340B Health Analysis

Part B Drug Payment Reduction to 340B Hospitals in 2018 Hospital Outpatient Prospective Payment System (OPPS) Final Rule

November 7, 2017

On November 1, 2017, the Centers for Medicare and Medicaid Services (CMS) released a Final Rule (Final Rule) that reduces payment to certain 340B hospitals for separately payable Part B drugs without pass-through status by nearly 30 percent. Such drugs are currently reimbursed at Average Sales Price (ASP) plus 6%, the same rate that is used for non-340B hospitals. The Final Rule, which updates calendar year (CY) 2018 payment rates for the Medicare Hospital Outpatient Prospective Payment System (OPPS), reduces the payment rate to ASP minus 22.5%, which was the rate included in CMS’s Proposed Rule issued on July 13, 2017. In a change from the Proposed Rule, the Final Rule includes exceptions from the payment reduction for certain types of 340B hospitals. CMS will redistribute the savings from the payment reduction by increasing the payment rate to all hospitals paid under the OPPS for non-drug items and services. The Final Rule will require all 340B hospitals to use modifiers to identify 340B drugs billed under the OPPS, including one for 340B hospitals that are subject to the payment reduction and a separate informational modifier for 340B hospitals that are not subject to the payment reduction. The payment reduction and the modifier requirements will take effect January 1, 2018.

340B Health submitted comments to CMS strongly opposing the proposed payment reduction to 340B hospitals and engaged Members of Congress, asking them to contact CMS in opposition to the proposal. A bipartisan group of 228 members of the House of Representatives wrote to CMS opposing the payment reduction, and 57 Senators also wrote expressing concern.

340B Health is now taking additional actions to stop the cuts, which include working with Congress to prevent the payment reduction from going into effect. Several hospital groups have also announced plans to challenge the payment reduction in court. We will provide updates to members in the coming weeks on how hospitals can support these efforts.

In the meantime, hospitals should be prepared to comply with the new requirements under the Final Rule by January 1, 2018.
Impact of the Final Rule

340B Hospitals Subject to Reduced Reimbursement

The payment reduction will apply to 340B hospitals that are designated by Medicare as a disproportionate share (DSH) hospital or rural referral center (RRC), unless a hospital meets the definition of a rural sole community hospital (SCH) under 42 § CFR 412.92. Effective January 1, 2018, DSH hospitals and RRCs (not including rural SCHs) will be reimbursed for separately payable Part B drugs without pass-through status billed under the OPPS at ASP – 22.5% instead of ASP + 6%.

340B Hospitals Not Subject to Reduced Reimbursement

The payment reduction will not apply to critical access hospitals (CAHs) participating in 340B, as they are not reimbursed under the OPPS. In a departure from the Proposed Rule, the Final Rule includes an exception from the payment reduction for children’s hospitals, PPS-exempt cancer hospitals, and rural SCHs “as described under the regulations at 42 § CFR 412.92 and designated as rural for Medicare purposes.” It appears that hospitals with a rural SCH designation for Medicare purposes will be excepted from reduced reimbursement even if they are enrolled in the 340B program as a DSH or RRC. These exceptions will be in place for CY 2018, but CMS believes further study is warranted and may revisit its exception policy for rural SCHs and other hospital designations in its OPPS regulation for CY 2019.

Drugs Subject to Reduced Reimbursement

CMS will reduce Part B reimbursement under the OPPS to the affected 340B hospitals for separately paid drugs without pass-through status, which includes most separately paid drugs. Affected drugs are those paid under HCPCS codes with a status indicator of “K” (i.e., non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals). You can find the affected HCPCS codes with a status indicator of “K” in the full list of HCPCS codes included in Addendum B of the Final Rule, which can be downloaded here (note that some drugs may be vaccines that may not be affected by the payment cut).

Drugs Not Subject to Reduced Reimbursement

The payment reduction will not apply to drugs that receive “pass-through” payment status (indicator “G”) or vaccines (status indicator “L” or “M”) and other non-340B drugs. Drugs and biological products that have “pass-through” status are new drugs that have not yet been accounted for in Ambulatory Payment Classifications (APCs) under the OPPS. A list of the 50 drugs and biologicals with pass-through status for CY 2018 or have been granted pass-through payment status as of January 2018 can be found in Table 70 on page 491 of the Final Rule. The payment reduction will generally not apply to retail drugs, including those dispensed by 340B contract pharmacies, as they are not paid under the OPPS.

