American Hospital Association

Regulatory Advisory

November 21, 2017

Medicare Outpatient PPS and ASC Final Rule for CY 2018

AT A GLANCE

At Issue:

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; on Nov. 2, it released the CY 2018 Medicare physician fee schedule (PFS) 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. Specifically, CMS will pay for separately payable, nonpass-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. In addition, the agency is requiring the use of two new modifiers to implement the rule's final policy on 340B drug payments. The PFS final rule makes additional cuts in site-neutral payment rates for services furnished in certain off-campus provider-based departments (PBDs) of a hospital, lowering the rates from 50 percent of the OPPS amount to 40 percent.

In addition, the OPPS final rule includes several other important changes. CMS:

- removes total knee arthroplasty (TKA) from the inpatient-only list, which allows for Medicare coverage of TKA in either an inpatient or an outpatient setting;
- reinstates the direct supervision enforcement moratorium for critical access hospitals and small rural hospitals for CYs 2018 and 2019;
- conditionally packages payment for low-cost drug administration services, except for vaccine administration services; and
- delays implementation of the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey-based measures until the agency can conduct further analysis.

The final rules take effect Jan. 1, 2018. (Please watch for a separate AHA Regulatory Advisory on the PFS final rule.) In addition, the AHA offers members more detailed summaries, prepared by Health Policy Alternatives Inc., of the CY 2018 OPPS final rule and the PFS final rule.

Our Take:

The 340B Drug Pricing Program is 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, it would actually increase Medicare beneficiaries' out-of-pocket costs for non-drug Part B benefits.

We will continue to 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 is working with Congress to address this issue. On Nov. 14, bipartisan legislation (H.R. 4392) was introduced by Reps. David B. McKinley (R-WV) and Mike Thompson (D-CA) that would prevent the cut from taking effect. In addition, on Nov. 13, the AHA, along with the Association of American Medical Colleges, America's Essential Hospitals and our members, filed a lawsuit to prevent these significant cuts to payments for 340B drugs from moving forward.

In the PFS rule, CMS finalized a policy that adversely affects patient access to care by reducing Medicare rates for services hospitals provide in "new" off-campus hospital clinics. We are particularly concerned about the impact on rural and vulnerable communities that do not have sufficient access. We also remain troubled that the agency's continued short-sighted policies on the relocation of existing off-campus provider-based clinics will prevent patients and communities from having access to the most up-to-date, high-quality services. **We will continue to urge CMS to provide adequate support to cover the costs of providing care so that we can continue to serve as the around-the-clock access point for community care.**

What You Can Do:

- ✓ **Learn more about the OPPS final rule policies, including an update on AHA's advocacy initiatives on payment for 340B-acquired drugs, by participating in a members-only webinar on Dec. 4 at 2 p.m. ET.** To register for this 60-minute webinar, visit here.
- ✓ **Please contact your representative today and urge him or her to cosponsor H.R. 4392.** It is critical that we secure as many cosponsors as possible so the bill could be included as part of a year-end legislative package.
- ✓ Share this advisory with your chief financial officer, chief medical officer, pharmacy leaders and other senior management, billing and coding staff, nurse managers and key physician leaders.
- ✓ Model the impact of the ambulatory payment classification (APC) changes on your expected CY 2018 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2017 will be available soon on the AHA's OPPS webpage. To access these documents, you must be logged on to the website.

Further Questions:

Please contact Roslyne Schulman, director of policy, at rschulman@aha.org for more information.

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BACKGROUND

On Nov. 1, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2018 outpatient prospective payment system (OPPS) and 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. CMS also finalizes policy changes to package low-cost drug administration services, remove total knee arthroplasty (TKA) from the inpatient-only list of procedures and not enforce direct supervision in critical access hospitals (CAHs) and small rural hospitals in CYs 2018 and 2019. Further, the Medicare physician fee schedule (PFS) final rule makes additional cuts in site-neutral payment rates for services furnished in certain off-campus provider-based departments (PBDs) of a hospital, lowering the rates from 50 percent of the OPPS amount to 40 percent. The final rules take effect Jan. 1, 2018.

This Regulatory Advisory highlights many of the rule's final policies. Watch for separate a Regulatory Advisory on the CY 2018 PFS final rule, which highlights a range of other policies contained in the PFS. In addition, the AHA offers members more detailed summaries, prepared by Health Policy Alternatives Inc., of the CY 2018 OPPS final rule and the PFS final rule.

CHANGES TO THE CY 2018 OPPS

OPPS Update and Linkage to Hospital Quality Data Reporting

The CY 2017 OPPS conversion factor is $75.001. To calculate the final conversion factor for CY 2018, the agency adjusted the 2017 conversion factor by the fee schedule increase factor and made further adjustments for various budget neutrality factors. The fee schedule increase factor equals the hospital inpatient market-basket increase factor of 2.7 percent, reduced by a productivity adjustment of 0.6 percentage points and an additional reduction of 0.75 percentage points, as required by the Affordable Care Act (ACA). Thus, CMS applies a fee schedule increase factor of 1.35 percent for the CY 2018 OPPS final rule conversion factor. The agency also applies a required wage index budget neutrality adjustment of 0.9997, a cancer hospital payment adjustment of 1.0008, an adjustment for drugs purchased under the 340B Program of 1.0319, and an adjustment of 0.2 percentage point of projected OPPS spending and outlier payments to arrive at the final CY 2018 conversion factor of $78.636.

Hospitals that do not meet the Outpatient Quality Reporting (OQR) program reporting requirements are subject to a further reduction of 2.0 percentage points, resulting in a fee schedule increase factor of -0.65 percent. Thus, the resulting CY 2018 OPPS conversion factor is $77.064 for hospitals that do not meet OQR reporting requirements.

CMS estimates that the fee schedule increase factor and all other policies in the final rule will result in the following per-case changes in payment:

All Hospitals	**1.5%**
Urban Hospitals	1.3%
Large Urban	1.3%
Other Urban	1.4%
Rural	2.7%
Sole Community	4.1%
Other Rural	0.9%

These payment adjustments, in addition to other changes in the rule are estimated to result in a net increase in OPPS payments of approximately $690 million in CY 2018. Taking into account estimated changes in enrollment, utilization and case-mix for CY 2018, CMS estimates that the OPPS expenditures, including beneficiary cost-sharing, will be approximately $69.9 billion, approximately $5.8 billion higher than estimated OPPS expenditures in CY 2017.

Payment Reduction for Drugs Purchased under the 340B Drug Pricing Program

CMS finalizes its proposed policy to pay for separately payable covered outpatient Part B drugs (assigned status indicator "K"), other than vaccines (assigned status indicator "L" or "M") and drugs on pass-through payment status (assigned status indicator "G"), that are acquired through the 340B Drug Pricing Program or through the 340B Prime Vendor Program (PVP)[1] at the rate of average sales price (ASP) minus 22.5 percent. Medicare will continue to pay drugs that were not purchased with a 340B discount at ASP plus 6 percent. Biosimilar biological products not on pass-through payment status that are purchased through the 340B program or through the 340B PVP will be paid at ASP minus 22.5 percent of the reference product's ASP, while biosimilar biological products on drug pass-through payment status will continue to be paid ASP+6 percent of the reference product.

