CMS ISSUES PROPOSED OPPS RULE FOR CY 2019

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On July 31, 2018, the Centers for Medicare & Medicaid Services ("CMS") published a proposed 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 Proposed Rule") in the Federal Register. [1] The OPPS Proposed Rule contains a number of important changes, including changes to reimbursement for off-campus hospital outpatient provider-based departments ("PBDs") not subject to the site-neutral payment rule implemented under Section 603 of the Bipartisan Budget Act of 2015. If finalized as proposed, the changes would result in substantial payment cuts to these PBDs beginning January 1, 2019. In addition, the OPPS Proposed Rule includes a proposal to collect data on services in off-campus emergency departments and changes to reimbursement for certain drugs and biologicals and hospital outpatient clinic visits in off-campus PBDs.

We have highlighted some key aspects of the OPPS Proposed Rule below and plan to follow-up with additional detail in subsequent alerts on a number of these areas. Comments are due by September 24, 2018.

PROPOSAL TO LIMIT SERVICE EXPANSION FOR EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

In the OPPS Proposed Rule, CMS proposes 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 base line period by each such excepted off-campus PBD and subsequently billed. [2] CMS included a similar limitation in its initial proposal to implement the site-neutral payment rule for CY 2017. [3] Ultimately CMS did not adopt that proposal, after many commenters expressed concerns regarding a lack of statutory authority for such a limitation and regarding the operational and administrative burden of implementation. [4]

Consistent with its CY 2017 proposal, CMS has organized the clinical families into 19 groupings of ambulatory payment classifications ("APCs"), listed in Table 32 of the OPPS Proposed Rule. [5] Beginning January 1, 2019, any item or service belonging to a clinical family from which the excepted off-campus PBD did not furnish an item or service during the applicable baseline period would be considered a service expansion and would need to be billed with a "PN" modifier, triggering site-neutral payment (currently proposed to be 40% of OPPS reimbursement). [6]

The applicable baseline periods as proposed are as follows: [7]

- For off-campus PBDs first furnishing services reimbursed under OPPS prior to November 1, 2014, the proposed baseline period is November 1, 2014 through November 1, 2015.

- For off-campus PBDs first furnishing services reimbursed under OPPS between November 2, 2014 and November 1, 2015, the proposed baseline period will be a one year period beginning on the first date (prior to November 2, 2015) on which the excepted off-campus PBD furnished items or services reimbursed under OPPS.
- For off-campus PBDs that have been determined by CMS to meet the mid-build exception (i.e., were being developed as of November 2, 2015 and met the other statutory requirements), but did not provide items or services reimbursed under OPPS until later, the proposed baseline period will be one year period beginning on the first date the excepted off-campus PBD furnished items or services reimbursed under OPPS.

OFF-CAMPUS EMERGENCY DEPARTMENT DATA COLLECTION

CMS proposes to create a new claims modifier for services furnished in off-campus provider-based emergency departments. In the OPPS Proposed Rule, CMS indicates that it has observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under OPPS since 2010 [8] and is interested in developing data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments. [9] To develop the data, CMS proposes to create 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. [10]

PROPOSED REIMBURSEMENT CUT FOR HOSPITAL OUTPATIENT CLINIC VISITS

CMS proposes a significant reimbursement cut to hospital clinic visits furnished in otherwise excepted off-campus PBDs. [11] While an excepted off-campus PBD would 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) in CY 2019, the payment rate for such services would be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier "PN". [12] That is, CMS will pay the site-neutral payment rate (as noted above, proposed to be 40% of OPPS for CY 2019) for clinic visits in otherwise excepted off-campus PBDs. [13]

Further, CMS proposes to implement this reimbursement change in a non-budget neutral manner. [14] 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] As proposed, this change would not affect reimbursement for the facility fee associated with hospital outpatient clinic visits furnished in on-campus PBDs or PBDs on the campus of a remote location of a hospital, as the "PO" modifier is not required for services furnished in those locations.

DRUG REIMBURSEMENT CHANGES

- *340B Reimbursement Cut for Nonexcepted PBDs*. CMS proposes 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 PBDs the 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, but represents a significant cut from the prior rate of ASP plus 6 percent. [16] CMS estimates the change would save Medicare and beneficiaries approximately $48.5 million. [17]