The payment reduction will not apply to drugs furnished in new off-campus hospital outpatient departments that are no longer paid under the OPPS in accordance with Section 603 of the Bipartisan Budget Act of 2015. However, CMS notes that it may consider adjusting payment for such drugs in CY 2019 OPPS rulemaking.
Redistribution of “Savings”

CMS finalized its proposal to redistribute the “savings” from reducing payments to 340B hospitals by increasing payment under the OPPS for non-drug items and services. CMS estimates the Final Rule will reduce 340B hospital payments by $1.6 billion, an increase from the $900 million estimate in the Proposed Rule. These savings will increase payment for non-drug items and services for all hospitals paid under the OPPS by 3.2%.

Financial Impact on Hospitals

CMS provides an estimate of the total payment effect in CY 2018 of the finalized payment adjustment to 340B hospitals. Column 4 in Table 88 on page 1094 of the Final Rule reflects the combined impact of the reduced payment rate for affected hospitals and the 3.2% payment increase to all hospitals paid under the OPPS for non-drug items and services. Some hospitals will see a net increase in payment because of increased payments for non-drug items and services. For example, rural SCHs will see a 2.6% payment increase, which reflects no change to drug payments due to their exception from 340B payment reduction and a 3.2% payment increase for non-drug items and services. Similarly, CMS says that children’s and PPS-exempt cancer hospitals will “receive a higher payment when providing a non-drug service,” although the agency does not provide an estimate of the impact on these hospitals.

CMS estimates that hospitals with lower DSH patient percentages, reflecting lower levels of care to low-income patients, and non-teaching hospitals will see overall payment increases, whereas hospitals with higher DSH patient percentages and “major” teaching hospitals will see payment decreases. Proprietary (i.e., for-profit) hospitals will see a 2.7% payment increase, whereas voluntary (i.e., non-profit) hospitals will see a -0.3% decrease and government hospitals will see a -1.6% decrease.

Modifier Requirements Effective January 1, 2018

Modifier for Hospitals Subject to the Payment Reduction

340B hospitals that are subject to reduced payment (i.e., DSHs and RRCs that are not rural SCHs) will be required to use modifier “JG” on the same claim line as the drug HCPCS code when billing under the OPPS, effective January 1, 2018, to identify separately payable Part B drugs “acquired through the 340B Program or through the 340B [Prime Vendor Program (PVP)] at or below the 340B ceiling price.” Application of the “JG” modifier will trigger the payment reduction. Drugs not acquired under the 340B program or the PVP at or below the 340B ceiling price should not be reported with modifier “JG” and will continue to be paid at ASP + 6%.

Modifier for 340B Hospitals Excepted from Payment Reduction

340B hospitals paid under the OPPS that are excepted from reduced payment (i.e., rural SCHs, children’s hospitals, and PPS-exempt cancer hospitals) will be required to use a different modifier to identify 340B drugs, effective January 1, 2018. These hospitals will report an informational modifier “TB” on the same claim line as the drug HCPCS code when billing under the OPPS to identify drugs “acquired through the 340B Program or through the 340B [Prime Vendor Program] at or below the 340B ceiling price.” The informational modifier “TB” will assist CMS with collecting and tracking 340B claims data for the 340B hospitals that are not subject to reduced reimbursement. CMS does not elaborate on how it will use the information collected by the “TB” modifier. Use of the “TB” modifier will not trigger reduced reimbursement.
Modifier for Packaged Drugs

CMS will accept modifier “JG” or modifier “TB” to be reported with a packaged drug, even though packaged drugs are not separately paid and will not be subject to reduced payment. It does not appear that CMS is requiring hospitals to use a modifier to identify packaged drugs purchased under 340B or the PVP. Rather, CMS appears to be responding to a hospital’s request that hospitals be allowed to use the modifier for packaged drugs to “reduce or prevent operational burden.” Hospitals that voluntarily use modifier “TB” or “JG” to identify packaged drugs will not receive reduced reimbursement for those drugs.

