The Centers for Medicare & Medicaid Services (CMS) yesterday released the calendar year (CY) 2019 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to standard updates, the OPPS proposed rule would expand Medicare site-neutral payment policies in several areas and make changes to the payment policies for 340B-acquired and other drugs. Comments on the proposed rule are due by Sept. 24.

With this proposed rule, CMS has once again shown a lack of understanding about the reality in which hospitals and health systems operate daily to serve the needs of their communities. CMS has misconstrued Congressional intent with its proposal to cut payments for hospital clinic services in “excepted” off-campus hospital provider-based departments (PBDs). In 2015, Congress clearly intended to preserve the existing outpatient payment rate for these excepted off-campus PBDs in recognition of the critical role they play in their communities. But CMS’s proposal runs counter to this and will instead impede access to care for the most vulnerable patients.

CMS also stepped up its assault on 340B hospitals that serve vulnerable communities by expanding last year’s nearly 30 percent cut to outpatient drug payments to a significant number of additional hospital outpatient departments and life-saving drugs. These, like the previous cuts to a program that requires no federal contributions but instead relies on discounts required of drug companies, exceed CMS’s statutory authority and remain subject to legal challenge.

Key Takeaways

- Update OPPS payment rates by 1.25 percent in CY 2019;
- Reduce payments for clinic visit services in excepted off-campus PBDs to 40 percent of the OPPS rate;
- Reduce payments for new families of services furnished in excepted off-campus PBDs to 40 percent of the OPPS rate;
- Reduce payments for 340B-acquired drugs in non-excepted off-campus PBDs to ASP minus 22.5 percent;
- Reduce payments for new drugs without ASP data to wholesale acquisition cost plus 3 percent;
- Remove 10 measures from the Outpatient Quality Reporting Program;
- Remove the Communication about Pain questions from the inpatient HCAHPS survey; and
- Remove seven measures from the ASC Quality Reporting Program.
HIGHLIGHTS OF THE OUTPATIENT PPS PROPOSED RULE

Payment Update: CMS proposes to update OPPS rates by 1.25 percent for CY 2019. This change includes a market-basket update of 2.8 percent, as well as a productivity cut of 0.8 percentage points and an additional reduction of 0.75 percentage points, as required by the Affordable Care Act (ACA). These payment adjustments, in addition to other proposed changes in the rule, are estimated to result in a net decrease in OPPS payments of 0.1 percent compared to CY 2018 payments. For those hospitals that do not publicly report quality measure data, CMS would continue to impose the statutory 2.0 percentage point additional reduction in payment.

Proposed Changes to Site-neutral Payment Policy for Off-campus Provider-based Department (PBD): Section 603 of the Bipartisan Budget Act of 2015 requires that, with the exception of dedicated emergency department (ED) services, services furnished in off-campus PBDs that began billing under the OPPS on or after Nov. 2, 2015, or that cannot meet the 21st Century Cures "mid-build" exception, will no longer be paid under the OPPS, but under another applicable Part B payment system. In the CY 2019 physician fee schedule (PFS) proposed rule, the agency continues to identify the PFS as the applicable payment system for most of these non-excepted services and proposes to set payment for most non-excepted services at 40 percent of the OPPS rate.

Proposed “Site-neutral” Reduction in Payment for Hospital Outpatient Clinic Visits in Off-campus PBDs. Citing “unnecessary” increases in the volume of clinic visits in hospital PBDs, CMS proposes to pay for visits furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs. Specifically, CMS proposes to pay for clinic visit (i.e., evaluation and management) services in excepted PBDs at the “PFS-equivalent” payment rate of 40 percent of the OPPS payment amount. The agency would implement this proposal in a non-budget neutral manner, which means that it is estimated to cut hospital payments under the OPPS by $760 million in CY 2019.

CMS requests comments on ways they could expand this policy to other items and services paid under the OPPS that may demonstrate “unnecessary increases in outpatient department utilization;” other possible policies to control the volume of services in hospital outpatient departments under the OPPS; and whether they should make adjustments to the proposed policy in provider shortages areas or rural areas.

Expansion of Services at Excepted Off-campus PBDs. Under current site-neutral payment policy, an excepted off-campus PBD may expand the type of services it furnishes and will receive the full OPPS rate for such services. However, in the proposed rule, CMS expresses concern that this policy incentivizes hospitals to purchase additional physician practices and add those physicians to an existing excepted off-campus PBD, in a manner that the agency believes is inconsistent with the intent of Sec. 603.

As such, for 2019, CMS proposes that if an excepted off-campus PBD begins to furnish a new service from a clinical family for which it did not previously furnish and bill for during a baseline period (from Nov. 1, 2014 through Nov. 1, 2015), the
new service would no longer be a covered outpatient department service. Instead, it would be a non-excepted service and paid under the PFS at 40 percent of the OPPS amount. To implement this policy, CMS proposes 19 groupings of clinical families of services. The agency would require that, as a condition of OPPS payment eligibility, excepted off-campus PBDs ascertain the clinical families from which they furnished services during the baseline period. The agency had previously proposed, but ultimately withdrew, a similar policy, which would penalize hospital outpatient departments that expand the types of critical services they offer to their communities – preventing them from caring for the changing needs of their patients.

