CMS ISSUES CY 2019 OPPS FINAL RULE

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U.S. Health Care Alert

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On November 2, 2018, the Centers for Medicare & Medicaid Services ("CMS") issued in pre-publication format the final rule for 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 ("OPPS Final Rule").[1] This alert provides an update on changes proposed by CMS in the CY 2019 OPPS Proposed Rule[2] that were described in our prior alert. Among the most significant updates:

- CMS did not finalize its proposal to limit the items and services that an off-campus hospital outpatient provider-based department ("PBD") not subject to site-neutral payment under Section 603 of the Bipartisan Budget Act ("Section 603") - i.e., an off-campus excepted PBD - can bill under OPPS to those items and services within the clinical families of services furnished during an applicable baseline period.
- CMS finalized the reduction in reimbursement for clinic visits in off-campus excepted PBDs, although CMS is phasing it in over two calendar years.
- CMS finalized its proposal to reduce reimbursement for certain drugs and biologicals acquired under the 340B Program and provided in off-campus PBDs subject to site-neutral payment under Section 603 from the current rate of average sales price ("ASP") plus 6 percent to ASP minus 22.5 percent.

We have highlighted some key aspects of the OPPS Final Rule below. The OPPS Final Rule is scheduled to be published in the Federal Register on November 21, 2018.

SERVICE EXPANSION LIMITATION FOR EXCEPTED OFF-CAMPUS PBD

In the OPPS Proposed Rule, CMS proposed to limit the items and services that an excepted off-campus PBD can bill under OPPS to those items and services that are within the clinical families of services furnished during an applicable baseline period by each such excepted off-campus PBD and subsequently billed.[3] CMS included a similar limitation in its initial proposal to implement the site-neutral payment rule for CY 2017.[4] Ultimately, CMS did not adopt that proposal in CY 2017, after many commenters expressed concerns regarding a lack of statutory authority for such a limitation and regarding the operational and administrative burden of implementation.[5] While some commenters expressed support for the service expansion limitation as proposed for CY 2019, CMS did not finalize its proposal, which was opposed by a majority of commenters, citing again concerns related to operational challenges and the administrative burden of implementation for both CMS and hospitals.[6] Commenters also stated that the proposal was arbitrary and capricious and that hospitals should be able to change the services offered at excepted off-campus PBDs in response to changes in clinical practice and community needs and receive OPPS reimbursement for those services.[7]

Notwithstanding that CMS did not adopt the clinical families limitation, CMS continues to express its concern that, absent a limitation on the expansion of services at excepted off-campus PBDs, hospitals may be able to purchase additional physician practices and add the physicians to existing excepted off-campus PBDs.[8] CMS reiterates that it believes it has the statutory authority to limit service expansion at excepted off-campus PBDs or impose a limitation on the volume of services at such locations.[9] CMS indicates its intent to continue to monitor claims data, including expansion of services, at excepted off-campus PBDs and may propose a limitation on service expansion in future rulemaking.[10]

OFF-CAMPUS EMERGENCY DEPARTMENT DATA COLLECTION

CMS created a new claims modifier for services furnished in off-campus provider-based emergency departments. In the OPPS Final Rule, CMS indicates that it has observed a noticeable increase in the number of off-campus hospital outpatient emergency department visits furnished under OPPS since 2010. CMS states its interest in developing data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments due to higher reimbursement or due to the exception to site-neutral payment under Section 603 for dedicated emergency departments, based on concerns expressed by MedPAC and other entities.[11] In order to develop this data, CMS created a HCPCS modifier (ER - Items and services furnished by a provider-based off-campus emergency department) that will be required to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department. Critical access hospitals are exempt from this requirement. While CMS received some comments regarding this new HCPCS modifier, CMS noted this was an announcement, not a proposal, and did not respond in detail to the commenters, stating it would consider such feedback in potential future policy developments.[12]

REIMBURSEMENT CUT FOR HOSPITAL OUTPATIENT CLINIC VISITS

In response to CMS' concerns that the growth in hospital outpatient clinic visits is being driven by increased reimbursement available under OPPS when such services could likely be safely provided in a lower cost setting,[13] CMS finalized its proposal to cap OPPS reimbursement for such visits at the Physician Fee Schedule ("PFS") rate. This will result in a significant cut to hospital reimbursement for clinic visits furnished in otherwise excepted off-campus PBDs, although this cut will be phased in over a two-year period. In CY 2019, these departments will be paid approximately 70 percent of the OPPS rate for HCPCS code G0463. In CY 2020, these departments will be paid the site-specific PFS rate for the clinic visit service (i.e., the rate equivalent to a nonexcepted off-campus PBD). Thus, while an excepted off-campus PBD will continue to bill HCPCS code G0463 (hospital outpatient clinic visit for assessment and management of a patient) with the "PO" modifier (excepted service provided at an off-campus, outpatient, provider-based department of a hospital) when fully phased in, the payment rate for such services will be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier "PN." [14]

CMS also finalized its implementation of this reimbursement change in a non-budget neutral manner. Accordingly, CMS is characterizing the change as a "volume control method" and is relying on its authority under section 1833(t)(2)(F) of the Social Security Act.[15] CMS has further indicated it may propose volume control methods for other hospital outpatient services in future rulemaking, while recognizing the "importance of not impeding development or beneficiary access to new innovations."[16]