Analysis of the Final Rule

Modifier Requirements

In the Proposed Rule, CMS stated its intention to establish a modifier for all hospitals to identify non-340B drugs. It appeared that CMS would require both 340B and non-340B hospitals to use such a modifier. Under the Final Rule, CMS will instead require the use of a modifier to identify 340B drugs, and only 340B hospitals will be required to use the new modifiers. CMS noted that several state Medicaid programs already mandate use of modifiers to identify 340B drugs and that CMS’s modifier requirement aligns with those requirements. Although some state Medicaid agencies require 340B hospitals to use a “UD” modifier to identify 340B physician-administered drugs billed to Medicaid, CMS is requiring use of a different modifier for 340B claims, which may create additional administrative and financial burdens for hospitals.

Hospitals will need to comply with the modifier requirements beginning January 1, 2018. Hospitals have reported that it may be difficult to implement systems to begin using the modifiers by January 1. 340B Health and others submitted comments expressing concern over the financial and administrative burden of implementing a new modifier and the length of time it would take to modify systems. In response, CMS states that “hospitals have been on notice since the proposed rule went on display at the Office of the Federal Register on July 13, 2017 that [CMS] intended to establish a modifier.” Moreover, CMS notes that hospitals have an additional two months from the date of the Final Rule’s release to operationalize the modifier requirements. CMS also points out that hospitals have 12 months after the date of service to timely file a Part B drug claim for payment, suggesting that hospitals that are not able to update their systems by January 1 would have additional time to comply with the modifier requirements. However, this may not be feasible, as hospitals may not be in a financial position to hold claims and delay Medicare payments while updating their systems.

CMS also reminds hospitals that Medicare requires the return of any payment it erroneously paid as the primary payer and that Medicare can fine providers who “knowingly, willfully and repeatedly bill incorrectly coded claims.” Providers are required to “submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.”

CMS will consider whether additional details need to be communicated to stakeholders about the modifiers through a subregulatory process, such as information posted to CMS’s website.
Redistribution of “Savings”

CMS estimates that the payment reduction will result in $1.6 billion in savings to Medicare but, as required under the Medicare law, the agency is implementing the payment reduction in a budget neutral manner. In CY 2018, CMS will redistribute the savings equally across the OPPS for non-drug items and services. CMS may revisit the redistribution methodology in the future.

CMS solicited comments in the Proposed Rule on whether the savings should be redistributed to specific services under the OPPS, to Part B services paid outside the OPPS, or to hospitals paid under the OPPS based on their provision of charity care or other safety net characteristics. 340B Health commented that any redistribution to non-340B providers would be inconsistent with the purpose of 340B, as it would share a portion of the 340B benefit with providers that do not have records of treating high volumes of low-income patients. 340B Health also expressed concern with redistributing the funds to hospitals based on their level of care to uninsured patients, as this could take away 340B savings from hospitals that treat high volumes of Medicaid and low-income Medicare patients as well as provide high levels of uncompensated and unreimbursed care. CMS ultimately declined to redistribute the savings based on hospitals’ provision of care to the uninsured but noted that the agency remains interested in exploring ways to better target the offsetting amount to hospitals that serve “low-income and uninsured patients, as measured by uncompensated care.”

Policy Rationale for Reduced Reimbursement

More Closely Align Reimbursement with 340B Acquisition Costs

CMS continues to assert, as it did in its Proposed Rule, that reduced reimbursement to 340B hospitals will align payments more closely with the resources expended by 340B hospitals to acquire drugs. CMS continues to rely on the Medicare Payment Advisory Commission (MedPAC) estimate that, on average, 340B hospitals receive a minimum discount of 22.5% of the ASP for drugs paid under the OPPS. 340B Health submitted comments noting that, in many cases, the payment reduction would leave the affected 340B hospitals with virtually no 340B savings on Part B drugs. CMS disagreed and states that ASP – 22.5% is a conservative estimate of the 340B discount and it will not strip 340B hospitals of all of their 340B discounts on Part B drugs.