Rural sole community hospitals (SCHs) (as described under the regulations at § 42 CFR 412.92 and designated as rural for Medicare purposes)[2], 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 drugs acquired under the 340B program. For rural SCHs, this exception applies to those hospitals that receive the OPPS rural SCH adjustment and is not tied to HRSA's 340B hospital designation policy. CAHs are not included in the 340B policy change because

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[1] The PVP is a Health Resources and Services Administration (HRSA) program under which the prime vendor can negotiate additional discounts (known as "subceiling prices") on some covered outpatient drugs.

[2] The hospitals to which this exception applies are the same hospitals that receive the OPPS rural SCH adjustment. This includes providers designated as SCHs, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103.

they are not paid under the OPPS. **Further, CMS notes that its policy to reduce payment for 340B-acquired drugs will not apply to drugs furnished in nonexcepted off-campus PBDs in CY 2018 because services in nonexcepted are no longer considered covered outpatient department services and are not paid under the OPPS.** However, CMS may consider adopting such a policy in CY 2019 rulemaking.

The AHA continues to believe that 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, it 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 is working with Congress to address this issue. On Nov. 14, bipartisan legislation (H.R. 4392) was introduced by Reps. David B. McKinley (R-WV) and Mike Thompson (D-CA) that would prevent the cut from taking effect. We also have joined with 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.

New Modifiers to Implement the 340B Drug Payment Reduction Policy. As a means to effectuate this payment change, the agency is implementing a modifier, "JG" (Drug or biological acquired with 340B Drug Pricing Program Discount), effective on Jan. 1, 2018, for hospitals to report with nonpass-through separately payable drugs (i.e., those drugs assigned status indicator "K") that *were* acquired under the 340B program. CMS states that the phrase "acquired under the 340B Program" is inclusive of all drugs acquired under the 340B program or the PVP, regardless of the level of discount applied to the drug. For separately payable drugs, application of modifier "JG" will trigger payment at ASP minus 22.5 percent. In response to some commenters' concerns that it would be operationally burdensome for hospitals to have to determine on a claim-by-claim basis whether a drug is eligible for separate payment, the agency states that it will allow the "JG" modifier to be reported with drugs that are packaged (status indicator "N" drugs), although such modifier will not result in a payment adjustment.

In addition, beginning Jan. 1, 2018, providers that are excepted from the 340B drug payment policy for CY 2018, which include rural SCHs, children's hospitals and PPS-exempt cancer hospitals, should not report modifier "JG". Instead, these excepted providers are required to report the informational modifier "TB" (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount.

The informational modifier "TB" will facilitate the collection and tracking of 340B claims data for OPPS providers that are excepted from the payment adjustment in CY 2018. However, it will not trigger a payment adjustment.

This final modifier policy is a reversal from CMS's proposed policy, which would have required that a modifier only be reported with drugs *not* purchased under the 340B program. CMS states that its final rule modifier approach will pose less of an administrative burden because it is aligned with the modifier requirement already mandated in several states under their Medicaid programs. The agency further believes that a consistent application of the modifier for a drug that was purchased under the 340B program (instead of a drug not purchased under the 340B program) will help improve program integrity by helping ensure that hospitals are not receiving "duplicate discounts" through both the Medicaid rebate program and the 340B Program.

Impact of 340B Drug Payment Reduction. 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 – which it claims would be similar to the adjustment it made after the agency implemented a policy to package the costs of most clinical lab services.**

Response to Public Comments and Other Considerations Regarding the 340B Drug Payment Policy. The preamble to the final rule (see pages 548-613 of the display version of the final rule) includes an extensive discussion of public comments and CMS's responses to the 340B drug payment policy. In particular, the agency sets out its response to commenters, including the AHA, who questioned CMS's statutory authority to make its proposed changes to payment for drugs acquired under the 340B program. CMS also responds to comments that assert that its proposal contrasts with longstanding practice, is a violation of Section 340B of the Public Health Services Act, is procedurally defective and inconsistent with recommendations made by CMS's Advisory Panel on Hospital Outpatient Payments, will not directly benefit Medicare beneficiaries with regard to cost-sharing and includes errors in its estimation of savings.

Other OPPS Drug Payment Policies for CY 2018

Packaging Policy for "Threshold-packaged" and "Policy-packaged" Drugs, Biologicals and Radiopharmaceuticals. The payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status are based on the first quarter of 2017

ASP data. Updates to the ASP-based rates will be published quarterly and posted on CMS's website through CY 2018.

CMS pays for drugs, biologicals and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment or separate payment (individual APCs). For CY 2018, CMS increases the packaging threshold for "threshold-packaged" drugs, including nonimplantable biologicals and therapeutic radiopharmaceuticals, to $120 per day, $10 more than in CY 2017. Therefore, drugs costing less than $120 will have their cost packaged in the procedure with which they are billed, such as an outpatient clinic visit. Drugs costing more than $120 will be paid separately through their own APC.

There are exceptions to this threshold-based packaging policy for certain "policy-packaged" drugs, biologicals and radiopharmaceuticals. Consistent with current CMS packaging policy, the agency will continue to package the costs of all anesthesia drugs; drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure, regardless of whether they meet the $120 per day threshold. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the final rule.

Payment for Drugs and Biologicals without Pass-through Status that are not Packaged. For CY 2018, with the exception of the final policy regarding drugs acquired through the 340B Drug Pricing Program (discussed above), CMS will continue its current policy and pay for separately payable drugs and biologicals at the "statutory default rate" of ASP plus 6 percent. CMS states that this payment requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

High-cost/Low-cost Threshold for Packaged Skin Substitutes. Consistent with current policy, CMS is assigning skin substitutes with a geometric mean unit cost (MUC) or a per-day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high-cost group. In addition, for CY 2018, CMS establishes that a skin substitute product that does not exceed the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high-cost group for CY 2017, is again assigned to the high-cost group for CY 2018. CMS's goal is to maintain similar levels of payment for skin substitute products for CY 2018 while the agency studies its current skin substitute payment methodology.

Changes to Site-neutral Payment Policy for Off-campus PBDs

Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that, with the exception of emergency department (ED) services as well as services provided in outpatient departments meeting the additional "under development" exception in the 21st Century Cures Act, services furnished in off-campus PBDs that began billing under the OPPS on or after Nov. 2, 2015 (referred to as "nonexcepted services") are no longer

paid under the OPPS. Instead, these services are covered and paid under "another applicable Part B payment system." For CY 2017, CMS finalized the PFS as the applicable Part B payment system for most of nonexcepted services and set payment for most nonexcepted services at 50 percent of the OPPS rate.

