American Hospital Association

Special Bulletin

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CMS RELEASES CY 2018 FINAL RULE FOR THE HOSPITAL OUTPATIENT/ASC PAYMENT SYSTEMS

Rule Finalizes Cut to 340B Program

On Nov. 1, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2018 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) final rule. In addition to standard updates, the OPPS rule finalizes drastic cuts in Medicare payment for separately payable drugs that are acquired under the 340B Drug Pricing Program.

For 25 years, the 340B Drug Pricing Program has been critical in helping hospitals stretch scarce federal resources to expand access to lifesaving prescription drugs and comprehensive health care for our nation's most vulnerable patients. The program constitutes less than 2.8 percent of the $457 billion in annual drug purchases made in the U.S. and does not cost the government or taxpayers a single penny. CMS's decision to cut Medicare payments to hospitals for drugs covered under the 340B program will dramatically threaten access to health care for many patients, including uninsured and other vulnerable populations. It is not based on sound policy and punishes hospitals and patients for participation in a program outside of CMS's jurisdiction. Contrary to the Administration's claims, this policy does nothing to address the stated goal of reducing the cost of pharmaceuticals. In fact, the agency's new policy would actually cause increases in Medicare beneficiaries' out-of-pocket costs for non-drug Part B benefits.

We will strongly urge CMS to abandon its misguided 340B rule, and instead take direct action to halt the unchecked, unsustainable increases in the cost of drugs. In the meantime, the AHA will work with Congress to address this issue. We also will be joining the Association of American Medical Colleges, America's Essential Hospitals and our members to pursue litigation to prevent these significant cuts to payments for 340B drugs from moving forward.

Key provisions of the final rule follow.

HIGHLIGHTS OF THE OUTPATIENT PPS FINAL RULE

Payment Update: CMS will update OPPS payment rates for CY 2018 through a 2.7 percent market-basket increase, further adjusted by a productivity cut of 0.6 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 increase in OPPS payments of 1.4 percent (approximately $5.8 billion) compared to CY 2017 payments. For those hospitals that do not publicly report quality measure data, CMS will continue to impose the statutory 2.0 percentage point additional reduction in payment.

Reduction in Payment for Drugs Purchased under the 340B Drug Pricing Program: CMS will pay for separately payable, non pass-through drugs (other than vaccines) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent. Rural sole community hospitals (SCHs), PPS-exempt cancer hospitals and children's hospitals will be excepted from this policy for CY 2018 and will continue to receive payment at ASP plus 6 percent for these drugs. This policy arises out of a recommendation made to Congress by the Medicare Payment Advisory Commission, as well as options proposed by the Government Accountability Office, the Office of the Inspector General and public comment from previous OPPS rulemaking.

In addition, as a means to effectuate this payment change, the agency is implementing a modifier, “JG”, effective on Jan. 1, 2018, for hospitals to report non pass-through separately payable drugs that *were* purchased under the 340B program. This modifier policy is a reversal from CMS’s proposed policy, which would have required that a modifier be reported with drugs *not* purchased under the 340B program. Furthermore, the three categories of hospitals excepted from these cuts – rural SCHs, PPS-exempt cancer hospitals and children’s hospitals – will be required to report an informational modifier, “TB,” to identify drugs purchased through the 340B Drug Pricing Program, although payments for these drugs will not be reduced in CY 2018.

CMS estimates that OPPS payments for separately payable drugs, including beneficiary copayment, will decrease by about $1.6 billion in CY 2018 under this policy. However, because the agency will implement this payment reduction in a budget-neutral manner within the OPPS, payment rates (and by extension, beneficiary out-of-pocket costs) for non-drug items and services will increase by an offsetting aggregate amount, estimated by CMS to be 3.2 percent.

CMS notes that due to the lack of publicly available data on drugs purchased with a 340B discount and the possibility of potential offsetting factors, such as changes in provider behavior and market changes, it is not possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount to ensure budget neutrality. Therefore, the agency warns that it may need to make an adjustment in future years to revise the OPPS conversion factor once more accurate data is available.

Packaging of Low-cost Drug Administration Services: CMS finalizes its proposal to conditionally package payment for low-cost drug administration services, except for Medicare Part B vaccine administration services.

