On July 25, the Centers for Medicare & Medicaid Services (CMS) issued its calendar year (CY) 2019 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to standard updates, the rule would substantially expand Medicare site-neutral payment policies in several areas and make changes to the payment policies for drugs, including 340B-acquired drugs. Comments on the proposed rule are due to CMS by Sept. 24.

**Our Take**

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). CMS also has resurrected a proposal, which it had previously deemed unwise, that 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. We will urge the agency to revise these punitive policies so that hospitals can continue to provide the highest quality health care.

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. These cuts – 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.

**What You Can Do**

- Participate in the AHA’s member-only call to discuss the proposed rule. [Click here](#) to register for this 90-minute webinar on Tuesday, Aug. 14 at 3:00 p.m. ET.
- 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 APC changes on your expected CY 2019 Medicare revenue.
- Submit a comment letter to CMS to explain your concerns by Sept. 24 at [www.regulations.gov](http://www.regulations.gov).

**Further Questions**

Contact Roslyne Schulman, director of policy, at rschulman@aha.org for payment policy questions and Caitlin Gillooley, associate director, at cgillooley@aha.org, for questions regarding quality.
HOSPITAL OUTPATIENT PPS/ASC
PROPOSED RULE FOR CY 2019

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Overview

On July 25, the Centers for Medicare & Medicaid Services (CMS) issued its calendar year (CY) 2019 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to standard updates, the rule would substantially expand Medicare site-neutral payment policies in several areas and make changes to the payment policies for drugs, including 340B-acquired drugs. The agency also proposes to make significant changes to payment policy for ASCs in order to encourage the shifting of outpatient surgical services to this setting. Among other changes, CMS also demonstrates its commitment to its Meaningful Measures initiative by proposing to remove 10 measures from the Outpatient Quality Reporting (OQR) Program.

Comments on the proposed rule are due to CMS by Sept. 24. The final rule is expected around Nov. 1, and would take effect Jan. 1, 2019.

Proposed Changes to the CY 2019 OPPS

OPPS Update and Linkage to Hospital Quality Data Reporting

The CY 2018 OPPS conversion factor is $78.636. To calculate the proposed conversion factor for CY 2019, the agency adjusted the 2018 conversion factor by the fee schedule increase factor and made further adjustments for various budget neutrality factors. The fee schedule increase factor equals the proposed hospital inpatient market-basket increase factor of 2.8 percent, reduced by a productivity adjustment of 0.8 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 1.25 percent for the CY 2019 OPPS proposed rule. Hospitals that do not meet the OQR program requirements are subject to a further reduction of 2.0 percentage points, resulting in a proposed fee schedule increase factor of -0.75 percent. The resulting proposed CY 2019 OPPS conversion factor is $77.955 for hospitals meeting OQR requirements and $74.953 for hospitals that do not meet OQR requirements.

These payment adjustments, in addition to other proposed changes in the rule (including CMS’s 2019 nonbudget-neutral proposal to reduce payment for hospital outpatient clinic visits in excepted off-campus provider-based departments (PBDs)) are estimated to result in a net decrease in OPPS payment of approximately, 0.1 percent, or $80 million, in CY 2019, including beneficiary cost-sharing, but excluding estimated changes in enrollment, utilization and case-mix. Taking into account estimated changes
in enrollment, utilization, and case-mix, CMS estimates that OPPS expenditures for 2019 will be approximately $74.6 billion; an increase of approximately $4.9 billion compared to 2018 OPPS payments.

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>All Hospitals</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Urban Hospitals</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Large Urban</td>
<td>0.1%</td>
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<tr>
<td>Other Urban</td>
<td>-0.2%</td>
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<tr>
<td>Rural</td>
<td>-0.1%</td>
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<tr>
<td>Sole Community</td>
<td>-0.4%</td>
</tr>
<tr>
<td>Other Rural</td>
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**Proposed 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 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](https://www.aha.org/news/stories/2018/08/proposed-pfs-changes-hospital), 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 Reduction in Payment for Hospital Outpatient Clinic Visits in Excepted Off-campus PBDs.** Citing “unnecessary” increases in the volume of hospital outpatient clinic visits in hospital PBDs, CMS proposes to pay for clinic visits (i.e., evaluation and management services) furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs. In CY 2019, this “PFS-equivalent” payment rate is proposed to be 40 percent of the OPPS payment amount. The agency would implement this proposal in a nonbudget-neutral manner, which means that it is estimated to cut hospital payments under the OPPS by $760 million in CY 2019.

The AHA believes that this proposed policy misinterprets Congressional intent by proposing to reduce payment for services in “excepted” off-campus PBDs that Congress explicitly protected from site-neutral cuts in Section 603. The policy also fails to recognize the critical role these off-campus PBDs play in their communities, including providing convenient access to care for the most vulnerable patients, including the sickest, most medically complex patients. Blaming increases in OPPS expenditures on the “unnecessary” shifting of services from physician offices to PBDs ignores other factors outside of hospitals’ control that may drive increases in OPPS expenditures. This includes factors such as rapid increases in the price of drugs; the impact of Medicare policies, such as the two-midnight policy, and the fact that physicians frequently refer Medicare beneficiaries to hospitals’ outpatient department for critical services they do not provide in their offices.
**Background.** CMS discusses its concerns about the growth of Medicare expenditures under the OPPS and references the Secretary’s authority under section 1833(t)(2)(F) of the Social Security Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services. CMS notes that, to date, it has not established policy under this authority and has instead attempted to address expenditure growth through such policies as increased packaging and the development of comprehensive ambulatory payment classifications (C-APCs). Despite these policies, the agency expresses concern about continued growth in OPPS spending, as illustrated in Tables 30 and 31 in the proposed rule.

CMS claims that much of this spending growth results from the shifting of services to hospital outpatient departments from physician offices due to higher payments under the OPPS than the PFS for comparable services. The agency considers these shifts in site of service “unnecessary” if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in a higher-cost setting. The proposed rule cites various reports and recommendations from the Medicare Payment Advisory Commission (MedPAC) to support its assertions. It notes that in MedPAC’s 2012 Report to Congress, the commission recommended that the payment rates for clinic visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office.

CMS also expresses concern about the impact that higher payments in the hospital outpatient department have on beneficiary cost-sharing. The agency asserts that this volume growth and the resulting increase in beneficiary cost-sharing is unnecessary because it appears to be due to the difference in payment between settings rather than patient acuity.

While the site-neutral payment policy enacted in 2017 under section 603 of BiBA partially addressed these concerns by paying under the PFS for services in new off-campus PBDs that opened after Nov.2, 2015, CMS indicates that the majority of hospital off-campus PBDs are excepted and continue to receive full OPPS payment.