Establishment of a Final Payment Rate for Nonexcepted Services in CY 2018. In the CY 2018 PFS final rule, **CMS reduces the site-neutral payment rate from 50 percent of the OPPS rate to 40 percent of the OPPS rate for most nonexcepted services.** The agency estimates that this change will save Medicare Part B $12 million in 2018 compared to 2017.

This final rule policy is a departure from the rate that CMS had proposed for 2018: 25 percent of the OPPS payment rate (referred to as a "PFS Relativity Adjuster" of 25 percent). The proposed CY 2018 PFS Relativity Adjuster of 25 percent was calculated based on a code-level comparison of the payment for a single hospital outpatient department service, the hospital outpatient clinic visit (the most commonly billed service in off-campus PBDs), to the weighted average difference between the nonfacility and facility PFS payment for outpatient visits in hospital outpatient departments. However, in establishing its final policy, CMS agreed with the AHA, who had expressed concern about the proposed payment rate for 2018 being based on a single code level comparison. In addition, CMS acknowledged that the proposed PFS Relativity Adjuster of 25 percent of the OPPS rate may be too low. The agency also agreed with commenters who expressed concern that it failed to account for the much greater packaging of payments for services under the OPPS compared to the PFS, but notes it is unable to fully calculate the effect of packaging under the OPPS.

CMS arrives at its final payment rate of 40 percent of the OPPS rate by comparing the payment rates under the PFS and OPPS for an updated list of the top 22 most frequently billed major HCPCS codes with a "PO" modifier (signifying that the service was billed by an off-campus PBD that is not an ED), including the hospital outpatient clinic visit, reported using HCPCS code G0463. Table 10 in the final rule shows the services and data used in calculating the 2017 PFS Relativity Adjuster. The resulting utilization-weighted average comparison between the PFS and the OPPS is 35 percent. That is, the applicable payment amount under the PFS is 35 percent of the amount that would have been paid under the OPPS for these commonly billed services. CMS states that because it is unable to fully calculate the effects of packaging under the OPPS, it believes it is appropriate to adjust the 35 percent calculation upwards to a 40 percent PFS Relativity Adjuster.

CMS also clarifies that drugs and biological products that are unconditionally packaged under the OPPS will continue to be packaged when furnished in a nonexcepted off-campus PBD. Drug administration services subject to conditional packaging (identified by status indicator "Q1" under the OPPS) will be packaged under the OPPS if the relevant criteria are met; otherwise they are separately paid. Drugs and biological products that are separately payable under the OPPS (identified by status indicator "G" or "K" under the OPPS) are paid consistent with payment rules in the physician office

setting. **In addition, drugs that are acquired under the 340B program and furnished by nonexcepted off-campus PBDs are paid under the PFS and are therefore not subject to the OPPS drug payment reductions.**

Other Site-neutral Payment Policies. CMS does not make any other changes to its site-neutral policy in CY 2018. This includes retaining its problematic policy that the relocation of an existing PBD will result in it losing its excepted status and being paid at the site-neutral rate, except in extraordinary circumstances. Further, for CY 2018, CMS continues policies under which:

- hospitals bill on the institutional claim (UB04/837I) using the claim line modifier "PN" to indicate that the service is a nonexcepted item or service;
- the geographic adjustments used under the OPPS will apply to nonexcepted payments;
- the following OPPS payment adjustments are not applied to nonexcepted services: outlier payments, the rural SCH adjustment, the cancer hospital adjustments, transitional outpatient payments, the hospital OQR payment adjustment, and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service;
- nonexcepted hospital partial hospitalization (PHP) program services will be paid at the community mental health center (CMHCs) per diem rate;
- the supervision rules that apply for hospitals will apply for nonexcepted services in off-campus PBDs; and
- beneficiary cost-sharing rules that apply under the PFS apply for all nonexcepted items and services furnished by off-campus PBDs, regardless of the cost-sharing obligation under the OPPS.

For more detail on the final Medicare off-campus PBD site-neutral policies, see the CY 2017 OPPS final rule.

Payment in CY 2019 and Future Years. CMS continues to believe that by enacting Section 603 of the BiBA, Congress intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for services they furnish there. Therefore, the agency still intends that its payment policy ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible, while allowing nonexcepted off-campus PBDs to bill in a straight-forward way for services they furnish.

CMS states that its current approach does not result in payment rates being equal on a procedure-by-procedure basis, but rather only moves toward equalizing payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs. Therefore, for certain specialties, service lines, and nonexcepted off-campus PBD types, total Medicare payments for the same services might be either higher or lower when furnished by a nonexcepted off-campus PBD rather than in a physician office. CMS remains concerned that such specialty-specific patterns in payment differentials could result in continued incentives for hospitals to buy certain types of physician offices

and convert them to nonexcepted off-campus PBDs. However, continuing a policy similar to the one finalized will allow hospitals to continue billing through a facility claim form and allow for continuation of the other OPPS-like policies more suitable for hospital outpatient departments.

Therefore, for CY 2019 and for future years, CMS intends to examine updated claims data[3] in order to determine not only the appropriate PFS Relativity Adjuster, but also whether additional adjustments to the methodology are appropriate. The agency's goal is to attain site-neutral payments that promote a level playing field under Medicare between physician office settings and nonexcepted off-campus PBD settings, without regard to the kinds of services furnished by particular off-campus PBDs.

Changes to the Inpatient-only List

Procedures to be Removed from the Inpatient-only List. CMS used its established methodology to identify six procedures it will remove from the inpatient-only list for CY 2018. These services are:

- CPT 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (TKA));
- CPT 43282 (Laparoscopy, surgical, repair of paraesophageal hernia with implantation of mesh);
- CPT 43772 (Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only);
- CPT 43773 (Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only);
- CPT 43774 (Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components); and
- CPT 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed).

Regarding TKA, CMS notes that the decision regarding the most appropriate care setting for a surgical procedure is a complex medical judgment made by the physician. It also notes that it would expect providers to carefully develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA. Therefore, it finalized its proposal to prohibit Recovery Audit Contractors review of 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.

CMS also states that it received many comments regarding how to modify current Medicare payment models that include TKA, such as the Bundled Payments for Care

[3]A full year of claims data regarding the mix of services reported using the "PN" modifier (from CY 2017) will first be available for use in PFS rate-setting for CY 2019.

Improvement (BPCI) and the Comprehensive Care for Joint Replacement (CJR) initiatives, to account for its removal from the inpatient-only list. However, the agency does not expect a significant volume of TKA cases to shift to the hospital outpatient setting, particularly between Jan. 1, 2018 (the effective date for the removal of TKA from the inpatient-only list) and the current end dates of the performance periods for the BPCI and CJR models, Sept. 30, 2018 and Dec. 31, 2020, respectively. Accordingly, it does not expect a substantial impact on the patient-mix for the BPCI and CJR models. However, CMS intends to monitor the overall volume and complexity of TKA cases performed in the hospital outpatient department to determine whether any future refinements to these models are warranted.

