340B UPDATE: CMS PROPOSES CHANGES TO OPPS REIMBURSEMENT FOR NONEXCEPTED PBDS

Date: 30 July 2018

U.S. Health Care Alert

By: Richard P. Church, Macy L. Flinchum, Amanda Makki

As part of the Calendar Year ("CY") 2019 Medicare Outpatient Prospective Payment System ("OPPS") Proposed Rule, the Centers for Medicare and Medicaid Services ("CMS") is proposing to reduce OPPS reimbursement for certain drugs acquired under the 340B Drug Pricing Program ("340B Program" or "340B"). In particular, CMS proposes to pay nonexcepted, off-campus provider-based departments ("PBDs") under the Medicare site-neutral rule their average sales price ("ASP") minus 22.5 percent for 340B-acquired drugs. This lower rate is consistent with the rate CMS adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS ("CY 2018 Change"), as discussed in our prior alert. These proposed cuts come amid ongoing litigation brought by providers in opposition to the 2018 changes and will likely lead to another round of litigation if finalized in their proposed form.

PROPOSED PAYMENT CHANGES

The ASP minus 22.5 percent rate has applied to hospitals and PBDs that were furnishing services prior to November 2, 2015 (i.e., excepted PBDs), and paid under the OPPS since January 1, 2018. Beginning in CY 2018, off-campus PBDs that were not furnishing services prior to November 2, 2015, are considered "nonexcepted" and are subject to site-neutral payment pursuant to Section 603 of the Bipartisan Budget Act of 2015. The lower rate of ASP minus 22.5 percent 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"). Part B drugs that would be separately payable under the OPPS (status indicator "K") but are not payable under the OPPS because they are furnished by nonexcepted PBDs are currently generally paid at ASP plus 6 percent.

Effective January 1, 2019, CMS is proposing to pay nonexcepted off-campus PBDs the adjusted payment amount under the PFS of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program. Similar to the CY 2018 Change, the change would not apply to rural sole community hospitals, children's hospitals, or PPS-exempt cancer hospitals. For drugs that do not have ASP pricing, the 340B payment adjustment for wholesale acquisition cost ("WAC") priced drugs is WAC minus 22.5 percent. Finally, average wholesale price ("AWP") priced drugs have a payment rate of 69.46 percent of AWP under the new policy. [1] CMS estimates the change would save Medicare and beneficiaries approximately $48.5 million under the PFS. [2] In making the proposal, CMS argues that the

current payment policy creates "significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished." [3]

ONGOING LITIGATION

As discussed in our prior alerts (see here and here), the American Hospital Association ("AHA") and other trade organizations, along with several lead plaintiff hospitals, challenged CMS's authority to implement the CY 2018 Change under the Social Security Act. The U.S. Court of Appeals for the District of Columbia recently affirmed the dismissal of the case on procedural grounds on July 17, 2018; however, the door is still open for plaintiffs to refile. [4]

Separately, on May 30, 2018, the Community Oncology Alliance ("COA") filed a lawsuit in the U.S. District Court for the District of Columbia seeking declaratory relief and an injunction to stop CMS from applying a 2 percent cut to Medicare Part B drug reimbursement as part of the budget sequester recently extended though 2027. [5] COA claims that HHS violated the separation of powers doctrine by applying the sequestration cuts to Part B drugs, as Congress never gave HHS authority to change the statutory reimbursement formula for Part B drugs. [6], [7]

The COA case raises a number of issues that will likely be relevant to FPS 340B Program reimbursement cut if CMS finalizes its proposal. The government budget sequester is authorized under the Budget Control Act of 2011, which amended the Balanced Budget and Emergency Deficit Control Act of 1985. However, the statutory formula for payment for certain Part B drugs under the PFS, including oncology drugs is equal to ASP plus 6 percent. By applying the sequestration cut, COA argues that CMS has impermissibly reduced the Part B payment formula to ASP plus 4.3 percent. [8] COA argues that CMS lacked statutory authority under the PFS schedule to make such a change in Part B drug reimbursement. [9]

NEXT STEPS

While the final OPPS 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 reimbursement impacts their decision-making. Further, providers may wish to comment on the Proposed Rule. Comments are due no later than 5 p.m. on September 24, 2018.