**Proposed Policy and Request for Comments.** CMS believes capping the OPPS payment at the PFS-equivalent rate in excepted PBDs would remove what it claims is the payment incentive to increase utilization in PBDs. Therefore, starting in CY 2019, CMS proposes to use its authority under section 1833(t)(2)(F) of the Social Security Act to pay the same amount for a hospital outpatient clinic visit (CPT code G0463) at an excepted off-campus PBD as at a non-excepted off-campus PBD. For CY 2019, this would be 40 percent of the OPPS rate. This proposal would not require changes in hospital billing practices because CMS proposes to still consider these clinic visit services to be “excepted,” i.e., billed using the “PO” modifier. Instead, CMS would make the systems changes necessary to reduce the payment amount for these services to the PFS-equivalent amount when a clinic visit is billed in an excepted off-campus PBD.

CMS proposes to implement this policy in a nonbudget-neutral manner, resulting in savings for the Medicare program. In the rule, the agency presents its legal analysis for why budget neutrality does not apply to section 1833(t)(2)(F) of the Act. CMS estimates
the savings including changes in enrollment, volume and case mix at $760 million, with $610 million of the savings accruing to Medicare, and $150 million saved by Medicare beneficiaries.

**CMS also requests comments on how to expand this proposed policy to additional items and services paid under the OPPS “that may represent unnecessary increases in outpatient department utilization.”** In addition, the agency seeks comments on how to maintain access to innovations in outpatient departments while controlling for unnecessary increases in the volume of services. It also requests comments on the following questions:

- How might Medicare define the terms “unnecessary” and “increase” for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered outpatient department services include consideration of factors such as enrollment, severity of illness, and patient demographics?
- Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?
- With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered outpatient department services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

**Expansion of Clinical Families of Services at Excepted Off-campus PBDs.**

**Background.** When CMS first implemented section 603 in CY 2017, the agency had proposed to limit the services for which payment would be made under the OPPS in an excepted off-campus PBD to those services furnished before Nov. 2, 2015 (the date that BiBA was enacted). It proposed to pay for other services that were not included as part of a clinical family of services furnished by the excepted off-campus PBD before that date as non-excepted service subject to payment under the PFS. However, comments from stakeholders expressed concerns about the proposal, including that CMS lacked the authority to implement the policy, that limiting service expansion would stifle innovative care delivery and new technologies, and that the proposal was not workable. As a result, the agency did not finalize this proposal but indicated it would continue to monitor service line expansion and consider how potential limitations on expansion might work by inviting stakeholder comments.
Proposal to Limit Expansion of Services in Excepted Off-campus PBDs in CY 2019. In the proposed rule, CMS again expresses concern that allowing expansion of services in excepted off-campus PBDs 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 section 603. As such, CMS proposes to revise the definition of “excepted items and services” to apply only to those services from clinical families of services from which the excepted off-campus PBD furnished a service (and subsequently billed for that item or service under the OPPS) during certain baseline periods (generally from Nov. 1, 2014 through Nov. 1, 2015). Table 32 in the rule (reprinted below) lists the clinical family of services CMS is proposing.

Table 32. Proposed Clinical Families of Services for Purposes of Sec. 603 Implementation

<table>
<thead>
<tr>
<th>Clinical Families</th>
<th>APCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway Endoscopy</td>
<td>5151-5155</td>
</tr>
<tr>
<td>Blood Product Exchange</td>
<td>5241-5244</td>
</tr>
<tr>
<td>Cardiac/Pulmonary Rehabilitation</td>
<td>5771; 5791</td>
</tr>
<tr>
<td>Diagnostic/Screening Test and Related Procedures</td>
<td>5721-5724, 5731-5735, 5741-5743</td>
</tr>
<tr>
<td>Drug Administration and Clinical Oncology</td>
<td>5691-5694</td>
</tr>
<tr>
<td>Ear, Nose, Throat (ENT)</td>
<td>5161-5166</td>
</tr>
<tr>
<td>General Surgery and Related Procedures</td>
<td>5051-5055; 5061; 5071-5073; 5091-5094; 5361-5362</td>
</tr>
<tr>
<td>Gastrointestinal (GI)</td>
<td>5301-5303; 5311-5313; 5331; 5341</td>
</tr>
<tr>
<td>Gynecology</td>
<td>5411-16</td>
</tr>
<tr>
<td>Major Imaging</td>
<td>5523-5525; 5571-5573; 5593-5594</td>
</tr>
<tr>
<td>Minor Imaging</td>
<td>5521-5522; 5591-5592</td>
</tr>
<tr>
<td>Musculoskeletal Surgery</td>
<td>5111-16; 5101-02</td>
</tr>
<tr>
<td>Nervous System Procedures</td>
<td>5431-5432; 5441-5443; 5461-5464; 5471</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>5481; 5491-5495; 5501-5504</td>
</tr>
<tr>
<td>Pathology</td>
<td>5671-5674</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>5611-5613; 5621-5627; 5661</td>
</tr>
<tr>
<td>Urology</td>
<td>5371-5377</td>
</tr>
<tr>
<td>Vascular/Endovascular/Cardiovascular</td>
<td>5181-5184; 5191-5194; 5200; 5211-5213, 5221-5224; 5231-5232</td>
</tr>
<tr>
<td>Visits and Related Services</td>
<td>5012; 5021-5025; 5031-5035; 5041; 5045; 5821-5823</td>
</tr>
</tbody>
</table>

Thus, beginning Jan. 1, 2019, excepted items and services would only include those services furnished and billed by an excepted off-campus PBD from the clinical families of service from which the excepted off-campus PBD furnished and billed (under the OPPS) at least one item or service during the baseline period. CMS also proposes that if an excepted off-campus PBD furnishes a new service from the same clinical family of services from which it furnished and billed a service during the baseline period, this would not be treated as a service expansion and would be paid under the OPPS.
CMS proposes a baseline period of Nov. 1, 2014 through Nov. 1, 2015 because it is the most recent 12-month period that precedes the enactment of section 603, and CMS believes a full 12-month period would adequately reflect the types of service lines furnished and billed by excepted off-campus PBDs. For excepted off-campus PBDs that did not furnish OPPS services until after Nov. 1, 2014, CMS proposes that the 12-month baseline period begin on the first date the PBDs furnished covered outpatient department services before Nov. 2, 2015. For providers that met the 21st Century Cures “mid-build” requirements, the baseline period would begin on the first date the excepted off-campus PBD furnished a service billed under the OPPS. The agency seeks comments on whether it should shorten the baseline period (e.g., to three or six months) for facilities that first began billing after Nov. 1, 2014 or met the mid-build requirement.

To comply with this proposed policy, CMS would require excepted off-campus PBDs to ascertain the clinical families of services from which they furnished services during the baseline period. CMS also notes that items and services not identified in Table 32 that are furnished by excepted off-campus PBDs would be required to be reported with modifier “PN,” indicating non-excepted services paid under the PFS.

The AHA is disappointed that CMS has resurrected the expansion of services proposal, which the agency had previously rejected. This policy would penalize hospital outpatient departments that expand the types of critical services they offer to their communities and prevent them from caring for the changing needs of their patients. It is notable that the agency does not share any claims-based or other evidence that demonstrates that excepted off-campus PBDs are taking advantage of the current policy, despite the fact that CMS had previously indicated that it would monitor service line expansion in excepted off-campus PBDs. Further, as with the proposed cuts for excepted clinic visit services, we believe that this proposed expansion of services does not comport with Congress’ intent to protect excepted off-campus PBDs from site-neutral cuts.