DRUG REIMBURSEMENT CHANGES

- 340B Reimbursement Cut for Nonexcepted PBDs. CMS finalized its proposal to reduce reimbursement for certain drugs and biologicals acquired under the 340B Program from the current rate of ASP plus 6 percent to ASP minus 22.5 percent. This change applies to 340B Program drugs purchased for use in nonexcepted PBDs, consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in excepted PBDs. Although some commenters opposed the change, CMS responded that the current payment methodology "creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality." According to CMS, the lower payment rate is designed to better align Medicare payments for such drugs with the actual resources expended to acquire such drugs in nonexcepted off-campus PBDs of a hospital.[17] Notably, rural sole-community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excluded from the payment reduction. Beginning January 1, 2019, these exempted providers must bill for 340B-acquired drugs under the PFS using the "TB" modifier and will be paid ASP plus 6 percent. Nonexcepted off-campus PBDs of a hospital paid under the PFS are required to report using the "JG" modifier for 340B-acquired drugs.[18]
- Payment for Biosimilar Biological Products. In the OPPS Final Rule, CMS wrote that it will continue in CY 2019 its policy of making all biosimilar biological products eligible for pass-through payment, rather than just the first biosimilar biological product for a reference product.[19] Additionally, CMS also finalized its proposed changes to the Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program — in particular, by paying for nonpass-through biosimilars acquired under the 340B Program at the drug's ASP minus 22.5 percent of the biosimilar's ASP (instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP).[20]
- Payment if ASP Data Not Available. CMS also finalized its proposal to pay separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B Program at the drug's wholesale acquisition cost ("WAC") plus 3 percent under the OPPS, rather than the current rate of WAC plus 6 percent.[21] If WAC data is not available for a drug or biological product, in CY 2019 CMS will continue paying for separately payable drugs and biological products at 95 percent of the average wholesale price ("AWP").[22] Drugs and biologicals that are acquired under the 340B Program would continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.[23]
- Competitive Bidding for Part B Drugs. Additionally, the OPPS Proposed Rule contained a Request for Information ("RFI") on leveraging CMS's authority for the Medicare Competitive Acquisition Program for Part B drugs and biologicals for purposes of a model through the Center for Medicare and Medicaid Innovation.[24] CMS envisioned that the 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."[25] In the OPPS Final Rule, CMS notes that it received approximately 80 comments on the proposal but does not indicate whether it intends to move forward or discuss any specific issues under the model.[26]

REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY AND ELECTRONIC HEALTHCARE INFORMATION EXCHANGE THROUGH POSSIBLE REVISIONS TO THE CMS PATIENT HEALTH AND SAFETY REQUIREMENTS FOR HOSPITALS AND OTHER MEDICARE- AND MEDICAID-PARTICIPATING PROVIDERS AND SUPPLIERS

In the OPPS Proposed Rule, CMS requested feedback on several specific questions related to means to advance the electronic exchange of health information among providers to facilitate safe transitions of care as well as to ensure patients and caregivers have access to health information.[27] CMS received over 60 comments in response to the RFI related to the interoperability of electronic health information.[28] CMS did not summarize the comments, but stated that it will use the feedback for information and planning purposes.[29]

REQUEST FOR INFORMATION ON PRICE TRANSPARENCY

In the OPPS Proposed Rule, CMS solicited comments on ways to improve the accessibility and usability of charge information for patients and potential actions that would facilitate consumer-friendly communication by providers and suppliers of their charges as part of CMS's price transparency initiatives.[30] In the OPPS Final Rule, CMS noted it received over 90 timely pieces of correspondence on this request for information.[31]

SUMMARY

As is apparent from the changes finalized by CMS, the concept of site-neutral payments remains one of CMS's motivators for implementing changes to reimbursement. Based on comments in the OPPS Final Rule, we anticipate this will continue to be an area of focus for CMS. The K&L Gates' health care practice regulatory advises clients in the area of Medicare reimbursement and stands ready to assist health systems and hospitals in assessing the impact of these rule changes on their current and future operations.

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1. "Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs" (pre-publication Nov. 2, 2018), available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24243.pdf [(hereinafter "OPPS Final Rule"].).
2. "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," 83 Fed. Reg. 37,046 (proposed Jul. 31, 2018) [(hereinafter "OPPS Proposed Rule"].).
3. Id. at 37,148-49.
4. "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive

Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program," 81 Fed. Reg. 45,604 (proposed Jul. 14, 2016).
5. "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider Based Department of a Hospital," 81 Fed. Reg. 79,562 (Nov. 14, 2016).
6. OPPS Final Rule, at 673-74, 677.
7. Id. at 675.
8. Id. at 673.
9. Id. at 676-77.
10. Id. at 678.
11. Id. at 586-587.
12. Id. at 589.
13. Id. at 605.
14. Id. at 624-625.
15. Id. at 622.
16. Id. at 626.
17. Id. at 644-45.
18. Id. at 658.
19. Id. at 494.
20. Id.
21. Id. at 490.
22. Id. at 22.
23. Id. at 23.
24. See OPPS Proposed Rule, 83 Fed. Reg. at 37,212-17.
25. Id. at 37,215.
26. OPPS Final Rule at 1,046.
27. OPPS Proposed Rule, 83 Fed. Reg. at 37,210-11.
28. OPPS Final Rule at 1,046.
29. Id.
30. OPPS Proposed Rule, 83 Fed. Reg. at 37,210-12.
31. OPPS Final Rule at 1,046.

