CMS SOLICITS COMMENTS ON PART B DRUG REIMBURSEMENT CHANGES FOLLOWING ON PRESIDENT'S DRUG PRICING BLUEPRINT

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U.S. Health Care Alert

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On July 31, 2018, the Centers for Medicare & Medicaid Services ("CMS") took a significant step forward in advancing the administration's "American Patients First" Drug Pricing Blueprint ("Blueprint"),[1] introducing new policy and payment updates to the Medicare Hospital Outpatient Prospective Payment System ("OPPS") and the Medicare Ambulatory Surgical Center payment system and quality reporting programs for calendar year ("CY") 2019 ("Proposed Rule").

In line with some top priorities frequently cited by the administration, the Proposed Rule contains several important changes related to the reimbursement of drugs and biological products that CMS says are designed to reduce prescription drug costs, as well as beneficiary out-of-pocket costs.

While the focus of this alert is on these drug reimbursement changes, please refer to our previous alert for an overview of other significant changes contained in the Proposed Rule.

340B REIMBURSEMENT CUT FOR CERTAIN SITE NEUTRAL NONEXCEPTED PROVIDER-BASED DEPARTMENTS ("PBDS")

CMS is also proposing a reduction in OPPS reimbursement for certain drugs acquired under the 340B Drug Pricing Program ("340B Program" or "340B"). Under the proposal, CMS would extend a previous reimbursement cut for drugs furnished in hospital departments, which took effect on January 1, 2018, to nonexcepted, off-campus PBDs. Beginning in CY 2018, off-campus PBDs that were not furnishing services prior to November 2, 2015, were considered "nonexcepted" and were subject to site-neutral payment pursuant to Section 603 of the Bipartisan Budget Act of 2015.[2]

Under the Proposed Rule, reimbursement for 340B drugs purchased by nonexcepted, off-campus PBDs would be calculated using the ASP minus 22.5% formula, representing a steep decrease from the previous formula of ASP plus 6%.[3]

For a more detailed explanation of this proposed change and an analysis of its implications, please refer to our previous alert on this topic.

CALCULATING PAYMENT WHEN ASP DATA IS NOT AVAILABLE

Similar to the proposed changes under the PFS for CY 2019, the Proposed Rule also addresses reimbursement in situations where sufficient ASP data on a drug is not readily available. Effective January 1, 2019, in the event that sufficient ASP data is not available, CMS will pay separately payable drugs and biological products (that do not have pass-through payment status and are not acquired under the 340B Program) at wholesale acquisition cost ("WAC") plus 3% under the OPPS rather than WAC plus 6%.[4]

The "WAC plus 3%" formula would apply whenever WAC-based pricing is used for a drug or biological product.[5] If WAC data are not available for a particular drug or biological product, CMS proposes to continue paying for separately payable drugs and biological products at 95% of the most recent average wholesale price ("AWP"). To the extent that ASP information becomes available for the first quarter of 2019, payment would be based on this ASP information.[6]

Drugs and biologicals that are acquired under the 340B Program would continue to be paid at ASP minus 22.5%, WAC minus 22.5%, or 69.46% of AWP, as applicable.[7]

PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS

Consistent with the Blueprint's objective of promoting the use of biosimilars, CMS indicated in the Proposed Rule that it will continue the policy currently in place to make all biosimilar biological products eligible for pass-through payment in lieu of just the first biosimilar biological product for a reference product.[8] Biosimilar manufacturers that apply for pass-through payment status for new drugs are entitled to reimbursement at ASP plus 6% for a period of at least two and no more than three years. In the CY 2018 OPPS final rule, CMS issued a technical correction clarifying that pass-through payment will be available to all biosimilar biological products, rather than only the first biosimilar biological product to enter the market.

CMS noted that it received numerous comments regarding its recently finalized policy[9] that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid ASP (of the biosimilar) minus 22.5% of the reference product.[10] Commenters noted that because the payment reduction would be based on the reference product's ASP (which is generally higher than the biosimilar's ASP), the payment reduction would be more significant than if based on the biosimilar's ASP.[11]

Accordingly, for CY 2019, CMS proposes changes to the Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program, which would pay non-pass-through biosimilars acquired under the 340B Program at ASP minus 22.5% of the biosimilar's ASP (rather than the biosimilar's ASP minus 22.5% of the reference product's ASP).[12]

COMPETITIVE BIDDING FOR MEDICARE PART B DRUGS

Finally, as part of the Proposed Rule, the CMS Center for Medicare and Medicaid Innovation ("CMMI") issued a new Request for Information ("RFI") seeking public comment on leveraging the authority for the Competitive Acquisition Program ("CAP") for Part B drugs to create a CMMI competitive bidding model for these medicines.