CMS believes that the families of service they identify in Table 32 recognize all clinically distinct service lines for which a PBD may bill under the OPPS.

CMS also seeks comment on whether specific groups of hospitals, such as rural hospitals, should be excluded from its proposal. The agency also seeks comment on alternative methodologies to limit the expansion of excepted services. In particular, it is interested in feedback on the adoption and implementation of MedPAC’s proposal to cap the amount of OPPS payments made to an excepted off-campus PBDs in a year based on payment for OPPS services furnished by the PBD during the 12-month baseline period that preceded the enactment of Section 603.

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 covered outpatient department services, but rather services covered under the PFS, 340B-acquired drugs furnished in these settings...
were not subject to this policy. As such, in CY 2018, they are paid at ASP plus 6 percent (the same rate at which other drugs payable under the PFS are required to be paid).

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. CMS proposes to exempt rural sole community hospitals, children’s hospital or PPS-exempt cancer hospitals from the payment adjustments consistent with its current 340B OPPS payment policy. The agency estimates that this change would result in a payment cut of $48.5 million in CY 2019, under the PFS.

CMS points to several sections of the Social Security Act to justify this policy despite the fact that these sites are no longer paid under OPPS. CMS principally cites section 1833(t)(21)(C) of the Act as its authority for applying the 340B policy to non-excepted off-campus PBDs. This section of the law, which was added by section 603 of BiBA, authorizes the Secretary to identify the “applicable payment system” (other than OPPS) to pay for services provided in non-excepted off-campus PBDs. As noted above, CMS has identified the PFS as the applicable payment system for payment of services in non-excepted off-campus PBDs. CMS further justifies that this same section allows the agency to pay for 340B-acquired drugs and biologicals under a special PFS rate. That PFS special rate, as proposed by CMS, would equal ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program and furnished by non-excepted off-campus PBDs.

Collecting Data on Services Furnished in Off-campus EDs. In the proposed rule CMS shares the concerns raised by MedPAC and others that the growth in the number of off-campus provider-based EDs may be a result of the higher Medicare payment rates for services furnished in these settings compared to similar services in physician offices or urgent care centers. Further, the agency speculates that Section 603’s exemption of services furnished in provider-based EDs may also be driving this growth.

Citing a MedPAC recommendation, CMS announces that it will be collecting data to assess the extent to which OPPS services are shifting to off-campus provider-based EDs. Therefore, effective Jan. 1, 2019, it will create a new Healthcare Common Procedure Coding System (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.

**Proposed Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**

Packaging Policy for “Threshold-packaged” and “Policy-packaged” Drugs, Biologicals, and Radiopharmaceuticals. The proposed payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status are based on first quarter of 2018...
average sales price (ASP) data. Updates to the ASP-based rates will be published quarterly and posted on CMS’s website through CY 2019.

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 2019, CMS proposes to increase the packaging threshold for “threshold-packaged” drugs, including nonimplantable biologicals and therapeutic radiopharmaceuticals, to $125 per day, $5 more than in CY 2018.** Therefore, drugs costing less than $125 would have their cost packaged in the procedure with which they are billed, such as an outpatient clinic visit. Drugs costing more than $125 would 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 proposes to continue to package the costs of all anesthesia drugs; intraoperative items and services; 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 (e.g., skin substitutes), regardless of whether they meet the $125 per day threshold. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the proposed rule.

**Proposed Payment for Drugs and Biologicals without Pass-through Status that are not Packaged.**

**Separately Payable Drugs and Biologicals.** For CY 2019 (with the exception of 340B-acquired drugs and biologicals), CMS proposes to continue its current policy and pay for separately payable drugs and biologicals at the “statutory default rate” of ASP plus 6 percent. CMS notes that this payment requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

**Proposed Reduction in Payment for New Drugs Before ASP Data Are Available.** 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 wholesale acquisition cost (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 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.

**Separately Payable 340B-acquired Drugs.** For CY 2019, CMS proposes to continue to pay for separately payable nonpass-drugs and biologicals acquired under the 340B program at the rate of ASP minus 22.5 percent. The agency clarifies that the 340B payment adjustment also applies to drugs that are priced using either WAC or Average
Wholesale Price (AWP). That is, the 340B payment adjustment for WAC-priced drugs continues to be WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

Proposed Change in Payment Policy for Separately Payable 340B-acquired Biosimilar Products. In CY 2018, CMS finalized a policy in which biosimilars without pass-through payment status that were acquired under the 340B program would be paid the ASP (of the biosimilar) minus 22.5 percent (of the reference product’s ASP). However, the agency notes stakeholder concern that the policy is inconsistent because it is calculated using two different prices and because it could unfairly lower the OPPS payment for separately payable biosimilars. This is because the payment reduction would be based on the reference product’s ASP, which would generally be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than warranted. Therefore, for CY 2019, CMS proposes to pay nonpass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar’s own ASP instead of the biosimilar’s ASP minus 22.5 percent of the reference product’s ASP.

Proposed High-cost/Low-cost Threshold for Packaged Skin Substitutes. Consistent with current policy, CMS proposes to assign 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 2019, in an effort to limit year-to-year fluctuations in payment, CMS again proposes to allow a skin substitute product that does not exceed the CY 2019 MUC or PDC threshold for CY 2019, but was assigned to the high-cost group for CY 2018, to be assigned to the high-cost group for CY 2019. Table 23 of the proposed rule shows the 2018 and proposed 2019 assignment of each skin substitute to either the high- or low-cost category.

In addition, CMS requests public comments on four alternative methodologies intended to improve pricing stability for skin substitutes that it will consider for the CY 2020 OPPS rulemaking:

- Establish a lump-sum “episode-based” payment for a wound care episode. Under this option, a hospital would receive a lump sum payment for an “episode” (such as 12 weeks) for all wound care services involving procedures using skin substitutes. Quality metrics could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.
- Eliminate the high-cost/low-cost categories. Under this option, CMS would establish a single payment category that has a payment rate between the current rates paid for high-cost and low-cost skin substitute procedures.
- Pay add-ons based on the size of the skin graft. Under this option, payment for skin substitutes would be made based on the size of the skin substitute product being applied.
- Change the threshold used to assign skin substitutes in the high-cost or low-cost group. Under this option, CMS would consider fixing the MUC or PDC threshold at an amount from a prior year or setting global payment targets for high-cost and low-cost skin substitutes and establishing a threshold that meets the payment targets.
Proposed Changes to the Device-Intensive Procedures Policy for 2019

Currently, CMS assigns device-intensive status to all procedures that require the implantation of a device that remains in the patient’s body after the procedure and that have an individual HCPCS code-level device offset of greater than 40 percent. All such device-intensive procedures are subject to the device edit and to the no cost/full credit and partial credit device policies.