Wage Index

The area-wage index adjusts payments to reflect differences in labor costs across geographic areas. CMS has historically adopted the final fiscal year (FY) inpatient prospective payment system (IPPS) wage index as the CY wage index for adjusting OPPS payments. Thus, the wage index that applies to a particular hospital under IPPS also applies to that hospital under the OPPS. The agency will continue this policy and use the final FY 2018 IPPS wage indices for calculating CY 2018 OPPS payments. (See AHA's Inpatient PPS Regulatory Advisory for more information about the wage index for FY 2018) For hospitals paid under the OPPS but not the IPPS, CMS will continue its longstanding policy for CY 2018 to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. As in prior years, 60 percent of the Ambulatory Payment Classification (APC) payment will be adjusted by the wage index.

Recalibration and Scaling of APC Relative Weights

CMS recalibrates the relative APC weights using hospital claims for services furnished during CY 2016. As in the previous year, the agency standardizes all of the relative payment weights to the APC 5012 (Level 2 Examinations and Related Services) because clinic visits are among the most frequently provided OPPS services. That is, CMS calculates an "unscaled" – i.e., not adjusted for budget neutrality – relative payment weight by comparing the geometric mean cost of each APC to the geometric mean cost of the APC 5012.

To comply with budget neutrality requirements, CMS compares the estimated unscaled relative payment weights in CY 2018 to the estimated total relative payment weights in CY 2017 using the service volume in the CY 2016 claims data. Based on this comparison, the CY 2018 unscaled APC payment weights are adjusted by a weight scalar of 1.4457. The effect of the adjustment is to increase the unscaled relative weights by about 44.57 percent in order to ensure that the CY 2018 relative payment weights are budget neutral.

Changes to Packaging Policies

Packaging of Low-cost Drug Administration Services. In the CY 2015 OPPS final rule, CMS began conditionally packaging payment for low-cost ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100. The packaged ancillary services are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances where hospitals provide such services without another primary service during an encounter. Under this policy, the agency assigns the conditionally packaged services to status indicator "Q1," which indicates that the service is separately payable when not billed on the same claim certain other primary services. Among the exclusion to this packaging policy were certain low-cost drug administration services.

However, for CY 2018, in order to establish a more consistent approach to packaging services under its current packaging categories, CMS examined drug administration billing patterns and payments under the OPPS in CY 2016. The agency found that APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration) had geometric mean costs of less than $100 and were often reported on the same claim with other separately payable services, such as an ED visit or clinic visit. **Accordingly, the agency finalized its proposal to conditionally package payment for these low-cost drug administration services, except for add-on codes and vaccine administrations (other than preventive services).** Table 8 in the rule lists the drug administration services included in APCs 5691 and 5692, along with their final status indicators.

Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. CMS again establishes separate thresholds for CMHCs and hospitals. For CY 2018, CMS set the projected target for outlier payments at 1 percent of total OPPS payments. The agency allocates 0.01 percent of outlier payments to CMHCs for PHP services.

The rule continues to include both a fixed-dollar and a percentage outlier threshold. But, in CY 2018, CMS increases the fixed-dollar threshold for outliers to $4,150, which is $325 more than in CY 2017, to ensure that outlier spending does not exceed the outlier target.

Thus, to be eligible for an outlier payment in CY 2018, the cost of a hospital outpatient service will have to exceed 1.75 times the APC payment amount (the percentage threshold), *and* $4,150 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare will make an outlier payment that is 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate.

Changes to Payment for X-rays Taken Using Computed Radiography Technology

CMS implements a nonbudget-neutral provision of the Consolidated Appropriations Act of 2016, which reduces OPPS payment for X-rays taken using computed radiography technology by 7 percent for services furnished in 2018 through 2022, and by 10 percent for services furnished in 2023 and subsequent years.

To implement this provision, CMS establishes a new modifier, "FY," that will be reported on claims for X-rays that are taken using computed radiography technology/cassette-based imaging. The payment reduction will be taken when this modifier is reported with the applicable HCPCS code(s) to describe imaging services that are taken using computed radiography technology. The HCPCS codes describing these imaging services to which this policy applies can be found in Addendum B to the final rule.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 requires professionals furnishing advanced diagnostic imaging services to report on the Medicare claim information about AUC reviewed by the ordering professional. Although statute required the program to begin Jan. 1, 2017, CMS has taken a measured approach by establishing different components of the AUC program framework through rulemaking over the past couple of years.

The agency proposed to begin the AUC reporting requirements on Jan. 1, 2019; however, as urged by the AHA, CMS delayed this start date until Jan. 1, 2020. In addition, 2020 will be considered an "educational and operations testing year," and CMS will pay claims regardless of whether they contain information on the required AUC consultation. The agency also plans to implement an 18-month voluntary reporting period beginning mid-2018. **The AHA urged CMS to allow providers adequate time to implement the AUC requirements before they begin affecting payment, and we are pleased with this policy**. Watch for our forthcoming CY 2018 PFS final rule Regulatory Advisory for further details.

New Technology APCs

CMS assigns new technology services that are ineligible for transitional pass-through payments and for which the agency has insufficient clinical information and cost data for appropriate assignment to a clinical APC group, to new technology APCs. These new technology APCs are designated by cost bands, which allow CMS to provide appropriate and consistent payment for designated new procedures that are not yet reflected in the claims data. An assignment to a new technology APC is temporary; the service is retained within a new technology APC until CMS acquires sufficient data to assign it to a clinically appropriate APC group. Currently, there are 51 levels of new technology APC groups with two parallel status indicators: one set with the status indicator of "S" and the other set with the status indicator of "T." These APCs have the same payment levels, but the T set is subject to the multiple procedure payment reduction and the S set is not subject to the multiple procedure payment reduction.

To improve its ability to have payments for services over $100,000 more closely match the cost of the service, for CY 2018 the agency narrows the increments for New Technology APCs 1901 through 1906 from $19,999 cost bands to $14,999 cost bands. It also adds New Technology APCs 1907 and 1908, New Technology Level 52 ($145,001-$160,000), which will allow for an appropriate payment of retinal prosthesis implantation procedures. Table 15 in the final rule includes the complete list of the modified and additional New Technology APC groups for CY 2018. The payment rates for these New Technology APCs are included in Addendum A to the rule.

Transitional Pass-through Payments

Congress created temporary additional, or "transitional pass-through payments," for certain innovative medical devices, drugs and biologicals to ensure that Medicare beneficiaries have access to new technologies in outpatient care. For CY 2018, CMS projects that pass-through payments will be 0.04 percent of total OPPS payments, or $28.06 million. This includes $10 million in pass-through payments for devices and $18.06 million for drugs and biologicals. These payments are implemented in a budget-neutral manner.

Cancer Hospital Adjustment

For CY 2018, CMS continues to provide additional OPPS payments to each of the 11 "exempt" cancer hospitals so that each cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, beginning CY 2018, a result of a provision in the 21st Century Cures Act requires this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a target PCR of 0.88 will be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustment for each cancer hospital will be the additional payments needed to result in a PCR equal to 0.88.

