American Hospital Association®

Regulatory Advisory

November 16, 2016

Medicare Outpatient PPS and ASC Final Rule for CY 2017

At a Glance

At Issue:

On Nov. 1, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2017 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) final rule. In addition to updating the OPPS and ASC payment weights and rates, the rule implements the site-neutral provisions of Section 603 of the Bipartisan Budget Act of 2015 (BiBA), which requires that, with the exception of dedicated emergency department (ED) services, services furnished in off-campus hospital provider-based departments (PBDs) that began furnishing covered outpatient department services on or after Nov. 2, 2015 no longer be paid under the OPPS. Instead, hospitals will be paid under the physician fee schedule (PFS) at newly established rates for these services. For 2017, the payment rate for these services will generally be 50 percent of the OPPS rate. In addition, CMS finalizes its proposal that the relocation of an existing PBD will result in its losing its excepted status and being paid at the new rate, except in extraordinary circumstances. CMS also finalizes its policy regarding a PBD that has a change of ownership. However, CMS will not apply reduced payment to excepted PBDs that expand services. The rule also includes proposals that continue to shift the OPPS more definitively away from a per-service fee schedule to a PPS with larger payment bundles and additional packaging policies. Additionally, the rule removes the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey pain questions from the hospital value-based purchasing (VBP) program scoring calculations, and offers flexibility in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs. CMS will accept comments until Dec. 31 on the site-neutral payment and other policies in the rule. The final rule will take effect Jan. 1, 2017.

Our Take:

CMS's final rule appropriately recognizes that providing no payment to new off-campus hospital PBDs for the services they provide to patients was an untenable policy. We will evaluate the new payment level to ensure that it is fair and reasonable, and review whether the agency will be able to implement it in an efficient manner for 2017. In addition, the AHA appreciates the modifications CMS made to its proposal to allow existing off-campus PBDs to expand their services to meet the changing needs of their patients and communities without being penalized. However, we are alarmed that by penalizing hospitals that need to relocate their PBDs, CMS continues to ignore the need for hospitals to modernize existing facilities so that they can provide the most up-to-date, high-quality services to their patients in locations that meet patients' needs. The AHA is pleased with CMS's proposal to remove the HCAHPS survey pain-management questions in the VBP program scoring methodology while the agency field tests new questions. Further, the AHA is pleased that CMS finalizes a 90-day reporting period in the Medicare and Medicaid EHR Incentive Programs for 2016 and 2017, additional flexibility in the reported measures and the reduced threshold for some Medicare Stage 3 requirements. However, we are disappointed that CMS finalizes the start of Stage 3 in 2018 and includes several unrealistic Stage 3 requirements, such as the required use of application program interfaces.

What You Can Do:

- ✓ Share this advisory with your chief financial officer, chief information officer, chief medical information officer and other members of 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 2017 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2016-2017 soon will be available on the AHA's OPPS webpage. To access these, you must be logged on to the website.
- ✓ Consider submitting comments to CMS on or before the Dec. 31 deadline about the impact that the Section 603 site-neutral provisions will have on your hospital or health system.

Further Questions:

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

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BACKGROUND

On Nov. 1, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2017 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) final rule with comment period. In addition to updating the OPPS and ASC payment weights and rates, the rule includes an interim final rule with comment (IFC), which implements the site-neutral provisions of Section 603 of the Bipartisan Budget Act of 2015 (BiBA). BiBA requires that, with the exception of dedicated emergency department (ED) services, services furnished in off-campus provider-based departments (PBDs) that began furnishing covered outpatient department services on or after Nov. 2, 2015 no longer be paid under the OPPS, but instead under another applicable Part B payment system. Additionally, the final rule changes the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey pain questions required under the hospital value-based purchasing (VBP) program, offers flexibility in the Medicare Electronic Health Record (EHR) Incentive Program, finalizes seven new measures for the CY 2020 Outpatient Quality Reporting (OQR) program, including five measures calculated from the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS), and makes several changes to the requirements for organ transplant centers and organ procurement organizations.

CMS will accept comments until Dec. 31 on the site-neutral payment and other policies in the rule. The final rule will take effect Jan. 1, 2017.

This Regulatory Advisory highlights many of the rule's policies. In addition, the AHA offers members a more detailed summary prepared by Health Policy Alternatives, Inc.