Proposal to Apply the 340B Drug Payment Policy to Non-excepted Off-campus PBDs. In CY 2018, CMS finalized an OPPS policy to reduce payment for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. However, because services furnished in non-excepted off-campus PBDs are no longer considered to be covered outpatient department services, 340B-acquired drugs furnished in these settings were not subject to this policy and so continued to be paid at ASP plus 6 percent in 2018.

In the CY 2019 proposed rule, CMS expresses concern that the difference in the payment amount for 340B-acquired drugs furnished in excepted and non-excepted off-campus PBDs creates an incentive for hospitals to move drug administration services for these 340B-acquired drugs to non-excepted PBDs. Therefore, for CY 2019, CMS proposes to pay for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program at a rate of ASP minus 22.5 percent when they are furnished by non-excepted off-campus PBDs. This policy would not apply to rural sole community hospitals, children’s hospital or PPS-exempt cancer hospitals. The agency estimates that this payment change would result in a cut of $48.5 million in CY 2019.

Collecting Data on Services Furnished in Off-campus EDs. Citing a recommendation made by the Medicare Payment Advisory Commission (MedPAC), CMS notes it will be collecting data to assess the extent to which OPPS services are shifting to off-campus provider-based EDs. Therefore, the agency announces that, effective Jan. 1, 2019, it will create a new HCPCS modifier (ER—Items and services furnished by a provider-based off-campus ED) that will be reported with every claim line for outpatient hospital services furnished in an off-campus ED. CMS states that this will be accomplished through a subregulatory mandate.

Payment Policy for Separately Payable Biosimilar Products Acquired Under the 340B Program: CMS proposes to pay for nonpass-through biosimilar products that are acquired under the 340B program at ASP minus 22.5 percent of the biosimilar’s own ASP rather than ASP minus 22.5 percent of the reference product’s ASP.

Comprehensive APCs: CMS proposes to create three new comprehensive APCs (C-APCs) for ear, nose, and throat (ENT) and vascular procedures. This proposal would increase the total number of C-APCs to 65.
Proposed Changes to the Inpatient-only List: CMS proposes to remove two procedures from the inpatient-only list: code 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery) and CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty). It would also add one procedure to the inpatient-only list: HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single).

Proposed Reduction in Payment for New Drugs Before ASP Data Are Available: Currently, Medicare reimburses new Part B drugs, those for which ASP data is unavailable during the first quarter of sales, at the rate of wholesale acquisition cost (WAC) plus 6 percent. The WAC is the manufacturer’s list price and does not incorporate prompt-pay or other discounts.

Consistent with a similar policy in the CY 2019 PFS proposed rule, CMS proposes to reduce payment for new nonpass-through Part B drugs and biologicals (that are not acquired under the 340B program) to WAC plus 3 percent, rather than WAC plus 6 percent. This rate would only apply during the period of time when ASP data for the new drug are unavailable. This proposal is consistent with recommendations included in the fiscal year (FY) 2019 President’s Budget Proposal and MedPAC’s June 2017 report to Congress. CMS notes this payment reduction would not apply to single source drugs that are required under law to be paid at 106 percent of the lesser of ASP or WAC. 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.

New Technology APC Payment for Extremely Low-volume Procedures: CMS proposes to apply a “smoothing methodology” based on multiple years of claims data to establish a more stable rate for services assigned to New Technology APCs with fewer than 100 claims per year under the OPPS. Under the smoothing methodology, the agency would use up to four years of claims data to calculate the geometric mean costs, the median costs, and the arithmetic mean costs for each of these procedures and present each statistic in the annual rulemaking for public comment. This methodology allows the option to use of one of these statistics to assign the most representative payment for the service. In addition, CMS proposes to exclude low-volume services from bundling into C-APC procedures.

Proposed Changes for Outpatient Quality Reporting Program (OQR): CMS proposes to remove 10 measures from the OQR. One measure, OP-27, would be removed beginning with the CY 2020 payment determination, which is based upon 2018 provider performance. Nine more measures would be removed beginning with the CY 2021 payment determination, which is based upon 2019 provider performance. CMS would remove the measures because they are “topped out,” do not reflect current
practice have limited links to improved outcomes, or have costs that exceed their value. The measures proposed for removal include:

- Influenza Vaccination Coverage among Healthcare Personnel (OP-27);
- Median Time to ECG (OP-5);
- Mammography Follow-up Rates (OP-9);
- Thorax Computed Tomography (CT) Use of Contrast Material (OP-11);
- The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (OP-12);
- Simultaneous Use of Brain CT and Sinus CT (OP-14);
- Tracking Clinical Results between Visits (OP-17);
- Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (OP-29);
- Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (OP-30); and
- Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (OP-31).

If these measures are removed as proposed, the OQR would include only 12 measures. As such, CMS is requesting public comment on future measure topics for the OQR, specifically outcome measures.