Under Medicare Part B, drug payment depends on a number of factors, including the site of care and the drug. Medicare Part B drugs typically can be placed into three categories:

(1) drugs furnished incident to a physician's service in the physician office or other nonfacility setting, hospital outpatient setting, or ambulatory surgical center (not including self-administered drugs);
(2) drugs administered via a covered item of durable medical equipment (e.g., drugs administered via infusion pumps or nebulizers); and
(3) other categories of drugs as specified by statute (e.g., immunosuppressive drugs, hemophilia blood clotting factors, certain oral anticancer and anti-emetic drugs, pneumococcal pneumonia, influenza and hepatitis B vaccines, erythropoietin for home dialysis patients, and certain osteoporosis drugs).

A CAP-based model would allow CMS to negotiate and contract with vendors on payment for these Part B drugs. CMMI is seeking information and feedback on numerous aspects of the competitive bidding model, including its scope, which providers should be included or excluded, the proper role of private-sector vendors, whether it should be limited to a set population, beneficiary protections, the inclusion of other payors, and model payment options.[13] CMMI notes that such a potential model would include competitively selected private-sector vendors to establish payment arrangements with manufacturers that incorporate "value-based pricing strategies, such as outcomes-based agreements, indication-based pricing, payment over time, shared savings or performance-based payments based on the impact on total cost of care, and reduced beneficiary cost sharing."[14] CMMI is also considering how the potential model could be structured to include Medicare Advantage organizations, state Medicaid agencies, and Medicaid Managed Care Organizations.[15]

In particular, CMMI outlined a list of questions to prompt public comment, which are divided into seven broad categories and designed to explore how a CAP-like model could be structured to advance the goals of the president's Blueprint, namely to increase competition, strengthen negotiation, create incentives for lower list prices, and result in lower out-of-pocket costs:

1. Included Providers and Suppliers
2. Included Drugs and Biologicals
3. Beneficiary Cost Sharing, Protections, and Fiscal Considerations
4. Model Vendors
5. Regulatory Barriers and Transparency Issues
6. Manufacturer Participation
7. Model Scope

CMS indicated that it is also interested in how best to handle Medicare payment for new high-cost therapies and whether a potential CAP-like model could be an appropriate payment-and-delivery structure for these drugs and biologicals.[16]

The questions posed in this most recent RFI are designed to build upon a prior RFI on this topic and to solicit more detailed feedback that would assist CMMI in developing such a model.[17]

NEXT STEPS

While the OPPS final rule is not typically published until the last quarter of the year, hospitals that are considering

next year's budget will nevertheless need to assess the extent to which a reduction in drug reimbursement impacts their finances and operations. Further, providers may wish to comment on the Proposed Rule, particularly on the drug reimbursement topics described above. Comments are due no later than 5 p.m. Eastern Standard Time on September 24, 2018.

K&L Gates' Health Care practice can assist health care providers in conducting this analysis and will continue to closely monitor further developments and changes to drug reimbursement formulas. Further, K&L Gates' Health Care practice and Public Policy and Law practice regularly advise clients on issues related to drug reimbursement, including 340B Program implementation and compliance matters, and facilitate stakeholder engagement with Congress and the administration, including through the development and submission of public comments.

Notes:

[1] U.S. Dep't of Health & Human Servs., American Patients First, https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.
[2] The lower rate of average sales price ("ASP") minus 22.5% that applies to grandfathered PBDs has not applied to nonexcepted PBDs under the site-neutral rule because items and services furnished by such PBDs are no longer reimbursed under the OPPS and are instead reimbursed under the Medicare Physician Fee Schedule ("PFS").
[3] 83 Fed. Reg. at 37,143.
[4] *Id.* at 37,122.
[5] *Id.* at 37,123.
[6] *Id.*
[7] *Id.* at 37,125.
[8] *Id.* at 37,123.
[9] 82 Fed. Reg. 59,367.
[10] 83 Fed. Reg. 37,123.
[11] *Id.*
[12] *Id.*
[13] 83 Fed. Reg. at 37,212–13.
[14] *Id.* at 37,215.
[15] *Id.* at 37,216.
[16] *Id.* at 27,213.
[17] CMS included a solicitation of comments on the CAP for Part B Drugs and Biologicals (81 Fed. Reg. 13,247) in a proposed rule on March 11, 2016, entitled "Medicare Program; Part B Drug Payment Model" (81 Fed. Reg. 13,230).