CHANGES TO THE CY 2017 OPPS

OPPS Update and Linkage to Hospital Quality Data Reporting

OPPS Update. The CY 2016 OPPS conversion factor is $73.725. To calculate the final conversion factor for CY 2017, the agency adjusted the 2016 conversion factor by the fee schedule increase factor and made further adjustments for various budget neutrality factors. Specifically, the fee schedule increase factor equals the hospital inpatient market-basket increase, which is 2.7 percent, reduced by a productivity adjustment of 0.3 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 1.65 percent for the CY 2017 OPPS final rule. Hospitals that do not meet the OQR program reporting requirements are subject to a further reduction of 2.0 percentage points, resulting in a fee schedule increase factor of -0.35 percent. The CY 2016 OPPS conversion factor is adjusted by the appropriate fee schedule increase factor, the required wage index budget neutrality adjustment of 0.9999, the cancer hospital payment adjustment of 1.0003, the packaging of unrelated laboratory tests adjustment factor of 1.0004, and the adjustment of 0.02 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments. The resulting CY 2017 OPPS conversion factor is $75.001.

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

All Hospitals	**1.8%**
Urban Hospitals	1.8%
Large Urban	1.7%
Other Urban	1.8%
Rural	2.2%
Sole Community	2.2%
Other Rural	2.1%

These payment adjustments, in addition to other changes in the rule, are estimated to result in a net increase in OPPS payments of approximately $773 million in CY 2017, including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization and case-mix. Taking into account estimated changes in enrollment, utilization and case-mix, the increase in OPPS expenditures for 2017 is estimated to be $5 billion. However, this figure does not include an estimated reduction of $50 million in program savings resulting from the implementation of the site-neutral payment provisions of Section 603 of the BiBA (discussed below).

Section 603 Site-neutral Policies

CMS implements Section 603 of the BiBA, which requires that, with the exception of dedicated ED services, services furnished in "new" off-campus PBDs (those that began billing for covered outpatient department services furnished on or after Nov. 2, 2015) will no longer be paid under the OPPS. Instead these services will be paid under other applicable Part B payment systems beginning Jan. 1, 2017. CMS estimates that implementation of the site-neutral payment provisions will reduce Medicare Part B expenditures by about $50 million in CY 2017.

Included within the larger final rule, the agency embeds an interim final rule with comment period (IFC) to establish new Medicare physician fee schedule (PFS) rates that will apply only to items and services furnished by new and relocated off-campus PBDs. Public comments on the IFC, as well as on other provisions subject to comment within the larger final rule, must be submitted to CMS by Dec. 31.

Broadly, CMS implements Section 603 by:

- Creating and defining the term "excepted items and services" to describe those items and services that are excluded, or "excepted," from the Section 603 site-neutral payment system policy and, therefore, will still paid under the OPPS.

- Defining "off-campus PBDs" and establishing the requirements that will allow certain off-campus PBDs to retain their "excepted" status, both in terms of the facility itself, as well as for the items and services it furnishes.

- Establishing new payment policies for "non-excepted" items and services.

CMS's final rule and IFC appropriately recognize that providing no payment to new off-campus hospital PBDs for the services they provide to patients was an untenable policy. We will evaluate the new payment level to ensure that it is fair and reasonable, and review whether the agency will be able to implement it in an efficient manner for 2017. The AHA appreciates the modifications CMS made to its proposal to allow existing off-campus PBDs to expand their services to meet the changing needs of their patients and communities without being penalized. However, we are alarmed that by penalizing hospitals that need to relocate their PBDs, CMS continues to ignore the need for hospitals to modernize existing facilities so that they can provide the most up-to-date, high-quality services to their patients in locations that meet patients' needs.

Excepted Items and Services. CMS defines excepted items and services as those furnished on or after Jan. 1, 2017 by:

- a dedicated ED, whether or not they are emergency services. This would apply to both existing and new off-campus PBDs that are EDs;
- a PBD that is located on the campus, or within 250 yards, of the hospital or within 250 years of a remote location of the hospital; or
- an off-campus PBD that was billing under the OPPS with respect to covered outpatient department services furnished prior to Nov. 2, 2015, that has not relocated or changed ownership in a manner not permitted by the final rule (as described below).

Dedicated ED. Section 603 exempts items and services furnished in an ED from the definition of "applicable items and services," meaning that they would continue to be paid under the OPPS. In doing so, the law references an existing definition in the Medicare Emergency Medical Treatment and Labor Act (EMTALA) that defines an ED as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, which meets *at least one of* the following requirements:

1. It is licensed by the State in which it is located under applicable State law as an emergency room or ED;

2. It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

3. During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

As such, consistent with the AHA's recommendation, CMS will continue to pay for all items and services furnished in a dedicated ED, whether or not they are

emergency services, under the OPPS, as long as the department maintains its status as an ED (as defined above).