K&L Gates' Health Care practice can assist 340B covered entities in conducting this analysis and will continue to closely monitor developments in 340B Program reimbursement and the OPPS and COA litigation. Further, K&L Gates' Health Care practice and Public Policy and Law practice regularly advise clients on 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] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the

Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model at 305 (to be published July 31, 2018) (hereinafter, "Proposed Rule"), https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf.
[2] Proposed Rule at 700. Notably, the proposed adjustment would not be budget neutral in the same manner as the 2018 OPPS cuts but would instead result in savings to CMS.
[3] *Id*. at 387.
[4] American Hospital Ass'n v. Azar, No. 18-5004 (D.C. Cir., July 17, 2018).
[5] Complaint of Cmty. Oncology Alliance in Cmty. Oncology Alliance v. Mulvaney, 1:18-cv-01256 (D. D.C. filed May 30, 2018).
[6] In conjunction with the complaint, COA President Jeff Vacirca and Executive Director Ted Okon also sent a letter to Secretary Alexander Azar ("Letter") explaining why legal action was taken and proposing potential solutions. Letter from Jeff Vacirca, President, Community Oncology Alliance and Ted Okon, Executive Director, Community Oncology Alliance to Secretary Alexander Azar, Dep't of Health and Human Services, https://www.communityoncology.org/wp-content/uploads/2018/05/COA_HHS-Sequester_Letter_5-30-18_FINAL.pdf (hereinafter, "2018 Letter"). This is not the first time the group has notified federal administrators of its concerns with the application of sequestration, as the COA board wrote an initial letter to then-HHS Secretary Tom Price and CMS Administrator Seema Verna on August 2, 2017, outlining its initial legal and constitutional arguments against sequester cuts to Part B drug reimbursement. Letter from Ted Okon, Executive Director, Community Oncology Alliance to Sec. Tom Price, Dep't of Health and Human Services and Admin. Seema Verma, Centers for Medicare & Medicaid Services (Aug. 2, 2017), https://www.communityoncology.org/wp-content/uploads/2018/05/COA_HHS-Sequester_Letter_5-30-18_FINAL.pdf (hereinafter, "2017 Letter"). In the Letter, COA states that since CMS applied the sequester cuts to oncology drugs: (1) one hundred thirty-five (135) cancer treatment clinics have closed; (2) there has been an increase in over 40 percent of consolidation of independent community cancer clinics into more expensive hospital settings; and (3) the percentage of chemotherapy administered in the physician setting as opposed to the outpatient hospital setting has declined by nearly 15 percent since the sequester cuts began in 2013 and nearly 35 percent total since 2004. Letter at 4–5. COA attributes these figures to the inability of oncology clinics to compete with hospital providers under the current reimbursement model.
[7] COA also cites the expansion of the 340B Program as a factor negatively impacting community oncology practices and contributing to many of these practices either closing or consolidating with hospitals. COA argues that given discounts from the 340B Program are not extended to independent clinics, hospitals have increasingly stopped primary care referrals of cancer patients to outside oncology practices in order to realize the profits generated through participation in the 340B Program. Compl. at ¶ 47; 2017 Letter at 2. Notwithstanding the substantial payment reduction recognized in the CY 2018 Change, COA contends that the 340B Program continues to be lucrative for hospitals as they still realize close to 30 percent margins on cancer drugs. 2018 Letter at 7.
[8] Note that the sequester cut applies only to the 80 percent of the drug price that Medicare pays for and does not apply to patients' 20 percent copayments, thereby resulting in a realized cut of about 1.7 percent.
[9] Compl. at ¶ 49.

KEY CONTACTS

RICHARD P. CHURCH
PARTNER
RESEARCH TRIANGLE PARK, CHICAGO
+1.919.466.1187
RICHARD.CHURCH@KLGATES.COM

MACY L. FLINCHUM
ASSOCIATE
RESEARCH TRIANGLE PARK
+1.919.466.1259
MACY.FLINCHUM@KLGATES.COM