In response to comments, and as part of an effort to better capture costs for procedures with significant device costs, for 2019 CMS proposes to modify the criteria for device-intensive procedures. CMS no longer believes that whether a device remains in the patient’s body should affect its designation as a device-intensive procedure. In addition, to allow a greater number of procedures to qualify as device-intensive, CMS is proposing to lower the device offset percentage threshold from 40 to 30 percent. The agency believes this will help ensure these procedures receive more appropriate payment in the ASC setting. CMS also states this change will help to ensure more procedures containing relatively high-cost devices are subject to device edits, which leads to more correct coding and greater accuracy in the claims data.

Specifically, CMS proposes that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a Current Procedural Terminology (CPT) or a HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device-offset amount must be significant, which is defined as exceeding 30 percent of the procedure’s mean cost.

Wage Index
The area wage index adjusts payments to reflect differences in labor costs across geographic areas. CMS has historically adopted the final 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 proposes to continue this policy and use the final FY 2019 IPPS wage indices for calculating CY 2019 OPPS payments. (See AHA’s IPPS Proposed Rule Regulatory Advisory for more information about the wage index for FY 2019). For hospitals paid under the OPPS but not the IPPS, CMS proposes to continue its longstanding policy for CY 2019 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 APC payment would be adjusted by the wage index.

Proposed Recalibration and Scaling of APC Relative Weights
CMS recalibrates the relative APC weights using hospital claims for services furnished during CY 2017. As in previous years, the agency standardizes all of the relative payment weights to the APC 5012 (Level 2 Examinations and Related Services) because that is the APC to which HCPCS code G0463 (hospital outpatient clinic visit for assessment and management of a patient) is assigned. G0463 is the most frequently
billed 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.

Although CMS proposes a CY 2019 policy to pay for clinic visits furnished in excepted off-campus PBDs at a PFS equivalent rate, CMS proposes to continue to use visits in these settings in determining the relative weight scalar. The agency notes that the PFS-equivalent adjuster would be applied to the clinic visit payment, not the relative weight, and that CMS’s proposal is not budget neutral while changes to the weights are budget neutral.

To comply with budget neutrality requirements, CMS compares the estimated unscaled relative payment weights in CY 2019 to the estimated total relative payment weights in CY 2018 using the service volume in the CY 2017 claims data. Based on this comparison, the CY 2019 unscaled APC payment weights are adjusted by a weight scalar of 1.4553. The effect of the adjustment is to increase the unscaled relative weights by about 45.53 percent in order to ensure that the CY 2019 relative payment weights are budget neutral.

Proposed Calculation and Use of Cost-to-charge Ratios. To convert billed charges on the outpatient claims to estimated costs, CMS multiplies the charges by a hospital-specific cost-to-charge ratio (CCR) associated with each revenue code and cost center. To calculate CCRs for 2019, CMS proposes to employ the same basic approach used for APC rate construction for 2007 and each subsequent year. CMS applies the relevant hospital-specific CCR to the hospital’s charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy of CCRs for each revenue code. CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report database at its most detailed level. Generally, the most detailed level will be the hospital-specific departmental level.

In the 2014 OPPS/ASC final rule, CMS created distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computerized tomography (CT) scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs associated with the CT and MRI APCs because of concerns about the lack of accuracy of this cost allocation method. CMS indicated that it would provide hospitals with four years to transition to a more accurate cost allocation method and would use cost data from all providers, regardless of the cost allocation statistic employed, beginning in 2018.

Table 1 of the proposed rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using “square feet” as the cost allocation method. Table 2 of the proposed provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. Table 1 and Table 2 are replicated below.
Table 1. Percentage Change in Estimated Cost for CT and MRI APCs when Excluding Claims from Providers Using “Square Feet” as the Cost Allocation

<table>
<thead>
<tr>
<th>APC</th>
<th>APC Descriptor</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>5521</td>
<td>Level 1 Imaging without Contrast</td>
<td>-3.6%</td>
</tr>
<tr>
<td>5522</td>
<td>Level 2 Imaging without Contrast</td>
<td>5.5%</td>
</tr>
<tr>
<td>5523</td>
<td>Level 3 Imaging without Contrast</td>
<td>4.3%</td>
</tr>
<tr>
<td>5524</td>
<td>Level 4 Imaging without Contrast</td>
<td>4.7%</td>
</tr>
<tr>
<td>5571</td>
<td>Level 1 Imaging with Contrast</td>
<td>7.7%</td>
</tr>
<tr>
<td>5572</td>
<td>Level 2 Imaging with Contrast</td>
<td>8.4%</td>
</tr>
<tr>
<td>5573</td>
<td>Level 3 Imaging with Contrast</td>
<td>2.8%</td>
</tr>
<tr>
<td>8005</td>
<td>CT and CTA without Contrast Composite</td>
<td>13.9%</td>
</tr>
<tr>
<td>8006</td>
<td>CT and CTA with Contrast Composite</td>
<td>11.4%</td>
</tr>
<tr>
<td>8007</td>
<td>MRI and MRA without Contrast Composite</td>
<td>6.6%</td>
</tr>
<tr>
<td>8008</td>
<td>MRI and MRA with Contrast Composite</td>
<td>7.4%</td>
</tr>
</tbody>
</table>

Table 2. CCR Statistical Values Based on Use of Different Cost Allocation Methods

<table>
<thead>
<tr>
<th>Cost Allocation Method</th>
<th>CT Median CCR</th>
<th>CT Mean CCR</th>
<th>MRI Median CCR</th>
<th>MRI Mean CCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Providers</td>
<td>0.0377</td>
<td>0.0527</td>
<td>0.0780</td>
<td>0.1046</td>
</tr>
<tr>
<td>Square Feet Only</td>
<td>0.0309</td>
<td>0.0475</td>
<td>0.0701</td>
<td>0.0954</td>
</tr>
<tr>
<td>Direct Assign</td>
<td>0.0553</td>
<td>0.0645</td>
<td>0.1058</td>
<td>0.1227</td>
</tr>
<tr>
<td>Dollar Value</td>
<td>0.0446</td>
<td>0.0592</td>
<td>0.0866</td>
<td>0.1166</td>
</tr>
<tr>
<td>Direct Assign and Dollar Value</td>
<td>0.0447</td>
<td>0.0592</td>
<td>0.0867</td>
<td>0.1163</td>
</tr>
</tbody>
</table>

CMS indicates that since it adopted its policy in 2014 of excluding providers that use the square foot cost allocation method, the number of valid MRI CCRs has increased by 17.4 percent to 2,174 providers, and the number of valid CT CCRs has increased by 14.8 percent to 2,244 providers. As shown in Table 1, eliminating these hospitals from the OPPS rate setting methodology increases the payment for all but one of the imaging APCs because hospitals that use the square foot allocation have lower CCRs for their imaging cost centers.

Although CMS believes it has appropriate imaging CCRs to use for determining payment, it is extending its policy of not using providers that use the square foot cost allocation methodology in calculating the OPPS relative weights for one additional year through 2019. However, the agency does not believe another extension in 2020 will be warranted and expects to determine the imaging APC relative payment weights for 2020 using cost data from all providers, regardless of the cost allocation method employed.