Rural Adjustment for Sole Community Hospitals

CMS will continue increasing payments to rural SCHs, including essential access community hospitals, by 7.1 percent for all services paid under the OPPS, with the exception of drugs, biologicals, services paid under the pass-through policy and items paid at charges reduced to costs. The adjustment is budget neutral to the OPPS and applied before calculating outliers and coinsurance.

Extension of Enforcement Moratorium on Supervision of Hospital Outpatient Therapeutic Services in CAHs and Small Rural Hospitals

In the CY 2009 and CY 2010 OPPS rules, CMS revised its regulations to require direct supervision for outpatient therapeutic services furnished in hospitals and CAHs. As a result of advocacy from 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 on enforcement having expired on Dec. 31, 2016. However, since Jan. 1, 2017, CMS has permitted its contractors to enforce the direct supervision policy in all hospitals and CAHs. The AHA continues to urge Congress to provide relief from this short-sighted policy by enacting bipartisan legislation (S. 243/H.R. 741) that would make permanent the enforcement moratorium on CMS's direct supervision requirements on CAHs and small rural hospitals.

As urged by 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 stated that it anticipates issuing guidance to address enforcement policy for the direct supervision requirement for outpatient therapeutic services for CY 2017, although it does not indicate what the guidance will entail. **While the AHA is pleased CMS includes a two-year moratorium on enforcement of its burdensome direct supervision requirement, we will continue to urge the agency, and Congress, to make the enforcement moratorium permanent and continuous (i.e., without a gap in 2017).**

Partial Hospitalization Program Payment

Payment for PHP Services in CY 2018. For CY 2018, CMS continues to apply its established policies and methodology to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the CY 2016 claims and cost data for each provider type. Specifically, the agency continues to use hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)) and CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) to pay for all PHP services. The resulting PHP geometric mean per diem costs and payment rates for CY 2018 are in the table below.

CY 2018 PHP GEOMETRIC MEAN PER DIEM COSTS AND PAYMENT

2018 APC	Group Title	CY 2018 PHP APC Geometric Mean Per Diem Cost	CY 2018 PHP APC Payment Rate
APC 5853	Partial Hospitalization (three or more services per day) for CMHCs	$143.22	$143.30
APC 5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$208.09	$208.21

PHP Eligibility Requirements. CMS remains concerned that providers may inappropriately provide too few services to beneficiaries enrolled in PHPs. The agency again emphasizes its longstanding eligibility requirement that PHP beneficiaries require a minimum of 20 hours per week in services per the plan of care and reiterates its view that a typical PHP beneficiary should receive five to six hours of services per day.

In the proposed and final rules, CMS describes an analysis it conducted using CY 2016 claims data to assess the intensity of PHP services provided. The agency found that a majority of PHP patients did not receive at least 20 hours of PHP services per week. Just over half of PHP beneficiaries received 20 hours or more of services in 50 percent or more of nontransitional weeks (i.e., PHP weeks other than admission and discharge weeks). In addition, only 16.4 percent of beneficiaries in CMHCs and 34.8 percent of beneficiaries in hospital-based PHPs received at least 20 hours of PHP services in 100 percent of nontransitional weeks.

The agency plans to continue to monitor the intensity of PHP services provided on a weekly basis in CY 2018. In addition, CMS describes comments it received on the advisability of applying a payment requirement conditioned on a beneficiary's receipt of a minimum of 20 hours of therapeutic services per week as well as reasons commenters noted for why PHP patients are sometimes unable to attend programs for 20 hours per week. The agency will consider these comments in future rulemaking and in developing subregulatory guidance.

Revisions to the Laboratory Date of Service Policy

Many hospitals do not perform in-house the more technologically advance laboratory tests, such as molecular pathology and advanced diagnostic laboratory tests (ADLTs), which use specimens collected from hospital outpatients. Rather, upon receipt of a physician's orders, hospitals often send patient specimens to independent laboratories for testing. However, hospitals are often required to bill Medicare for these laboratory tests that they do not perform due to CMS's laboratory date-of-service (DOS) policy and the "under arrangements" regulations. In these circumstances, the laboratory must seek payment for these laboratory tests from the hospital.

In response to concerns from the AHA and other stakeholders that the current DOS policy is administratively burdensome for hospitals and for the laboratories that furnish these tests and that it can create delays and other barriers to patient access to critical diagnostic testing, in the final rule, CMS establishes a new exception to the current DOS policy. **Consistent with AHA's recommendations, CMS adds an additional exception to its current laboratory DOS regulations that will enable independent laboratories performing certain ADLTs and molecular pathology tests excluded from the OPPS packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital.**

The new exception establishes that the DOS for molecular pathology tests and certain ADLTs[4] is the date the test was performed only if:

- the test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- the specimen was collected from a hospital outpatient during an encounter;
- it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- the results of the test do not guide treatment provided during the hospital outpatient encounter; and
- the test was reasonable and medically necessary for the treatment of an illness.

The agency notes that it intends to continue to study the laboratory DOS policy and determine whether any additional changes are warranted. In particular, it will consider whether there should be any changes to the "under arrangements" provisions, including with respect to the hospital inpatient setting.

Hospital Outpatient Quality Reporting Program

The Tax Relief and Health Care Act of 2006 required CMS to establish a program under which hospitals must report data on the quality of outpatient care to receive the full annual update to the OPPS payment rate. Hospitals failing to report the data incur a reduction in their annual payment update factor of 2.0 percentage points.

CMS finalizes its proposal to remove six measures from the OQR program starting with the CY 2020 payment year, which is based on 2018 provider performance. CMS also finalizes the delay of the implementation of the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures in the OQR until further notice.

The AHA is pleased that CMS is actively removing measures that provide little to no value to patients and responded to our comments to remove these measures as soon as possible. However, we continue to be concerned that several measures in the OQR do not have or have lost endorsement by the National Quality Forum (NQF). CMS should include NQF endorsement as a criterion for a measure's inclusion in the OQR, and should assess measures for the impact of sociodemographic factors on performance and incorporate adjustments where needed.

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[4] The policy applies to tests designated by CMS as "Criterion (A)" ADLTs in which "the test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays."

Similarly, the AHA agrees that the OAS CAHPS survey-based measures are not ready for inclusion in the OQR, and that further analysis of the data provided by the survey is necessary before provider performance on survey-based measures is tied to payment.

