Off-Campus Hospital Outpatient Departments Take Another Hit in CMS Final Rule

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On November 2, 2018, CMS released an on-line display copy of <u>its Outpatient Prospective Payment</u> <u>System (OPPS) Final Rule</u> implementing payment changes effective January 1, 2019. The official Federal Issuance is expected on November 21, 2018. One anticipated set of changes in the Final Rule is related to off-campus outpatient hospital departments (OCODPs).

Background

Medicare reimbursement for these provider-based OCODPs has been under a sustained attack on multiple fronts for the past three years, starting with Section 603 of the <u>Bi-partisan Budget Act of 2015</u>, which drew a line in the sand that as of November 2, 2015, most OCODPs (with a couple of exceptions) not billing under OPPS prior to that date would be subject to significant payment reductions from Medicare. The grandfathered OCODPs are referred to as "excepted" from the payment reductions, and the others are considered "non-excepted." Congress <u>softened the impact of Section 603</u> slightly the following year in the 21st <u>Century Cures Act</u>. This change allowed for the protection of grandfathered status for cancer hospitals and also OCODPs that were in the process of a "mid-build" in 2015 so long as they made certain filings by a February 11, 2017 deadline. (Audits of these mid-build attestations by a contractor are underway and expected to be concluded by the end of 2018.)

CMS <u>finalized its Section 603</u> Payment Policy in the November 3, 2016 regulation setting reimbursement for the non-excepted OCODPs at 50% of the OPPS rate, subsequently further reduced to 40% of the OPPS rate (82 Fed. Reg. 53028 (Nov. 3, 2016)). Still, CMS indicated that further limitations on reimbursement for OCODPs were under consideration.

Over the past few years, as CMS has been reducing reimbursement for OCODPs, it has also been implementing significant reductions in payment for separately payable drugs billed through the OPPS system when those drugs are purchased under the 340B Program. The goal of these reductions is to reduce Medicare payments to approximate the reduced prices hospitals pay for drugs under the 340B Program. Since January 1, 2018, separately payable OPPS drugs purchased under 340B have been reimbursed at a rate equal to the Average Sales Price (ASP) minus 22.5% (as contrasted to

reimbursement at ASP plus 6% for non-340B drugs). The OPPS reductions for 340B drugs are "budget neutral," meaning that the cost savings associated with reduced reimbursement for 340B drugs increase payments for other services reimbursed under the OPPS. In last year's (CY 2018) OPPS, CMS' 340B payment policy was *not* applied to non-excepted OCODPs (*i.e.*, those OCODPs with reimbursement reduced to 40% of OPPS). However, CMS indicated that it was considering extending the rate cuts to non-excepted OCODPs.

Signaling its view that CMS didn't think Congress went far enough, in the CMS Proposed Rule for cost year 2019, <u>several additional proposals were considered</u> to apply a number of payment reductions to both excepted and non-excepted OCODPs and to further extend the 340B cuts to OCODPs. The Final Rule displayed on November 2nd implements the most controversial of these proposals, each of which is addressed in our August 2018 blog entries on the Proposed Rule.

Payment Reductions for Clinic Visits for all OCODPs – Grandfathered or Not

Effective January 1, 2019, CMS will implement payment reductions for excepted OCODPs for hospital outpatient clinic visit for assessment and management of a patient ("clinic visits" described at HCPCS code G0463). These services are the most common hospital outpatient services billed to Medicare. What this means is that for these outpatient clinic visits, when performed in an off-campus setting, Medicare will apply the same payment reduction methodology for both grandfathered and non-grandfathered OCODPs.

The payment reduction will be phased-in over two years, with a 30% reduction for CY 2019 and a 60% reduction for CY 2020 and thereafter.

340B Payment Reduction

Also effective January 1, 2019, CMS will reduce payment for separately payable drugs purchased under 340B and dispensed at a non-excepted OCODP to ASP minus 22.5%. With this reduction, CMS has created parity in reimbursement for 340B drugs furnished at non-excepted and excepted OCODPs, as illustrated in the table below.

Reimbursement for 340B Hospitals of Drugs that are Separately Payable under the OPPS and Purchased under 340B

CY	Site-Neutral HOPD	Other HOPD
2017	ASP + 6%	ASP + 6%
2018	ASP + 6%	ASP – 22.5%
2019	ASP – 22.5%	ASP – 22.5%

However, CMS has now created a significant disparity between reimbursement for separately payable 340B drugs dispensed at a non-excepted OCOPD of a 340B hospital and drugs paid through the physician fee schedule. As a result of the 340B cuts, non-excepted OCOPDs that purchase drugs under the 340B program will now be reimbursed significantly less than a freestanding physician office for separately payable drugs.

Limitations on Grandfathered Sites to Same "Clinical Families of Services" NOT Imposed

One proposal <u>under consideration in the Proposed Rule Link</u> that CMS elected not to implement would have further limited the services excepted from the Section 603 payment reductions to only those services the grandfathered OCODP provided during a one-year baseline period prior to November 2, 2015. This is a relief to hospitals that would have had to live with their grandfathered OCODPs frozen in 2015 indefinitely.

What do the New Medicare Changes Mean for the Hospital Community?

Future plans for outpatient services should recognize that more services will need to be performed oncampus in order to receive fair reimbursement from the Medicare program. On-campus outpatient departments are not affected by the OPPS payment reductions described above.

Hospitals should consider seeking litigation challenging the application of these payment reductions to OCODPs. Congress drew a bright line in 2015 grandfathering facilities in operation prior to November 2, 2015, and directed CMS to reduce reimbursement to new OCODPs. By choosing to impose payment reductions on the excepted OCODPs as well as the non-excepted, CMS has improperly expanded the direction and authority provided in the statute.

Similarly, the new 340B rate reductions for non-excepted OCODPs are inconsistent with Congress' direction to pay non-excepted OCODPs the amounts they would receive under other applicable payment systems, such as the physician fee schedule. Because the physician fee schedule is not subject to 340B rate reductions, CMS may have overstepped in its authority in reducing rates below what a comparable physician's office would receive. CMS' proposal to reduce Medicare reimbursement for 340B drugs was not directed by Congress, and is currently being challenged in court.

What to do Next?

Significant payment reductions for millions of Medicare transactions will commence as of January 1, 2019, with deeper cuts rolling out in 2020. Hospitals that have budgeted for outpatient services, buildouts, staffing, and other costs anticipating Medicare reimbursement based on those costs will need to reopen those budgets due to Medicare's rate cuts. In addition, hospitals that had counted on savings from the 340B program to continue to make non-excepted OCODPs financially viable will need to reevaluate in light of the proposed reductions.

The American Hospital Association <u>promptly issued a press release</u> that it, the Association of American Medical Colleges, and individual hospitals will bring a court challenge as "[t]hese actions clearly exceed the administration's legal authority." Hospitals and Health Systems should consider participating in this process, as well as informing their Congressional delegations about the impact this will have on operations and budgets. We have heard from some hospitals that the financial harms of these activities will be in the millions of dollars – and the delegations need to know this.

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National Law Review, Volume VIII, Number 318

Source URL: <u>https://natlawreview.com/article/campus-hospital-outpatient-departments-take-another-hit-cms-final-rule</u>