Proposed Change to Packaging Policy for Drugs that Function as a Supply

Drugs that function as a supply are packaged under the OPPS and the ASC payment systems, regardless of the costs of the drugs. CMS examined this policy for 2019 in response to a recommendation in the President’s Commission on Combating Drug Addiction and the Opioid Crisis that CMS review and modify rate setting policies that could discourage the use of non-opioid treatments for pain. The Commission’s concern
is that the policy leads to incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications, because the non-opioid payment is packaged.

CMS evaluated utilization patterns associated with specific non-opioid drugs that function as a supply from 2013 to 2017 to determine whether the packaging policy has reduced the use of these drugs. CMS did not observe significant declines in the utilization in hospital outpatient departments for a majority of the drugs included in its analysis, and, in fact, observed the opposite effect for several drugs that function as a supply. However, CMS’s findings in the ASC setting were different from the hospital outpatient departments. For the non-opioid pain management drug Exparel, the agency found that ASCs had a decrease in claims and utilization of the drug after pass-through payments ended and the drug was packaged into the surgical procedures with which it was billed.

Therefore, CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for 2019. However, the agency does not propose to pay separately for these drugs in hospital outpatient departments. CMS believes the proposed change will provide incentives to use non-opioid pain management drugs with surgical procedures in the ASC setting and is responsive to the Commission’s recommendation.

CMS is also seeking comments on:

- Whether separate payment would provide incentives to use Exparel or other non-opioid drugs or devices during a hospital outpatient visit or procedure and lead to a decrease in opioid use and addiction among Medicare beneficiaries;
- Whether to use its statutory equitable adjustment authority to provide an add-on payment for non-opioid treatment alternatives; or
- Ways to reorganize or establish more granular APC groupings to provide incentives for increased use of non-opioid alternatives.

**Comprehensive APCs**

There are currently 62 C-APCs that package together an expanded number of related items and services contained on the same claim into a single payment for a comprehensive primary service under the OPPS.

**Proposed Additional C-APCs for 2019.** CMS proposes to add three C-APCs under the existing C-APC payment policy beginning in CY 2019: proposed C-APC 5163 (Level 3 ENT Procedures); proposed C-APC 5183 (Level 3 Vascular Procedures); and proposed C-APC 5184 (Level 4 Vascular Procedures). Table 3 of the proposed rule includes a list of all of the C-APCs for 2019. This proposal would increase the total number of C-APCs to 65.

**Exclusion of Procedures Assigned to New Technology APCs from C-APC Packaging.** CMS proposes to exclude procedures assigned to new technology APCs from being packaged into C-APCs because of a concern that packaging payment reduces claims
for the new technology that are available for APC pricing. The proposed rule indicates that packaging in this circumstance is contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

Proposed Changes to the Inpatient-only List
The inpatient-only list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. For CY 2019, CMS proposes to use the same methodology to review the inpatient-only list as it has in prior years.

For CY 2019, CMS proposes to remove two services from the inpatient-only list:

- CPT 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).

In addition, CMS proposes to add one service 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 vessel).

Further, CMS request comments on removing CPT Code 0266T from the inpatient-only list on the basis that it is similar to other codes already removed from the list. CPT code 0266T describes the implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed). Similar services already removed from the inpatient-only list are CPT codes 0267T and 0268T.

New Technology APC Payment for Low-volume Procedures
Currently, there are 52 levels of New Technology APC groups with two parallel status indicators. One set with a status indicator of “S” (Significant procedure, not discounted when multiple) and the other set with a status indicator of “T” (Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A ($0 - $10)) through the highest cost band assigned to APC 1908 (New Technology – Level 52 ($145,001 - $160,000)). Payment for each APC is made at the mid-point of the APC’s assigned cost band. The proposed payment rates for these New Technology APCs are included in Addendum A to the proposed rule.

One of CMS’s objectives in establishing New Technology APCs is to generate sufficient claims data for a new procedure for assignment to an appropriate clinical APC. CMS
considers procedures with fewer than 100 claims annually as low-volume procedures and is concerned that the payment data for these procedures may not have a normal statistical distribution, which could affect the quality of its standard cost methodology used to assign services to an APC.

Therefore, CMS proposes to establish a different payment methodology for these low-volume services using its equitable adjustment authority. Specifically, CMS proposes to use four years of claims data to establish a payment rate for each applicable low-volume service both for assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of its payment through a New Technology APC. The agency would calculate the cost of furnishing the applicable service using the geometric mean, the median, and the arithmetic mean and include the results of each statistical methodology in annual rulemaking. Based on stakeholder comments, CMS would assign the service to the appropriate New Technology APC.

**Hospital Outpatient Outlier Payments**
Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. CMS again proposes to establish separate thresholds for community mental health centers (CMHCs) and hospitals. For CY 2019, CMS proposes to set the projected target for outlier payments at 1 percent of total OPPS payments. The agency proposes to allocate 0.01 percent of outlier payments to CMHCs for Partial Hospitalization Program services.

The rule continues to include both a fixed-dollar and a percentage outlier threshold. But, in CY 2019, CMS proposes to increase the fixed-dollar threshold for outliers to $4,600, which is $450 more than in CY 2018, to ensure that outlier spending does not exceed the outlier target.

Thus, to be eligible for an outlier payment in CY 2019, the cost of a hospital outpatient service would have to exceed 1.75 times the APC payment amount (the percentage threshold), and at least $4,600 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare would 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.

**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 2019, CMS projects that pass-through payments will be 0.18 percent of total OPPS payments, or $126.7 million. This includes $10 million in pass-through payments for devices and $116.7 million for drugs and biologicals. These payments are implemented in a budget-neutral manner.

**Partial Hospitalization Program (PHP) Payment**
Proposed Payment for PHP Services in 2019. For CY 2019, CMS proposes to continue to apply its established policies and methodology to calculate the PHP APC per diem payment rates for CMHCs and hospital-based PHP providers based on geometric mean
per diem costs using the CY 2017 claims and cost data for each provider type. Specifically, the agency proposes to continue 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 proposed PHP geometric mean per diem costs and payment rates for CY 2019 are in the table below.

**Proposed CY 2019 PHP Geometric Mean Per Diem Costs and Payment**

<table>
<thead>
<tr>
<th>FY 2019 APC</th>
<th>Group Title</th>
<th>Proposed PHP APC Geometric Mean Per Diem Costs</th>
<th>Proposed Payment Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>APC 5853</td>
<td>Partial Hospitalization (three or more services per day) for CMHCs</td>
<td>$119.51</td>
<td>$117.35</td>
</tr>
<tr>
<td>APC 5863</td>
<td>Partial Hospitalization (three or more services per day) for hospital-based PHPs</td>
<td>$220.52</td>
<td>$216.55</td>
</tr>
</tbody>
</table>

Proposed Changes to the Revenue-Code-to-Cost Center Crosswalk. CMS added a new cost center for “Partial Hospitalization Program,” on line 93.99 of Worksheet A for hospital-based PHPs for cost reporting periods ending on or after Sept. 30, 2017. The cost center includes all costs associated with providing PHP services and excludes costs for non-PHP outpatient mental health services.