Removal of Measures. In the CY 2013 OPPS/ASC final rule, CMS finalized a set of criteria for determining whether to remove measures from the Hospital OQR program on a case-by-case basis. The six measures that will be removed each meet at least one of these criteria. While CMS proposed to remove four measures beginning with the CY 2021 payment determination, which is based on CY 2019 provider performance, the AHA and other commenters requested that these measures be removed as soon as possible. Upon further consideration, CMS determined that it is "operationally feasible" to remove all six measures one year sooner than initially proposed, in CY 2020 (which is based on CY 2018 provider performance). CMS believes that removing all of these measures one year earlier than proposed will reduce hourly and financial burden on hospitals. **The AHA greatly appreciates CMS's consideration of our and others' request to remove these measures as soon as possible, and applauds this effort to reduce regulatory burden.**

The measures that will be removed and the rationale for removing them are as follows:

- *Median Time to Pain Management for Long Bone Fracture (OP-21)*: This process measure assesses the median time from ED arrival to time of initial oral, nasal, or parenteral pain medication (opioid or non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture. CMS is removing this measure because it could unintentionally create pressure on providers to prescribe opioid medications. While CMS acknowledges that pain control is an important issue for patients and clinical care and the agency is unaware of any scientific studies that support an association between the measure and opioid prescribing practices, CMS holds that removing the measure would align with the agency's overarching strategy to impact the national opioid misuse epidemic. **AHA agrees with this rationale and supports CMS's ongoing efforts to relieve pressure to prescribe opioids by revising requirements for quality measurement.**
- *Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (OP-26)*: This measure is submitted via CMS's web-based QualityNet portal and reflects surgical procedure volume data on eight categories of procedures frequently performed in the outpatient hospital setting. CMS cites a lack of evidence linking the measure to improved quality and acknowledges the burden of data collection. **AHA agrees that this measure lacks proven scientific evidence showing improved patient outcomes as a result of merely a count of procedures.**
- *Median Time to Fibrinolysis (OP-1)*: This chart-abstracted measure assesses the median time from ED arrival to administration of fibrinolytic therapy in ED patients with ST-segment elevation on the ECG performed closest to ED arrival and prior to transfer. In addition to this measure, the OQR also contains OP-2, Fibrinolytic

Therapy Received within 30 Minutes of ED Arrival. The latter measure is designed based on a clinical standard and provides more meaningful and clinically relevant data on fibrinolytic therapy than OP-1. In other words, the data collected to inform OP-1 is not only redundant with data collected to inform OP-2, it also provides less useful information on patient care than OP-2. **AHA appreciates CMS's removal of OP-1.**

- *Aspirin at Arrival (OP-4)*: This chart-abstracted measure assesses the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival or before transferring from the ED. CMS determined that there is no distinguishable difference in provider performance between the 75th percentile and 90th percentile in this measure; in other words, the top 25 percent of providers perform exactly as well as the top 10 percent of providers. In fact, CMS acknowledges that performance on this measure nationwide is nearly 100 percent; this means that there is little to no variation across the country in prescribing aspirin to patients with a suspected heart attack. These measure factors meet CMS's definition of "topped out." **AHA agrees that "topped out" measures should be removed as soon as possible to alleviate burden on providers and allow for focus on the most meaningful quality measures.**
- *Door to Diagnostic Evaluation by a Qualified Medical Professional (OP-20)*: This chart-abstracted measure assesses the time from ED arrival to provider contact for ED patients. CMS sites concerns raised by a technical Expert Panel (TEP) regarding a lack of evidence linking the measure to improved patient outcomes, questionable accuracy of door-to-door timestamps on charts, and the potential for skewed measure performance due to disease severity and facility-specific characteristics that might affect the measure (but not patient outcomes). **AHA supports the removal of any measure that lacks a proven link to improved outcomes. AHA continues to encourage CMS to remove measures that might suffer from the same inaccuracies cited by this TEP.**
- *Safe Surgery Checklist Use (OP-25)*: This structural measure assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data reporting period. CMS determined that, similar to the aspirin measure above, nationwide performance on this measure is so high and unvarying that meaningful distinctions among providers cannot be made. **AHA appreciates the removal of this "topped out" measure.**

Delay of OAS CAHPS Survey-based Measures. In the CY 2017 final rule, CMS finalized the adoption of five measures (OP-37a-e) that would be derived from the OAS CAHPS survey. The survey has been under development for several years and is part of the same family of surveys as the Hospital CAHPS (HCAHPS) survey that is required for both the hospital inpatient quality reporting (IQR) and value-based purchasing (VBP) programs. However, the OAS CAHPS would be administered only to patients receiving surgeries and certain other procedures in the hospital outpatient department setting. On Jan.1, 2016, CMS initiated a voluntary national reporting program for OAS CAHPS, and the CY 2017 final rule finalized requirements for providers to collect and submit data on

a quarterly basis starting with visits on Jan. 1, 2018 and using CMS-approved survey vendors to collect and submit the data.

However, since publishing the CY 2017 final rule, CMS has determined that they "lack important operational and implementation data" regarding the survey. Specifically, CMS cites the following concerns:

- Survey measures may not take patient response rates into account; response rates may differ widely by provider or by how the survey is administered.
- The national OAS CAHPS data may not be reliable.
- Administering the survey in the outpatient setting may result in high burden for providers.

AHA raised the same and related concerns regarding the OAS CAHPS survey and the measures based upon the survey in comments submitted to CMS, which can be found here.

In response to these uncertainties, CMS will delay the implementation of measures OP-37a-e "until further action in future rulemaking," and will conduct analyses of the voluntary national reporting program data to determine what modifications to the survey are necessary. CMS continues to "believe that these measures address an area of care that is not adequately addressed in our current measure set," but acknowledges that they must allow time for modifications to the survey before it is required under the Hospital OQR program. This means that providers will no longer be required to collect and submit data on those measures beginning in 2018 for payment determination in CY 2020. This delay will apply to the ASCQR program as well.

In the final rule, CMS also responds to several programmatic suggestions raised in comments to the proposed rule. One suggestion was that vendors should provide electronic or email options for conducting the survey in order to increase response rates. CMS responded that web-based surveys are currently not available survey modes, but the agency is "actively investigating" these options for the future. Another comment noted the high expense of using third-party vendors to administer the survey. CMS noted that, while the agency is investigating other modes of survey administration, it does not expect that CMS will ever directly administer the survey.

The AHA has long been supportive of rigorously designed surveys of patient experience of care, including the HCAHPS survey. However, we agree that the OAS CAHPS survey and the associated measures are premature, and we appreciate CMS's plan to delay the adoption into the OQR until the agency can address the serious issues around survey administration burden and data validity and reliability.

Future Measure Topics. CMS notes that the agency is "moving towards the use of outcome measures and away from the use of clinical process measures" across its various quality and VBP programs. In this vein, CMS invited public comment on

possible measure topics for future consideration in the Hospital OQR program, specifically around outcomes measures that should be added and process measures that should be eliminated. **The AHA applauds CMS's acknowledgment that many clinical process measures do not provide meaningful insight into the quality of care provided. However, we will continue to advise CMS to incorporate appropriate risk adjustment – including adjustment for sociodemographic factors where warranted – to ensure measures account for the environment in which care is provided.**

In the proposed rule, CMS noted that the agency is considering transforming current measure OP-2, Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival, into an electronic measure. CMS believes that these e-measures (called electronic clinical quality measures, or eCQMs), informed by electronic extraction and reporting of clinical quality data, will reduce administrative burden for providers, and thus is interested in potentially developing electronic measure specifications for OP-2 because it believes this measure is the "most feasible" out of all the existing Hospital OQR measures. CMS will consider public comments and potentially propose the measure as an eCQM in future rulemaking.