- *Payment for Biosimilar Biological Products.* CMS proposes to continue the policy in place to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. CMS notes that it received numerous comments regarding its recently finalized policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid ASP (of the biosimilar) minus 22.5 percent of the reference product. Commenters noted that because the payment reduction would be based on the reference product's ASP (generally higher than the biosimilar), the payment reduction would be more significant than if based on the biosimilar's ASP. Accordingly, for CY 2019, CMS proposes changes to the Medicare Part B drug payment methodology for biosimilars acquired under the 340B program, to pay nonpass-through biosimilars acquired under the 340B Program at 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). [18]
- *Payment if ASP Data Not Available*. Similar to the proposed changes in the CY 2019 Medicare Physician Fee Schedule ("PFS") proposed rule for CY 2019, if sufficient ASP data is not available, CMS proposes 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 wholesale acquisition cost ("WAC") plus 3 percent under the OPPS instead of WAC plus 6 percent. If WAC data is not available for a drug or biological product, CMS proposes to continue paying for separately payable drugs and biological products at 95 percent of the average wholesale price ("AWP"). 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. [19]
- *Competitive Bidding for Part B Drugs*. Following on President Trump's drug pricing blueprint, the Center for Medicare and Medicaid Innovation ("CMMI") issued a Request for Information ("RFI") as part of the OPPS Proposed Rule seeking public comment on a potential competitive bidding model for Part B drugs. CMMI is seeking information and feedback on numerous aspects of the model, including its scope, which providers should be included or excluded, the proper role of private sectors vendors, whether it should be limited to a set population, beneficiary protections, the inclusion of other payors, and options for model payments. [20] 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." [21]

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

While CMS recognizes the high rate of adoption of certified EHR technology (CEHRT), CMS notes that barriers still exist for the exchange of electronic health information across the continuum of care. [22] Several new initiatives related to electronic exchange of health information will be implemented over the next few years. For example, through the 21st Century Cures Act, Congress has directed that the Office of the National Coordinator for Health Information Technology (ONC) ". . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." [23] In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement, which establishes minimum standards for trusted exchange to enable interoperability across disparate health information networks. ONC will finalize the Trusted Exchange Framework based on public comments and release a final version. [24]

In light of the widespread adoption of EHR, CMS is interested in hearing how it can use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities 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. [25] CMS notes several proposed and final rules that also address such communication among providers -- a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113-185); a proposed rule (81 FR 39448) that would update a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs; and a final rule (81 FR 68688) that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. [26]

In the OPPS Proposed Rule, CMS requests feedback on several specific questions, including the following:

- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this goal be achieved anyway in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-91), and implementation of relevant policies in the 21st Century Cures Act?

- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- CMS is also interested in comments on how to advance the Federal Government's MyHealthEData initiative, which is aimed at giving patients control of their medical data. [27]

REQUEST FOR INFORMATION ON PRICE TRANSPARENCY

As in the CY 2019 PFS Proposed Rule and FY 2019 IPPS/LTCH Proposed Rule, in the OPPS Proposed Rule, CMS continues to express its concerns about insufficient pricing transparency, noting that patients may be surprised by unexpected bills, such as for out-of-network physician services at in-network facilities, for facility fees, and for physician services in emergency departments. CMS also expresses its concern that charge information may not adequately assist patients in understanding what they are likely to owe for services rendered. [28] Therefore, CMS is considering 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 in the CY 2019 PFS Proposed Rule, CMS is soliciting comments in a number of areas, such as:

- The definition of "standard charges" across various provider and supplier settings, what the definition should be based on, and whether it should be different depending on whether or not the setting maintains a chargemaster.
- The types of information most beneficial to patients, how providers and suppliers can best enable patients to use charge and cost information in their decision-making, and how CMS, providers and suppliers can help third-parties create patient-friendly interfaces with these data.
- Whether providers and suppliers should be required to inform patients of the out-of-pocket costs for a service before the service is rendered and how that information would be provided to better support patient choice and decision-making.
- How CMS can help beneficiaries better understand their Medicare cost-sharing obligations for each Medicare covered service and what role providers and suppliers should play in helping inform patients of their out-of-pocket costs.
- Whether CMS can require providers and suppliers to inform patients of Medicare reimbursement for particular services performed by that provider or supplier and, if so, what changes would need to be made by providers and suppliers and what burdens would be imposed as a result. [29]

CMS is also seeking comments in similar areas on improving Medigap patients' understanding of their out-of-pocket costs prior to receiving services. [30]

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, 83 Fed. Reg. 37,046 (proposed Jul. 31, 2018) [hereinafter OPPS Proposed Rule].
[2] *Id*. at 37,148-49.
[3] 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).
[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 Nonexcepted Off-Campus ProviderBased 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).
[5] OPPS Proposed Rule, 83 Fed. Reg. at 37,150.
[6] *Id*. at 37,148.
[7] *Id*. at 37,149.
[8] *Id*. at 37,137.
[9] *Id*. at 37,138.
[10] *Id*.
[11] *Id*. at 37,049-50.
[12] *Id*. at 37,142.
[13] *Id*.
[14] *Id*. at 37,142-43.
[15] *Id*.
[16] *Id*. at 37,143.
[17] *Id*. at 37,226.
[18] *Id*. at 37,123.
[19] *Id*. at 37,125.
[20] *Id*. at 37,212–13.
[21] *Id*. at 37,215.
[22] *Id*. at 37,209.
[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] *Id*. at 37,210.
[27] *Id*. at 37,210-11.
[28] *Id*.

[29] *Id*. at 37,212.
[30] *Id*. at 37,212.

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