The Revenue-Code-to-Cost Center crosswalk identifies primary, secondary (if any), and tertiary (if any) cost centers associated with each PHP revenue code which are used for the CCRs in rate setting. CMS must update the crosswalk for hospital-based PHP cost estimation to correctly match hospital-based PHP revenue code charges with the PHP cost center CCR for future rate setting.

Therefore, CMS proposes that, for CY 2019 and subsequent years, hospital-based PHPs would follow a new Revenue-Code-to-Cost-Center crosswalk that only applies to hospital-based PHPs. Specifically, this new PHP-only crosswalk would be comprised of the existing PHP allowable revenue codes and would map each to the new PHP cost center (Line 93.99) as the primary cost center source for the CCR. The agency would designate as the new secondary cost center the cost center that is currently listed as the existing primary cost center, and designate as the new tertiary cost center the cost center that is listed as the existing secondary cost center. In addition, CMS proposes to make one exception to this policy for the mapping for revenue code 0904, which is the only PHP-allowable revenue code in the existing crosswalk with a tertiary cost center source for the CCR. This exception is described fully in the proposed rule. The current and proposed PHP-only Revenue-Code-to-Cost-Center Crosswalks are displayed in Table 26 in the proposed rule.

**PHP Service Utilization.** CMS has previously expressed concern about the low frequency of individual therapy in PHP services. CMS believes that appropriate treatment for PHP patients includes individual therapy and its analysis of 2017 claims data (the first year of data that reflect the change to the single-tier PHP APCs) shows
that although hospital-based PHPs have greatly increased individual therapy, the provision of individual therapy by CMHCs has decreased. Table 27 of the proposed rule shows claims data from 2015 through 2017.

Because of its single-tier payment policy, CMS continues to be concerned that PHP providers may provide only three services per day when payment is heavily weighted to providing four or more services. Based on its review of 2017 claims, CMS believes that PHPs maintained an appropriately low utilization of three service days as compared to the two preceding years, but the agency will continue to monitor utilization of days with only three PHP services.

Cancer Hospital Adjustment
For CY 2019, CMS proposes to continue 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, 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 proposed target PCR of 0.88 would be used to determine the CY 2019 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital. Table 6 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals. The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis.

Rural Adjustment for Sole Community Hospitals
CMS proposes to continue increasing payments to rural sole community hospitals, 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.

Beneficiary Coinsurance
Medicare law provides that the minimum coinsurance is 20 percent of the OPPS payment amount. The statute also limits a beneficiary’s actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,340 in 2018. CMS estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2019 will be 18.5 percent, the same percentage estimated for 2018.

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 proposes to remove a total of 10 measures from the OQR program, with one measure removed starting with the CY 2020 payment year, which is based on 2018
provider performance, and nine more removed starting with the CY 2021 payment year, which is based upon 2019 provider performance. In addition, the proposed rule requests feedback on potential future changes to measures and clarifies certain OQR program logistics.

The AHA is pleased that CMS is actively removing measures that provide little to no value to patients. 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); we believe that 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.

Proposed Updates to Measure Removal Factors. As part of CMS’s Meaningful Measures initiative (which applies to all CMS quality reporting programs), the agency is reviewing measures currently in use to determine how quality reporting programs can be developed in the least burdensome manner possible. In the CY 2013 OPPS/ASC final rule, CMS finalized a set of seven factors to determine whether a measure should be removed from the OQR on a case-by-case basis; if a measure meets one or more of these removal factors, CMS would consider permanently removing the measure from the OQR. CMS notes that it might choose to retain a measure that meets removal criteria if the measure addresses significant gaps in care or if removing the measure might result in decreases in quality.

In this rule, CMS proposes to update measure removal factor 7. Currently, this factor states “collection or public reporting of a measure leads to negative unintended consequences such as patient harm.” CMS proposes to change this factor so that instead of “such as patient harm” it would read “other than patient harm,” as a measure resulting in patient harm would be immediately removed from the program and would not go through the consideration process. This is the same language that is used for factor 7 in other quality reporting programs.

In addition, CMS proposes to add an eighth measure removal factor, which would consider a measure for removal if its costs outweighed its benefits. CMS defines “costs” as those affecting providers and clinicians (collection and submission/reporting burden, compliance with other programmatic requirements, participation in multiple quality programs, compliance with other federal or state regulations) as well as the costs to the agency associated with program oversight. CMS reiterates that the measure removal evaluation process would continue to be done on a case-by-case basis, and measures that are considered burdensome or “costly” might be retained in the quality reporting program if the benefit to beneficiaries justifies the reporting burden. The AHA supports the change in the language of factor 7 and the addition of the eighth measure removal factor.

If finalized, the measure removal factors would be aligned with those used in other quality reporting programs. The factors would include:
Factor 1: Measure performance among providers is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made (measure is “topped out”).

Factor 2: Performance or improvement on a measure does not result in better patient outcomes.

Factor 3: The measure does not align with current clinical guidelines or practice.

Factor 4: A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

Factor 5: A measure that is more proximal in time to desired patient outcomes for the particular topic is available.

Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

Factor 7: Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.

The AHA intends to suggest CMS add a ninth factor that would allow the agency to consider removal of a measure that has lost NQF endorsement.

Removal of Measures. The measures proposed for removal and the rationale for removing them are in the table below. If these measures are removed as proposed, the OQR would comprise only 12 measures as the implementation of the Outpatient and ASC Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)-based measures has been delayed indefinitely. In light of this, CMS requests public comment on future measure topics for the OQR, specifically outcome measures.