The AHA does not agree that eCQMs are inherently less burdensome than chart abstracted measures, and thus does not support transforming current measures into eCQMs merely because it might be deemed "feasible."

Public Reporting. Currently, providers report data on measure OP-18, Median Time from ED Arrival to ED Departure for Discharged ED Patients – Psychiatric/Mental Health Patients. The measure data is stratified into four separate calculations (OP-18a, b, c, and d), which provide four different rates. Only OP-18b is currently publicly reported; this rate excludes psychiatric/mental health patients and transfer patients (i.e., it excludes specific ICD-10 codes from the calculation). CMS finalizes its proposal to also publicly report the OP-18c rate, which includes ICD-10 codes that account for substance abuse among other conditions.

However, several commenters noted that publicly reporting this measure may result in unintended consequences, such as the creation of pressure on providers to inappropriately limit care in order to quickly discharge mental health patients. In response, CMS will not post this data on the publicly available *Hospital Compare* website until the agency has been able to evaluate these concerns. Instead, this data will be published on data.medicare.gov as a downloadable data file, as this approach is less public facing.

Changes to Notice of Participation Deadlines. As finalized in the CY 2014 OPPS/ASC final rule, in order to participate in the Hospital OQR program, hospitals must register on the QualityNet website before beginning to report data, identify and register a QualityNet security administrator, and complete and submit an online participation form. Currently, hospitals must submit the online participation form, called the Notice of

Participation (NOP), by the following deadlines:

- If the hospital has a Medicare acceptance date before Jan. 1 of the year prior to the affected annual payment update, the hospital must submit the NOP by July 31 of the calendar year prior to the affected annual payment update.
- If the hospital has a Medicare acceptance date on or after Jan. 1 of the year prior to the affected annual payment update, the hospital must submit the NOP no later than 180 days from the date identified as its Medicare acceptance date.

CMS initially proposed to revise the deadlines such that NOP submissions can be submitted any time before registering on the QualityNet website, which must be done prior to the data submission deadline, instead of before the deadlines described above. CMS proposed this change because registration with QualityNet is required to submit data; removing the specific deadlines effectively extends the period of time hospitals have to complete and submit their NOPs.

However, CMS is not finalizing this change, participants in the Hospital OQR program must first log into the QualityNet website in order to access the NOP form. In other words, participants cannot submit an NOP form before registering on the QualityNet website. CMS intends to revisit this issue in future rulemaking, as the agency believes that extending the NOP submission deadline would better enable hospitals to meet participation requirements.

Data Submission for New Participants. CMS finalizes the revision of the data submission requirements for hospitals that did not participate in the previous year's Hospital OQR program. Previously, timelines specifying the initial quarter for which hospitals that did not participate in the previous year's program must submit data are based upon whether the hospital's Medicare acceptance date is before or on/after Jan. 1 of the year prior to the affected payment rule.

Instead of these various timelines, hospitals that did not participate in the previous year's OQR program must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update. Hospitals must still follow data submission deadlines for the quarter for which they are reported data, but this newly finalized timeline will align the initial data submission schedule for all hospitals that did not participate in the previous year's OQR program, regardless of Medicare acceptance date.

Validation Requirements for Chart-abstracted Data. In the CY 2012 OPPS final rule, CMS finalized the data validation process for the Hospital OQR. In this process, CMS selects a random sample of 450 hospitals for validation purposes and selects an additional 50 hospitals based on specific criteria. These criteria include a failed validation or an outlier, Value for a measure. However, CMS realized that this criteria did not specify whether it intended to consider outlier values far above or far below average. Therefore, CMS provides clarification that the validation process will target hospitals with outlier values that indicate particularly poor performance on a particular

measure—specifically, more than 5 standard deviations below the mean performance of other hospitals.

In addition, CMS finalizes its proposal to formalize the educational review and correction process on the QualityNet website. Currently, the process is informal: providers may review their validated data from chart-abstracted measures, and if they believe that CMS has provided them an incorrect score after validation they may submit a reconsideration request; however, the results of the data validation are not changed. Participating hospitals communicated to CMS that they found the process helpful, albeit limited in impact. Based on this feedback CMS will formalize the process and allow for correction of validation scores.

In the current educational review process, hospitals that were selected and received a score for validation receive validation results on a quarterly basis and can request informal education reviews for each quarter. Under this informal process, the hospital has 30 calendar days from the date the validation results are posted on QualityNet to contact CMS's contractor and request an educational review. CMS will formalize this process for the CY 2020 payment year (based on validations of CY 2018 data).

CMS also finalizes the proposal to modify the review process to allow for score correction. As finalized in the CY 2011 OPPS final rule, hospitals selected for validation must attain at least a 75 percent validation score across all four quarters in order to "pass" validation (meaning that at least 75 percent of the measures calculated and submitted by the hospital must match the results when the measures are calculated independently by the contractor). Under the newly finalized process, CMS and the contractor will respond to reconsideration requests by evaluating the validation score by reviewing only data elements that were labeled as mismatched between the measure originally submitted by the hospital and the score calculated in validation. CMS notes that it also will take written justifications from the hospitals into account during this evaluation. If the evaluation finds that CMS was incorrect in any one of its quarterly validation scores, CMS will use the corrected score for whichever quarter was deemed incorrect in order to compute the total validation score at the end of the calendar year.

In addition, CMS will only use the corrected score if it is better than the original score. If a hospital's validation score is recalculated and results in a lower validation score, the corrected score will not be used. CMS believes this provision will encourage participation in the educational review system.

CMS will implement all of these changes for the CY 2020 payment determination and subsequent years.

CHANGES FOR THE CY 2018 ASC PAYMENT SYSTEM

The final rule also includes the annual review and update to the ASC list of covered surgical procedures and covered ancillary procedures, as well as updated payment rates.

Updates and Changes to ASC Payment Policy

ASC Payment Update. The ACA requires that, beginning in CY 2011, the annual inflation update under the ASC payment system (the Consumer Price Index for All Urban Consumers (CPI-U)) be reduced by a productivity adjustment. For CY 2018, the CPI-U update is projected to be 1.7 percent and is reduced by a productivity adjustment, which is projected to be 0.5 percentage points, resulting in a net 1.2 percent update. CMS further applies a 1.0007 ASC wage index budget neutrality adjustment. The net CPI-U update, together with the wage adjustment for budget neutrality, results in a CY 2018 ASC conversion factor of $45.575. In contrast, the CY 2018 OPPS conversion factor is $78.636.

ASCs that fail to meet their quality reporting requirements will have their conversion factor update reduced by 2.0 percentage points. The net update for ASCs not meeting quality reporting requirements will be -0.8 percent, which, together with the wage adjustment for budget neutrality, results in a proposed reduced CY 2018 ASC conversion factor of $44.663. In contrast, the reduced OPPS conversion factor is $77.064.