**Inpatient Quality Reporting Program (IQR) HCAHPS Pain Questions.** In the FY 2018 inpatient PPS final rule, CMS removed previously adopted pain management questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and replaced them with new “Communication about Pain” questions. This was in response to the nationwide opioid epidemic and was an attempt to remove inadvertent incentives to overprescribe opioids to control pain. Rather than asking about whether the patient felt pain, the new questions ask whether hospital personnel talked with the patient about pain. However, stakeholders voiced concerns that these questions could still potentially impose pressure on staff to overprescribe opioids.

While CMS asserts that there are no scientific studies specifically supporting an association between the HCAHPS “Communication about Pain” questions and increased prescribing of opioids, it nevertheless proposes to remove the questions beginning with January 2022 discharges. CMS proposes this date rather than an earlier removal date because it believes it needs more time to make necessary updates to data collection tools and the HCAHPS Survey administration protocols. In addition, collecting the data until 2022 would allow time to assess the potential impact of using the revised questions. This would not change how performance scores are calculated for the remaining questions.

**HIGHLIGHTS OF THE MEDICARE ASC PROPOSED RULE**

**ASC Payment Update:** For CYs 2019 through 2023, CMS proposes to update the ASC payment system using the hospital market-basket update instead of the Consumer Price Index for all urban consumers (CPI-U). However, the agency requests comments on
ASCs’ cost structure to assess whether the hospital market basket is an appropriate proxy for ASC costs. During this five-year period, CMS will assess whether there is a migration of services from the hospital setting to the ASC setting as a result of the use of a hospital market-basket update, as well as whether there are any unintended consequences.

Using the hospital market-basket methodology, for CY 2019, CMS proposes to increase payment rates under the ASC payment system by 2.0 percent for ASCs that meet the ASC quality reporting requirements. This proposed increase is based on a proposed hospital market-basket percentage increase of 2.8 percent minus a proposed multifactor productivity (MFP) adjustment required by the ACA of 0.8 percentage point.

In addition, CMS indicates it will assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information in the future.

**Proposed Changes to the List of ASC-covered Surgical Procedures:** CMS proposes to revise its definition of “surgery” in the ASC payment system to account for certain “surgery-like” procedures that are assigned codes outside the Current Procedural Terminology surgical range. In addition, the agency proposes to add 12 cardiac catheterization procedures to the ASC covered procedures list.

**Payment for Non-opioid Pain Management Therapy:** In response to a recommendation from the President’s Commission on Combating Drug Addiction and the Opioid Crisis, CMS proposes to change the packaging policy for certain drugs when they are administered in the ASC setting. Specifically, the agency would provide separate payment at ASP plus 6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure performed in an ASC.

**Proposed Changes for ASC Quality Reporting Program (ASCQR):** CMS proposes to remove seven measures from the ASCQR. One measure, ASC-8, would be removed beginning with the CY 2020 payment determination, which is based upon 2018 provider performance. Eight more measures would be removed beginning with the CY 2021 payment determination, which is based upon 2019 provider performance. CMS would remove the measures because they are “topped out,” do not reflect current practice, have limited links to improved outcomes, or have costs that exceed their value. The measures proposed for removal include:

- Influenza Vaccination Coverage among Healthcare Personnel (ASC-8);
- Patient Burn (ASC-1);
- Patient Fall (ASC-2);
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC-3);
- All-Cause Hospital Transfer/Admission (ASC-4);
- Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (ASC-9);
• Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (ASC-10); and
• Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (ASC-11).

REQUESTS FOR INFORMATION (RFIs)

Interoperability RFI: CMS requests comments on ways to promote interoperability by making changes to the Medicare conditions of participation, conditions for coverage, and requirements for participation for long-term care facilities. Examples include requiring that hospitals transferring medically necessary information to another facility upon patient transfer or discharge do so electronically, or requiring that hospitals and other facilities electronically send discharge information to a community provider via electronic means if possible, or requiring that hospitals make certain information available to patients or a specified third-party application via electronic means, if requested. The AHA previously commented on this RFI when it was included in the FY 2019 inpatient PPS proposed rule.

Price Transparency RFI: CMS requests comments about whether providers and suppliers can and should be required to inform patients about charges and payment information for health care services and out-of-pocket costs, what data elements the public would find most useful, and what other changes are needed to empower patients. The AHA previously commented on this RFI when it was included in the FY 2019 inpatient PPS proposed rule.

Leveraging the Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model RFI: Building on the President’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket costs, the CMS Center for Medicare and Medicaid Innovation is seeking comment on how best to develop a model using the authority provided to the agency under the Competitive Acquisition Program in order to reduce expenditures while maintaining or improving the quality of care furnished to beneficiaries. CMS seeks feedback ways to design a potential model that tests private-sector vendor-administered payment arrangements for certain separately payable Part B drugs and biologicals, including high cost therapies. The AHA recently provided comments to the Administration on how to structure a Competitive Acquisition Program.

NEXT STEPS

Watch for detailed Regulatory Advisory in the coming weeks and an invitation to an AHA members-only call to discuss the proposed rule. CMS will accept comments on this rule through Sept. 24. Contact Roslyne Schulman, director of policy, at rschulman@aha.org, for questions on payment, and Caitlin Gillooley, associate director of policy, at cgillooley@aha.org, for questions on quality reporting.