, provider-based location furnished services that it had not furnished and billed for prior to November 2, 2015, and if those services were not from the same clinical family of services that it had furnished and billed for prior to November 2, 2015, CMS would not pay for the new services at OPPS rates, but instead would make payments in accordance with the new payment limitations. CMS then proposed to define service types by referring to 19 clinical families of hospital outpatient services. Ultimately, however, CMS did not adopt this "new" service proposal. Thus, under the

CY 2017 rule and continuing in 2018, excepted off-campus, provider-based departments have been paid OPPS rates for all billed items and services furnished in those excepted locations, regardless of whether those services were furnished in those locations prior to the enactment of § 603. (For background, see our earlier articles, "CMS Final Rule and 21st Century Cures Act Include Good and Bad News for Provider-Based Sites," and "CMS Proposes Major 'Site-Neutral' Changes for Off-Campus Locations.")

Earlier this year, CMS proposed new "site-neutral" changes. See our article "CMS Proposes Major 'Site-Neutral' Changes to Payments for Off-Campus Locations." In its recently published final rule, as described below. CMS has adopted some, but not all, of its proposals.

CMS's CY 2019 Final Rule

1. Hospital-Based Clinic Services Reimbursed Under OPPS

For much of the past decade, the Medicare program expenditures for OPPS have continued to increase at a rate of roughly eight percent per year, making OPPS the fastest growing Medicare payment system of all payment systems. In its proposed rule, CMS opined that this rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, may be affecting the choice of site-of-service. In support, CMS cited to past MedPAC reports in which MedPAC observed that one-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as hospital outpatient services, and that from 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent. Supported by these MedPAC statistics, CMS stated its belief that (1) the increase in the volume of hospital clinic visits has been due to the payment incentives to provide services in a higher cost setting; (2) the services generally could be safely provided in a lower cost setting; and (3) the growth, therefore, has been unnecessary.

To address this issue, CMS proposed and has now decided to use its authority under § 1833(t)(2)(F) of the Social Security Act (42 U.S.C. § 1395l(t)(2)(F)) to lower payments for clinic E&M visits furnished in excepted off-campus hospital departments to an amount equal to the payment rate for items and services furnished by non-excepted, off-campus, provider-based departments. In other words, hospital clinic visits for the evaluation and management of patients - HCPCS Code G0463 - if furnished in an off-campus outpatient department, will be paid at the non-excepted location rate regardless of whether that department is a "new" location under § 603 of BBA 2015 or an "excepted" location. This is a significant change: the code represents 50 percent of all separately payable or conditionally packaged services furnished in outpatient departments every year. The changes will be phased in over a two-year period, with an initial \$380 million cut in 2019 and a further \$760 million cut in 2020.

Notably, the American Hospital Association (AHA) and the Association of American Medical Colleges (AAMC) have filed suit challenging this reduction.

2. Reductions in Payments to Non-Excepted Departments for 340B-Acquired Drugs and Biologicals

CMS mandated last year that, effective January 1, 2018, excepted off-campus hospital outpatient departments would be paid for 340B drugs and biologicals at a rate of average sales price (ASP) minus 22.5 percent. In the 2019 rule, CMS has now decided to extend its "ASP minus 22.5 percent" payment policy for 340B-acquired drugs and biologicals to apply to non-excepted, off-campus locations as well. This is a substantial reduction from the current ASP plus six percent rate. The change does not apply to critical access hospitals, sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals.

3. Collecting Data Related to Services Furnished by Off-Campus, Provider-Based Emergency **Departments**

In recent years there has been significant growth in the number of off-campus facilities that are devoted to furnishing emergency department services. This growth has raised guestions among regulators and others regarding whether hospitals may be moving services to the higher acuity / higher cost emergency department settings largely to obtain the higher payment rates for those services and to take advantage of the exemption under § 603 of BBA 2015 for services provided in dedicated emergency departments. In the proposed rule, CMS stated that it will require, effective January 1, 2019, that hospitals add a new HCPCS modifier "ER" on the UB-04 form for hospital outpatient services furnished in off-campus emergency departments so that CMS can track the incidence of services furnished in that setting. CAHs will not be required to do this.

CMS's actions could lead to lower OPPS payment rates for ED services in the coming years. Prior to the enactment of § 603 of the BBA 2015, CMS required that hospitals identify, through the use of a modifier, hospital outpatient services furnished in the provider-based, off-campus departments. Then in the BBA 2015, Congress reduced reimbursement for a number of those off-campus services. One might anticipate, therefore, that CMS may use the information that it collects from the use of this new modifier to seek future statutory or regulatory limitations on hospitals' receipt of full OPPS payment amounts for services provided in providerbased, off-campus emergency departments.

4. No New Payment Limits on Expansion of Services Furnished in Excepted Locations

Not all of the news coming out of the 2019 OPPS final rule was bad, however. As noted above, in the 2016 proposed regulation implementing § 603 of BBA 2015, CMS put forward the idea that services furnished in excepted outpatient departments would be reimbursed under the OPPS rates only if they were in the same clinical family of services that the particular location had provided and billed for prior to November 2, 2015. Most commenters were strongly opposed to this suggestion, raising both legal and practical concerns relating to its implementation. Hearing these concerns, CMS backed away from its proposal in the CY 2017 final rule, but it signaled that it might later revisit the issue.

In the CY 2019 proposed rule, CMS once again advanced its "same clinical family" proposal, and once again the commenters were largely opposed. In its response in the final rule, CMS has now again backed away from this proposal, just as it had done in 2016.

Implications for Providers

In the final OPPS rule, CMS has adopted two policies that will have a significant impact on hospital outpatient payments and the development of off-campus, provider-based departments, and one policy that could lead to future reductions.

- First, the rule will substantially cut payment amounts for clinic-based E&M services furnished in the hospital outpatient department setting if that setting is off the hospital's main campus. Once fully implemented, this change alone could reduce hospitals' OPPS payment by 1.2 percent or more.
- Second, CMS will extend its controversial payment limit for 340B-acquired drugs and biologicals so that the limit applies not just to excepted, off-campus locations but to non-excepted locations as well.
- Finally, CMS will track services provided in hospital off-campus emergency departments, suggesting that services in those areas, too, might become subject to future payment cutbacks.

Further, CMS has evidenced every intent to make further site-neutral reductions in the future. Hospitals must stay tuned.

For further information, please contact any member of Baker Donelson's Reimbursement Team.