On-campus Locations. **Consistent with Section 603, CMS will except from the site-neutral payment reductions all on-campus departments of a provider and the items and services provided by such departments.** Thus, on-campus PBDs will continue to bill and be paid under the OPPS. In accordance with Section 603, CMS references an existing definition in the current provider-based regulations, which defines on-campus to mean "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings *but are located within 250 yards of the main buildings*, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus." The AHA supports CMS's interpretation of on-campus.

Remote Locations of a Hospital[1]*.* **In accordance with Section 603, CMS also excepts from site-neutral payment all items and services furnished within 250 yards of a remote location of a hospital facility.** CMS notes that neither the law nor the provider-based regulations specify the exact point from which to measure. Therefore, as supported by the AHA, CMS will interpret this to mean that a hospital may measure 250 yards from any point of the physical facility that serves as the site of services of the remote location to any point in the PBD. The agency believes this implementation is consistent with how it has historically implemented the 250-yard criterion when making on-campus determinations under the provider-based regulations.

Policies Regarding Changes to Excepted Off-campus PBDs. As noted previously, Section 603 excepts from the site-neutral payment policy off-campus PBDs that were billing under the OPPS for covered outpatient department services furnished prior to Nov. 2, 2015. CMS reviews and updates its proposed policies based on comments it received from providers about whether changes to an excepted off-campus PBD, such as a relocation, expansion of service or a change of ownership, will affect its excepted status.

Relocation of Excepted Off-campus PBDs. **CMS finalizes, with modifications, its proposal that an excepted off-campus PBD must maintain the same physical address that was listed on the provider's hospital Medicare enrollment form as of Nov. 1, 2015 in order to maintain its excepted status and continue to be paid at the OPPS rates. Unless the PBD receives an "extraordinary circumstances" exception (described below), an excepted PBD that relocates to another off-campus site would lose its excepted status and be subject to the site-neutral payment policy.** CMS noted that in the case of addresses with multiple units, such as a

[1] Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity.

multi-office building, the unit number is considered part of the address. In other words, an excepted hospital PBD cannot move into another unit in its building and remain excepted. In addition, CMS stated that an excepted on-campus PBD that relocates to an off-campus site on or after Nov. 2, 2015 would result in the PBD no longer being paid under OPPS.

However, CMS will permit an excepted off-campus PBD to relocate temporarily or permanently, without loss of their excepted status, for extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues. CMS notes that this policy is intended to be applied in a limited and rare manner. CMS Regional Offices (ROs) will evaluate and make the final decisions about whether to approve or deny these relocation exception requests. The agency indicates that it will provide instruction through sub-regulatory guidance on the process hospitals will use to make a request for a relocation exception. Furthermore, the agency notes that it will not provide an exhaustive list of scenarios for which relocation is necessary because it believes that it is infeasible to establish criteria that would apply to every type of extraordinary circumstance that may arise and wishes to allow the ROs added flexibility.

Unfortunately, CMS did not accept the AHA's recommendation to apply flexibility for the relocation of excepted off-campus PBDs similar to the flexibility it has permitted in regulations allowing grandfathered critical access hospitals (CAHs) to relocate and rebuild so long as they met specific requirements that ensured they remained essentially the same provider and continued to provide services to the same rural service area. CMS expressed concern that this type of exception could allow fairly unlimited relocation and expansion and would pose significant operational, enforcement and administrative resources challenges to the agency.

Service Expansion in an Excepted Off-campus PBDs. **Consistent with AHA's recommendations, CMS did not finalize its proposed policy to limit service line expansions in excepted off-campus PBDs. Therefore, an excepted off-campus PBD will receive payments under the OPPS for all billed items and services, regardless of whether it furnished such items and services prior to Nov. 2, 2015.** In making this policy change, CMS agreed with AHA and other commenters that the proposed service line expansion policy would have been operationally complex and would pose administrative burden to hospitals, CMS and their contractors to identify, track and monitor billing for clinical services.

However, CMS remains concerned that allowing unlimited expansion of services could allow hospitals to add newly purchased physician practices to existing excepted off-campus PBDs, and bill their services at the OPPS rate, leading to a continuation of a practice that CMS believes Section 603 intended to prevent. Therefore, CMS states that it will monitor expansion of clinical service lines by off-campus PBDs and consider limiting expansion in the future**. To that end, the agency requests public comments on what data are currently available or could be collected that would allow CMS to implement a limitation on service expansion. The agency also is interested in**

suggestions for changes to the clinical families of services described in the proposed rule.