### Measures Proposed for Removal

<table>
<thead>
<tr>
<th>Measure</th>
<th>Measure Number</th>
<th>Type</th>
<th>Removal Factor</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza Vaccination Coverage among Healthcare Personnel</td>
<td>OP-27</td>
<td>Process</td>
<td>8</td>
<td>OP-27 is only hospital outpatient department measure reported through the National Healthcare Safety Network (NHSN), which requires extensive registration/administration processes; Information largely captured in Inpatient version of same measure; to be removed in CY 2019 (for CY 2020 payment)</td>
</tr>
<tr>
<td>Median Time to ECG</td>
<td>OP-5</td>
<td>Efficiency</td>
<td>8</td>
<td>Little variation in performance; National Quality Forum (NQF) endorsement removed</td>
</tr>
<tr>
<td>Mammography Follow-up Rates</td>
<td>OP-9</td>
<td>Process</td>
<td>3</td>
<td>Not in line with recently updated clinical practices</td>
</tr>
<tr>
<td>Thorax Computed Tomography (CT) Use of Contrast Material</td>
<td>OP-11</td>
<td>Process</td>
<td>1</td>
<td>Statistically indistinguishable difference in performance between the 75th and 90th percentiles</td>
</tr>
<tr>
<td>Measure</td>
<td>Measure Type</td>
<td>Weight</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------</td>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data</td>
<td>Process</td>
<td>2</td>
<td>Assesses transmittal of data, but does not directly assess quality or patient outcomes; not NQF-endorsed</td>
<td></td>
</tr>
<tr>
<td>Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT</td>
<td>Process</td>
<td>1</td>
<td>Statistically indistinguishable difference in performance between the 75th and 90th percentiles; not NQF-endorsed</td>
<td></td>
</tr>
<tr>
<td>Tracking Clinical Results between Visits</td>
<td>Process</td>
<td>2</td>
<td>Assesses transmittal of data, but does not directly assess quality or patient outcomes; NQF endorsement removed</td>
<td></td>
</tr>
<tr>
<td>Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients</td>
<td>Process</td>
<td>8</td>
<td>Hospitals also report on other colonoscopy-related measure that is more closely associated with relevant outcomes; same measure is available for gastroenterologists in the Merit-Based Incentive Payment System (MIPS)</td>
<td></td>
</tr>
<tr>
<td>Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use</td>
<td>Process</td>
<td>8</td>
<td>Hospitals also report on other colonoscopy-related measure that is more closely associated with relevant outcomes; same measure is available for gastroenterologists in the MIPS</td>
<td></td>
</tr>
<tr>
<td>Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery</td>
<td>Outcome</td>
<td>8</td>
<td>Measure has history of delayed implementation due to inconsistencies in survey instruments used to inform measure calculation; Only 1.2 percent of facilities reported this voluntary measure</td>
<td></td>
</tr>
</tbody>
</table>

Extension of Reporting Period for Facility Seven-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32). This measure is calculated based on Medicare claims data, and currently uses one calendar year of data. CMS conducted several “dry run” calculations of this measure using various reporting periods, and found that using three years of data yielded the most reliable data. Because of this, CMS proposes to change the reporting period from one year to three beginning with the CY 2020 payment determination. Thus, CY 2020 performance rates would be based on claims data from Jan. 1, 2016 through Dec. 31, 2018. Reporting requirements for facilities would not change.
Frequency of OQR Specifications Manual Release. Currently, CMS releases the OQR Specifications Manual every six months, and addenda as necessary. However, CMS believes it is unnecessary to release two manuals a year unless there are substantive changes to the program; in fact, it could even be confusing to providers. Therefore, CMS would update the release policy to be every six to 12 months beginning with CY 2019. In other words, instead of automatically releasing a manual twice per year, CMS could release it just once if there are no substantive changes (but could release it more frequently to address any major changes).

Notice of Participation (NOP) Form. CMS proposes to remove the requirement to submit a NOP form for participation in the OQR beginning with the CY 2018 reporting period/CY 2020 payment determination. CMS believes the form does not provide any unique information and is unnecessarily burdensome for hospitals to complete and submit. Instead, hospitals would indicate participation status in the OQR simply by submitting any OQR Program data through a registered QualityNet account.

**Proposed Changes to the Inpatient Quality Reporting Program (IQR)**

**Inpatient Quality Reporting Program (IQR) HCAHPS Pain Questions**
In the FY 2018 IPPS 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 done in response to the nationwide opioid epidemic in 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.

Although the agency asserts that there are no scientific studies specifically supporting an association between the HCAHPS “Communication about Pain” questions and increased prescribing of opioids, CMS proposes to remove the questions beginning with Jan. 2022 discharges. CMS proposes this date rather than an earlier removal date as the agency 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 questions. This would not change how performance scores are calculated for the remaining questions.
Proposed Changes to the CY 2019 ASC Payment System

The proposed rule 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. For CYs 2019 through 2023, CMS proposes to update the ASC payment system using the hospital market-basket update rather than the Consumer Price Index for all urban consumers (CPI-U). CMS cites several advantages including that an alternative update factor could stabilize the differential between the OPPS payment and the ASC payment and encourage the migration of services to lower cost settings as clinically appropriate. The agency acknowledges concerns that Medicare does not currently collect cost data from ASCs, which makes it difficult to assess payment adequacy or establish an ASC-specific market basket.

CMS seeks comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs. In addition, 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. Further, CMS reports 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.

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. CMS notes that if the CPI-U had been used, the proposed update would have been 1.3 percent. CMS proposes to continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.0 percent (or no update) for such ASCs. The resulting 2019 ASC conversion factor proposed by CMS is $46.500 for ASCs reporting quality data, and $45.589 for those that do not.¹

Proposed Expansion of the Definition of “Surgery” for ASC-covered Surgical Procedures
Since the implementation of the ASC payment system, CMS has defined a surgical procedure as any procedure within the range of Category I CPT codes that the AMA CPT Editorial Panel defines as surgery. CMS also includes procedures described by Level II HCPCS codes or Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that it determines do not pose a

¹ By comparison, the proposed CY 2019 OPPS conversion factor is $77.955 for hospitals meeting OQR reporting requirements and $74.953 for hospitals that do not meet OQR reporting requirements.
significant safety risk, would not be expected to require an overnight stay, and are separately paid under the OPPS.

Stakeholders have suggested that certain procedures outside the CPT surgical range that are similar to procedures already covered in the ASC setting should also be ASC-covered. In particular, some stakeholders have suggested adding certain cardiovascular procedures to the ASC-covered procedures list due to their similarity to currently covered peripheral endovascular procedures in the surgical code range.

In response, 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 CPT surgical range. Specifically, CMS would define these newly-eligible “surgery-like” procedures to be those procedures that are described by Category I CPT codes that are not in the surgical range but that directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. In addition, these Category I CPT codes would need to meet the ASC setting criteria – do not pose a significant safety risk, are not expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

**Proposed Additions to the List of ASC-covered Surgical Procedures**
Using its proposed revised definition of surgery, as discussed above, CMS conducted its annual review of procedures paid under the OPPS but not included on the list of covered ASC procedures to assess which procedures should be proposed for addition to the ASC-covered procedures list.

CMS proposes to add 12 cardiac catheterization procedures (CPT codes 93451-93462) to the list of covered surgical procedures that the agency believes could be safely performed in the ASC setting and would not require an overnight stay. The agency notes that although these procedures involve blood vessels that could be considered major, it believes these procedures are similar to other procedures currently on the ASC list, and that they may be appropriately performed in an ASC. CMS requests comments about whether these procedures may be safely performed in an ASC.

**Payment for Non-opioid Pain Management Therapy**
As described above, in response to a recommendation from the President’s Commission on Combating Drug Addiction and the Opioid Crisis, for 2019, CMS proposes to pay separately for non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting. This is intended to reverse the decreased utilization of these drugs and to encourage use of non-opioid pain management drugs rather than prescription opioids. Specifically, CMS proposes to unpack and pay separately, at ASP plus 6 percent, for non-opioid pain management drugs that function as surgical supplies in the ASC setting for 2019. This proposal would only currently apply to Exparel – which is the only non-opioid pain management drug that functions as a supply when used in a surgical procedure that is covered under Medicare Part B.
Proposed Changes for ASC Quality Reporting Program (ASCQR)

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 proposes to adopt the same measure removal factors for the ASCQR as are used in other quality reporting programs, including the OQR. CMS also would remove a total of eight measures from the ASCQR program, with one measure removed starting with the CY 2020 payment year, which is based on 2018 provider performance, and seven more removed starting with the CY 2021 payment year, which is based upon 2019 provider performance.