Changes to the Inpatient-only List: CMS removes total knee arthroplasty (TKA) from the inpatient-only list, which allows for Medicare coverage of the TKA in either an inpatient or an

outpatient setting. The TKA procedure, CPT code 27447, will be assigned to C-APC 5115 with status indicator “J1”. The agency notes that the decision regarding the most appropriate care setting for such a surgical procedure is a complex medical judgment made by the physician. Therefore, the agency will prohibit Recovery Audit Contractors review for patient status for TKA procedures performed in the inpatient setting for a two-year period in order to allow time and experience for these procedures in these settings.

Modifier for X-rays Taken Using Computed Radiography Technology: Consistent with the requirements of the Consolidated Appropriations Act of 2016, effective for services furnished starting in 2018, the OPPS payment for X-rays taken using computed radiography technology will be reduced by 7 percent. To effectuate the payment cuts, CMS establishes a new modifier, “FY,” that must be reported on claims to identify X-rays that are taken using computed radiography technology/cassette-based imaging.

Direct Supervision of Hospital Outpatient Therapeutic Services: In the CYs 2009 and 2010 OPPS/ASC rules, CMS revised its regulations to require direct supervision for outpatient therapeutic services furnished in hospitals and critical access hospitals (CAHs). As a result of advocacy from the AHA and others, for several years there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium having expired on Dec. 31, 2016. As urged by the AHA, in the CY 2018 final rule, CMS reinstates the enforcement moratorium for CAHs and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019 in order to give these hospitals more time to comply with the supervision requirements and to give providers time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in supervision level. The agency does not explicitly extend the enforcement moratorium for CY 2017, but anticipates issuing guidance to address enforcement policy for the direct supervision requirement for outpatient therapeutic services for CY 2017. CMS does not indicate what the guidance will entail.

Revisions to the Laboratory Date of Service Policy: For a clinical diagnostic laboratory test, the date of service (DOS) is typically the date the specimen was collected, unless certain conditions are met. In the final rule, CMS adds an additional exception to the current laboratory DOS regulations that will generally permit laboratories to bill Medicare directly for advanced diagnostic laboratory tests and molecular pathology tests excluded from OPPS packaging policy if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient’s discharge from the hospital outpatient department.

Changes for Outpatient Quality Reporting (OQR): CMS will remove six measures from the OQR. While CMS initially proposed four of the measures would be removed beginning with the CY 2021 payment determination, which is based on CY 2019 provider performance, several commenters (including the AHA) requested that these measures be removed as soon as possible. In response, CMS agreed to remove all six measures one year sooner than initially proposed, in CY 2020 (which is based on CY 2018 provider performance).

CMS cites various reasons for removing the measures, including "topped out" performance, lack of evidence linking the measures to quality, and unintended negative consequences. The measures that will be removed are:

- Median Time to Pain Management for Long Bone Fracture
- Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures
- Median Time to Fibrinolysis
- Aspirin at Arrival
- Door to Diagnostic Evaluation by a Qualified Medical Professional
- Safe Surgery Checklist Use

Delay of Outpatient and ASC Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures: In the CY 2017 final rule, CMS adopted five measures that would be derived from the OAS CAHPS survey. According to that rule, data would be collected and submitted quarterly starting with visits on Jan. 1, 2018. However, CMS determined that they "lack important operational and implementation data" regarding the collection and reliability of the OAS CAHPS survey data.

Due to concerns expressed by commenters, including the AHA, CMS finalizes its proposal to delay mandatory implementation of the survey and the associated measures "until further action in further rulemaking." Instead, the agency will conduct analyses of survey data that already have been voluntarily reported, and undertake any necessary modifications to the survey tool and/or CMS systems before the survey is required under the Hospital OQR Program.

HIGHLIGHTS OF THE MEDICARE ASC FINAL RULE

ASC Payment Update: ASC payments are annually updated for inflation by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U). For CY 2018, the CPI-U update is 1.7 percent. As required by the ACA, this update is reduced by a productivity adjustment of 0.5 percentage points, resulting in a 1.2 percent update for CY 2018.

Changes to the List of ASC-covered Surgical Procedures: For CY 2018, CMS adds three procedures to the ASC covered procedures list.

NEXT STEPS

The OPPS/ASC final rule will be published in the Nov. 13 Federal Register. Watch for an AHA Regulatory Advisory with further details in the coming weeks.

Please contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org for questions.