Updating the ASC Relative Payment Weights for CY 2018. CMS updates the relative payment weights in the ASC payment system each year using the national OPPS relative payment weights (and PFS non-facility practice expense amounts, as applicable) for that same calendar year and uniformly scales the ASC relative payment weights to make them budget neutral. For CY 2018, CMS uses an ASC scalar of 0.8990.

Changes to the List of ASC-covered Surgical Procedures. CMS adds three procedures, listed below, to the list of ASC-covered surgical procedures for CY 2018.

- CPT 22856: Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.

- CPT 22858: Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure).

- CPT 58572: Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g.

ASC Quality Reporting Program

The ACA required CMS to establish a program under which ASCs must report data on the quality of care delivered in order to receive the full annual update to the ASC payment rate. ASCs failing to report the data will incur a reduction in their annual payment update factor of 2.0 percentage points.

CMS will adopt two new measures for the ASCQR program, which will be collected via claims for the CY 2022 payment year. CMS did not finalize its proposal to adopt a third new measure for the CY2021 payment year. **The AHA recognizes the need for measures that address the important topics of patient safety as it relates to surgical outcomes; however two of the measures have only recently completed their NQF field testing. We believe that measures should receive NQF endorsement prior to implementation in quality payment programs.**

Toxic Anterior Segment Syndrome (TASS) (ASC-16). This measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS, an acute, noninfectious inflammation of the eye resulting from surgery complications, within two days of the procedure. This procedure is commonly performed at ASCs and the measure addresses the NQF Measure Application Partnership (MAP)-identified priority measure area of procedure complications. However, this measure is not endorsed by NQF. Specifications for this measure can be found here.

CMS received comments noting the low volume of TASS patients and the administrative difficulty of incorporating the measure into the clinical workflow. In response to these concerns, CMS agreed that the measure is not appropriate for implementation in the ASCQR program, and that the burden of the measure would outweigh its benefits. Thus, CMS is not finalizing the adoption of this measure.

Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (ASC-17). This measure assesses the rate of all-cause unplanned hospital visits (ED visits, observation stays, and unplanned inpatient admissions) in the seven days following orthopedic surgery at an ASC. CMS is adopting this measure due to the increasing prevalence of orthopedic surgery at ASCs and because this measure addresses the National Quality Strategy domains of making care safer by reducing harm caused in the delivery of care and promoting effective communication and coordination of care. This measure was reviewed by the MAP in December 2016, when it was still undergoing field testing. Field testing has now ended, and the measure will be presented to the MAP in fall 2017.

This measure is calculated using Part A and Part B Medicare administrative claims and Medicare enrollment data. The data collection period will be the two calendar years prior to the applicable payment determination year, so the first payment determination (CY 2022) will be based upon data from CY 2019 and CY 2020. ASCs will not need to submit any additional data directly to CMS.

The facility-level score is a risk-standardized (based on number of surgeries performed, case mix, and surgical complexity mix) rate calculated by multiplying the ratio of the predicted to expected number of post-surgical hospital visits among the given ASC's patients by the national observed hospital visit rate for all ASCs. The patient cohort for the measure includes all Medicare beneficiaries aged 65 years and older undergoing outpatient orthopedic surgery at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. Procedures in question are those that are routinely performed at ASCs, involve some increased risk of post-surgery hospital visit, are routinely performed by orthopedists, and are on Medicare's list of covered ASC procedures.

The measure will undergo a dry run prior to the official data collection period or any public reporting. In this dry run, CMS will provide confidential feedback reports based on the most current 2-year set of complete claims available, which will include patient-level data indicating whether the patient had a hospital visit and the ASC's risk-standardized hospital visit rate. These results will not be publicly reported and will not affect payment.

Hospital Visits after Urology Ambulatory Surgical Center Procedures (ASC-18). This measure assesses the rate of all-cause unplanned hospital visits (ED visits, observation stays, and unplanned inpatient admissions) in the seven days following urology procedures at an ASC. CMS cites the growing number of urology procedures performed in ASCs, and also notes that "urology surgery performed at an ASC is a significant predictive factor for unanticipated admissions compared to other procedures." This measure was reviewed by the MAP in December 2016, when it was still undergoing field testing. Field testing has now ended, and the measure will be presented to the MAP in fall 2017. Thus, the measure is not yet endorsed by NQF.

This claims-based measure will use the same data source (Medicare claims data) and reporting period as ASC-17 to calculate a risk-standardized score. The patient cohort for the measure includes all Medicare beneficiaries aged 65 years and older undergoing outpatient urology procedures at an ASC who have 12 prior months of Medicare fee-for-service Parts A and B enrollment. Procedures in question are those that are routinely performed at ASCs, involve some increased risk of post-surgery hospital visit, are routinely performed by urologists, and are on Medicare's list of covered ASC procedures.

As with ASC-17, the measure will undergo a dry run prior to the official data collection period or any public reporting. CMS will provide similar data timeframes for this measure as it will for ASC-17.

Removal of Measures. In the CY 2015 OPPS/ASC final rule, CMS adopted a process for removing measures from the ASCQR program. Based on the criteria outlined in that rule, CMS will remove three measures for the CY 2019 payment determination and subsequent years. The measures that will be removed and the rationale for removing them are as follows:

- *Prophylactic Intravenous (IV) Antibiotic Timing (ASC-5):* This measure assesses whether intravenous antibiotics given for prevention of surgical site infection were administered on time. Based on their analysis, CMS determined that provider performance on this measure is "topped out." In addition, NQF endorsement for this measure was removed in 2015.
- *Safe Surgery Checklist Use (ASC-6):* This structural measure assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data reporting period. CMS determined that this measure was also "topped out." CMS is also removing the Hospital OQR version of this measure from that program.
- *ASC Facility Volume Data on Selected Procedures (ASC-7):* This structural measure of facility capacity collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting. CMS notes that the agency has adopted and intends to continue to adopt more measures assessing ASC performance on specific procedure types, and that these procedure-type-specific measures provide more useful information to patients regarding ASC performance than volume-based measures like ASC-7. In addition, the measure is burdensome to collect and report.

Delay of OAS CAHPS Survey-based Measures. Look in the Hospital OQR section of this advisory for details on the finalized proposal to delay these measures.

Batch Data Submission. Currently, for individual facility data entry, users must use one file per facility to upload data to the QualityNet portal. However, because this file only allows data entry for one facility at a time, it can be burdensome for providers who are responsible for submitting data for multiple facilities (like multi-facility ASCs). To alleviate this burden, CMS will expand the QualityNet tool to allow for batch submission, wherein data for multiple facilities is simultaneously submitted using a single electronic file, beginning with data submitted for the CY 2020 payment determination year (which uses CY 2018 data). Additional details regarding the logistics of batch submission will be included in future guidance in the specifications manual.

NEXT STEPS

Learn more about the OPPS final rule policies, including an update on AHA's advocacy initiatives around 340B-acquired drugs, by participating in a members-only webinar on Dec. 4 at 2 p.m. ET. To register for this 60-minute webinar, visit here.

FURTHER QUESTIONS

Please contact Roslyne Schulman, director of policy, at rschulman@aha.org for more information about the final rule.