Proposed Updates to Measure Removal Factors. Consistent with the agency’s Meaningful Measures initiative (which applies to all CMS quality reporting programs), CMS proposes to alter the set of ASCQR measure removal factors so that it would align with other programs. The agency would use the same factors listed earlier in this advisory for the OQR program.

Removal of Measures. The measures proposed for removal and the rationale for removing them are in the table below. If these measures are removed as proposed, the ASCQR would comprise only three measures as the implementation of OAS CAHPS-based measures has been delayed indefinitely.

Measures Proposed for Removal

<table>
<thead>
<tr>
<th>Measure</th>
<th>Measure Number</th>
<th>Type</th>
<th>Removal Factor</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza Vaccination Coverage among Healthcare Personnel</td>
<td>ASC-8</td>
<td>Process</td>
<td>8</td>
<td>ASC-8 is only ASC measure reported through NHSN, which requires extensive registration/administration processes; similar measure available in MIPS; to be removed in CY 2019 (for CY 2020 payment)</td>
</tr>
<tr>
<td>Patient Burn</td>
<td>ASC-1</td>
<td>Outcome</td>
<td>1</td>
<td>NQF endorsement removed in 2016</td>
</tr>
<tr>
<td>Patient Fall</td>
<td>ASC-2</td>
<td>Outcome</td>
<td>1</td>
<td>NQF endorsement removed in 2018</td>
</tr>
<tr>
<td>Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant</td>
<td>ASC-3</td>
<td>Outcome</td>
<td>1</td>
<td>NQF endorsement removed in 2016</td>
</tr>
<tr>
<td>All-Cause Hospital Transfer/Admission</td>
<td>ASC-4</td>
<td>Outcome</td>
<td>1</td>
<td>NQF endorsement removed in 2016</td>
</tr>
<tr>
<td>Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients</td>
<td>ASC-9</td>
<td>Process</td>
<td>8</td>
<td>ASCs also report on other colonoscopy-related measure that is more closely associated with relevant outcomes; same measure is available for gastroenterologists in the Merit-Based Incentive Payment System (MIPS)</td>
</tr>
<tr>
<td>Endoscopy/Polyp Surveillance: Colonoscopy Interval</td>
<td>ASC-10</td>
<td>Process</td>
<td>8</td>
<td>ASCs also report on other colonoscopy-related measure that is more closely associated with relevant outcomes; same measure is available for gastroenterologists in the Merit-Based Incentive Payment System (MIPS)</td>
</tr>
</tbody>
</table>
for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use

| Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery | ASC-11 | Outcome 8 | Measure has history of delayed implementation due to inconsistencies in survey instruments used to inform measure calculation; Only 1.2 percent of facilities reported this voluntary measure |

**Possible Future Validation of ASCQR Measures.** Currently, ASCQR measure data is not validated. This means that once ASCs submit chart-abstracted data, CMS does not conduct tests to estimate whether the data was abstracted correctly. CMS validates provider-submitted data in other quality reporting programs. In this proposed rule, CMS requests public comment on whether to adopt the validation methodology used in the OQR program for the ASCQR; details on this validation methodology can be found in our [Regulatory Advisory](#) on the CY 2018 OPPS/ASC Final Rule. CMS suggests that this validation would start with just one measure, ASC-13: Normothermia Outcome, prior to expanding to other measures.

**Extension of Reporting Period for Facility Seven-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (ASC-12).** Consistent with its proposal for OP-32 in the OQR program (see earlier discussion in this advisory), CMS proposes to change the reporting period for ASC-12 from one year to three beginning with the CY 2020 payment determination to improve measure reliability. Thus, CY 2020 performance rates would be based on claims data from Jan. 1, 2016 through Dec. 31, 2018. Reporting requirements for facilities would not change.

**Requests for Information (RFIs)**

**RFIs on Promoting Interoperability and Price Transparency**
CMS includes in the rule two RFIs that it previously included in its CY 2019 hospital IPPS [proposed rule](#), released on April 24. First, CMS repeats its RFI on ways to promote interoperability by making changes to Medicare conditions of participation, conditions for coverage, and requirements for participation for long-term care facilities and post-acute care providers. Second, CMS restates its RFI on ways to make more useful pricing information available to consumers. The agency seeks input on how to define “standard charges;” how hospitals can best enable patients to use charge and cost information; whether providers should be required to disclose out-of-pocket costs before a service is furnished; and how the agency can best enforce these requirements, among other issues.

Given the importance of these issues, the AHA submitted responses to both the promoting interoperability RFI and the price transparency RFI when they were first issued. We will direct the agency to our previously submitted comments.
Leveraging the Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model RFI

The Administration has indicated an interest in pursuing policies and programs to put downward pressure on drug prices. In the President’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket costs, the Administration specifically identified drug acquisition under Part B as one area of focus. Specifically, the Blueprint suggested that Part B costs could be reduced through incorporating more negotiation and CMS seeks input on how the agency could develop a pilot program to test this concept.

CMS identifies two models that leverage a vendor intermediary as a starting place to identify potential program features: 1) the Competitive Acquisition Program, which is currently authorized in statute but was in operation only from 2006-2008, and 2) the “Drug Value Program,” a proposal developed by MedPAC. In the rule, CMS reviews the features of each of these models and then poses a series of questions about how it could design a pilot program that would attract provider, vendor, and drug manufacturer participation and reduce costs for Medicare beneficiaries and the program.

The agency specifically seeks feedback on the providers and suppliers who should be eligible to participate, the drugs and biologicals that should be included in the program, whether and how the program should incorporate value-based purchasing strategies, and what beneficiary protections should be in place. CMS also seeks input on the criteria it should use to identify vendors, as well as how to reimburse them. Finally, the agency is interested in exploring whether the model could be structured so that other payers, such as Medicare Advantage plans and Medicaid agencies, can participate.

Next Steps

The AHA will host a member-only webinar on Tuesday, Aug. 14 from 3 p.m. to 4:30 p.m. ET. Please register for this 90-minute event at this link. Related materials and a recording of this webinar will be available on the AHA’s OPPS webpage.

We encourage members to model the impact of the APC changes on expected CY 2019 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2018 are available on the AHA’s OPPS webpage. To access these, you must be logged on to the website.

Submitting Comments. The AHA urges hospitals and health systems to submit comments to CMS. Comments are due Sept. 24, and may be submitted electronically at www.regulations.gov. Follow the instructions for “Comment or Submission” and enter the file code "CMS–1695–P." CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

Questions. If you have further questions regarding the proposed rule’s payment provisions, please contact Roslyne Schulman, director of policy, at rschulman@aha.org. Questions regarding the quality provisions should be directed to Caitlin Gillooley, associate director, at cgillooley@aha.org.