Reduce Beneficiary Copays

CMS continues to state that the payment reduction will reduce patient costs by lowering beneficiary copay amounts. Because the Part B beneficiary copay is 20% of the OPPS payment for a drug, reducing the Medicare payment amount would reduce the copay. Commenters noted that many beneficiaries have supplemental insurance that covers Part B copayments. As such, the payment reduction would not lower out-of-pocket costs for many beneficiaries. CMS notes that, in these cases, the payment reduction will reduce the copayment amount that supplemental plans make on behalf of beneficiaries, which should decrease the cost of supplemental plan coverage for beneficiaries. 340B Health also noted that because the payment reduction is budget neutral and reimbursement will increase for non-drug items and services, beneficiary copays will increase for those services, thereby resulting in no net savings to beneficiaries.

Thanking commenters for their feedback about high drug costs for Medicare beneficiaries, CMS stated that the agency “look[s] forward to working with Congress to provide HHS additional 340B programmatic flexibility, which could include tools to provide additional considerations for safety net hospitals, which play a critical role in serving our most vulnerable patients.” CMS did not elaborate on the meaning of this statement.
Address Unnecessary Drug Utilization

CMS also continues to state that the payment reduction will address unnecessary drug utilization in 340B hospitals. The agency cites to a 2015 Government Accountability Office (GAO) report, which found that per beneficiary Part B drug spending was more than twice as high at 340B DSH hospitals than at non-340B hospitals. 340B Health commented that it would not be appropriate for CMS to rely on the GAO’s suggestion that there may be inappropriate drug use in 340B hospitals because research shows 340B DSH hospitals incur higher drug spending not because of inappropriate drug use, but because their patients are more expensive to treat. Moreover, HHS previously commented that GAO’s suggestion was “not supported by the study methodology” and indicated that further analysis was needed. In response, CMS acknowledged the various reports we referenced in our comments but stated, “However, we continue to believe, based on numerous studies and reports, that 340B participation is not well correlated to the provision of uncompensated care and is associated with differences in prescribing patterns and drug costs.”

Actual Acquisition Cost Billing

CMS solicited comments in the Proposed Rule on potential ways to obtain acquisition costs for 340B drugs, including by requiring hospitals to report their acquisition cost on the claim when billing under the OPPS for a 340B drug. 340B Health submitted comments noting the administrative and financial challenges of acquisition cost billing. CMS did not adopt an actual acquisition cost (AAC) billing policy for 340B hospitals for CY 2018. However, CMS stated it would take these comments into consideration for future use. The agency also noted that some states already require AAC billing for 340B drugs, indicating that “the magnitude of the challenges to implement may be less than [suggested].”

Statutory Authority

340B Health and other commenters strongly disagreed with CMS’s position that the agency has the authority to target 340B hospitals for reduced payment. We explained that CMS’s proposed payment reduction to 340B hospitals was inconsistent with the intent of the 340B program because it would take away a portion of a financial benefit that Congress intended to provide to hospitals serving high volumes of low-income patients and share the benefit with providers that do not have a record of treating high volumes of low-income patients. In response, CMS stated that the payment reduction does not run afoul of Congress’s intent in creating the 340B program and noted that the policy applies to Medicare payments and does not “change a hospital’s eligibility for the 340B program.” CMS also stated, “There is no requirement in the Public Health Service Act that the 340B Program ‘guarantee’ or provide a certain profit from the Medicare program.”

We also argued that the Medicare provision to which CMS cites for its authority does not allow CMS to vary payment for the same drug to different hospital groups. In the Final Rule, CMS continues to assert it has this authority, stating that the Medicare statute grants CMS “broad discretion to adjust payments for drugs.”

Comments and Questions

If you have questions about the new requirements effective January 1, 2018, please contact Amanda Nagrotsky, at amanda.nagrotsky@340bhealth.org or 202-552-5866. If you have questions about legislative actions to stop the payment cuts, please contact Kathryn DiBitetto at Kathryn.dibitetto@340bhealth.org or 202-552-5855, or Jeff Davis at jeff.davis@340bhealth.org or 202-552-5867.