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Vizient Office of Public Policy and Government Relations
Urgent Regulatory Update: CMS Final Rule – OPPS Payment Rate for 340B Purchased Drugs

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Background & Summary

On Wednesday, November 1, the Centers for Medicare & Medicaid Services (CMS) issued the annual final rule with comment period to update the 2018 Medicare payment and policies for the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) Payment System. The OPPS and ASC payment systems are updated annually to include changes to payment policies, payment rates, and quality provisions.

This final rule follows the annual proposed rule issued on July 13. Vizient, along with other provider groups, was alarmed by a proposal made by CMS that would significantly change the current Medicare Part B drug payment methodology for certain 340B hospitals when 340B drugs are used. On behalf of our members, Vizient submitted a comment letter on the proposed rule strongly opposing this significant payment reduction, and urged CMS not to move forward in finalizing the proposal. Additionally, Vizient worked closely with other hospital stakeholders to encourage Congress to weigh in with CMS Administrator, Seema Verma. 228 bipartisan members of the House and 57 bipartisan Senators weighed in with Administrator Verma urging the agency to "carefully consider stakeholder concerns and feedback, and to act to ensure that reimbursement for 340B providers enables them to continue serving the most vulnerable."

Despite the strong opposition to this proposal from providers, CMS finalized its proposal to pay for separately payable, non pass-through drugs (other than vaccines) purchased through the 340B Program at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent, effective January 1, 2018. Excluded from this payment adjustment in CY 2018 are the rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals. Critical Access Hospitals are not reimbursed under OPPS, so this rule does not apply to them.

Final OPPS Payment Rate for 340B Purchased Drugs

In addition to this reimbursement reduction to 340B hospitals, CMS is establishing two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program – one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction, but which do acquire drugs under the 340B Program. CMS is implementing the modifier such that it is required for drugs that were acquired under the 340B Program (rather than requiring its use on drugs that were *not* acquired under the 340B Program, as was originally proposed).

Effective January 1, 2018, CMS is implementing modifier "JG" for the payment adjustment for 340B-acquired drugs. Hospitals paid under the OPPS (besides those exempted from this final 340B payment policy) are required to report modifier "JG" on the same claim line as the drug Healthcare Common Procedure Coding System (HCPCS) code to identify a 340B-acquired drug. The phrase "acquired under the 340B Program" is inclusive of all drugs acquired under the 340B Program or PVP, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program should not be reported with the modifier "JG". For calendar year (CY) 2018, hospitals that are excluded from the payment adjustment will be required to report informational modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP plus 6 percent. CMS notes that providers have 12 months after the date of service to timely file a claim for payment. Therefore, for those hospitals that may need more time to ensure that they are in compliance with the modifier requirements, they have 12 months from the date of service to do so.

Applying this final payment policy for drugs purchased under the 340B Program results in an estimated reduction of approximately $1.6 billion in separately paid OPPS drug payments. To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments will be redistributed in an

equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under the OPPS for CY 2018.

CMS asserts that this new payment methodology "is an amount that allows hospitals to retain a profit on these drugs for use in the care of low-income and uninsured patients."

What's Next?

CMS indicates that they may revisit this new payment methodology in CY 2019 rulemaking. The agency notes that in the near-term, ASP minus 22.5 percent "adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS." Additionally, CMS may consider requests for exceptions for certain drug classes in development of the CY 2019 OPPS/ASC proposed rule. CMS may also reconsider the policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction in the CY 2019 OPPS rulemaking. The agency believes further study of the effect of the policy is warranted for classes of hospitals that receive statutory payment adjustments under the OPPS (such as rural SCHs and PPS-exempt cancer hospitals).

Additionally, CMS recognizes that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix. Accordingly, in the longer term, the agency is interested in exploring ways to more closely align the actual acquisition costs that hospitals incur rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals.

While CMS is implementing this policy in a budget neutral manner equally across the OPPS for CY 2018 for non-drug items and services, the agency states that they may reexamine how any future savings may be allocated differently. CMS states that they "continue to be interested in ways to better target the savings to hospitals that serve the uninsured and low-income populations or that provide a disproportionate share of uncompensated care."

CMS will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus provider-based departments (PBDs) as the agency continues to explore whether to pursue future rulemaking on the issues of clinical service line expansion or volume increases, and other implementation policies related to Section 603 of the Bipartisan Budget Act of 2015. CMS did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus provider-based departments in CY 2018 but may consider adopting such a policy in the Medicare Physician Fee Schedule (PFS) CY 2019 notice-and-comment rulemaking.

CMS also states that "given the limitations in calculating a precise discount for each OPPS separately payable drug, [they] did not attempt to do so" – indicating future regulatory action to further alter or refine the methodology is possible. In response to commenters concern about the ability to implement the modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program by January 1, 2018, CMS states that they realize it is important for the agency to communicate as soon as possible any additional information to providers. The agency will consider "whether additional details will need to be communicated through a subregulatory process, such as information posted to the CMS website."

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this final rule. Stakeholder input plays a major role in shaping future changes to policy. Although it is possible that future rulemaking, legislation, or legal action could alter this final rule with comment period, it does go into effect on January 1, 2018 and we urge members to assume as though this rule will be implemented as-is. Please reach out to our office if you have any questions.

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.