Changes of Ownership and Excepted Status. CMS finalizes its proposal that if a hospital, in its entirety, has a change of ownership and the new owners accept the existing Medicare provider agreement from the prior owner, the hospital's off-campus PBDs may maintain their excepted status. If the provider agreement is terminated, all excepted off-campus PBDs and the excepted items and services furnished by such an off-campus PBD will no longer be excepted. Further, individual excepted off-campus PBDs will not be permitted to be transferred from one hospital to another and maintain their excepted status.

Definition of an Excepted Off-campus PBD. Section 603 excepts from site-neutral payment those off-campus PBDs that were "billing under this subsection [OPPS] with respect to covered outpatient department services furnished prior to [Nov. 2, 2015]." In the proposed rule, CMS interpreted this provision to mean that a hospital PBD had to have submitted an OPPS bill for services prior to Nov. 2, 2015 in order to be excepted. However, consistent with the AHA's recommendation, CMS adopts a revised interpretation of this provision of the law based on the date by which a covered outpatient department service was furnished and not when it was billed. **Therefore, CMS will consider an off-campus PBD to be eligible to continue to receive OPPS payments as an excepted off-campus PBD if it furnished a service prior to Nov. 2, 2015, and billed under the OPPS in accordance with timely filing limits.**

Provider-based Federally Qualified Health Center (FQHC). In response to a question from a commenter, CMS clarifies that while Section 603 does not apply to FQHCs paid under the FQHC PPS, it would apply to provider-based FQHCs paid under the OPPS, because these entities are considered departments of a provider.

Interim Final Rule with Comment Period: Establishment of Payment Rates under the Medicare PFS for Non-excepted Items and Services Furnished by Non-excepted Off-campus PBD of a Hospital

CMS states that, under Section 603, items and services furnished by non-excepted PBDs, and certain items and services furnished by excepted off-campus PBDs, are not covered outpatient department services under the OPPS. Instead, it requires that payment must be made for those applicable items and services under another "applicable payment system" if the requirements for such payment are otherwise met. However, the agency notes that the law does not reference or define a specific "applicable payment system" under which payment is to be made.

In the proposed rule, CMS had proposed that the Medicare PFS would be the "applicable payment system" and that physicians furnishing services in non-excepted PBDs would bill on the professional claim (CMS 1500 Form) and be paid at the higher "non-facility" rate under the PFS for the services for which they are eligible to bill. There would have been no payment made directly to the hospital by Medicare.

However, in the final rule, CMS agreed with the AHA's analysis that it would be difficult for hospitals to form financial arrangements with physicians that would comply with the physician self-referral (Stark) and other fraud and abuse laws under the agency's proposal to make no direct payment to non-excepted PBDs. As a result of this and other arguments the AHA made, the agency did not finalize this proposal.

For CY 2017, CMS issues an IFC that finalizes its policy establishing the PFS as the "applicable payment system" for the majority of non-excepted items and services furnished in an off-campus PBD. However, in response to concerns by the AHA and many others, CMS establishes new interim final PFS rates for items and services furnished in a non-excepted PBD that is based upon the OPPS rates. Hospitals will be able to continue to bill and be paid directly by Medicare for these non-excepted items and services at the new PFS rates.

Hospitals will continue to bill on the institutional claim (UB04/837I) using a new claim line modifier "PN" to indicate that the service is a non-excepted item or service. For CY 2017, the payment rate for most of these items and services will generally be 50 percent of the OPPS rates. CMS will continue to pay for certain services, such as therapy services and preventive services at the PFS rate and pay for separately payable Part B drugs at the current rate of Average Sales Price (ASP) plus six percent. Based on an analysis of the information the agency has available at this time, CMS believes that these payment rates reflect the estimated relative resource costs involved in furnishing these technical component services in non-excepted PBDs compared to other PFS services. Several OPPS payment policies, such as comprehensive ambulatory payment classifications (C-APCs) and OPPS packaging logic, are adopted under the new site-of-service PFS rates. **CMS seeks comment on the new payment rates and mechanisms, and states that it will make adjustments as necessary based on that input as early as 2017.**

Impact on 340B Drug Pricing Program Eligibility. In response to concerns raised by commenters, CMS provides information related to non-excepted off-campus PBDs remaining eligible as "child sites" under the 340B program. CMS notes that the amendments made by Section 603 did not change the status of off-campus PBDs as provider-based departments, it changed only the manner in which they are reimbursed for their non-excepted items and services. The agency states that under its finalized policy, services provided in non-excepted off-campus PBDs identified with the "PN" modifier will continue to be reflected on Provider Statistical and Reimbursement (PS&R) reports, thus recognized as reimbursable costs on the Medicare hospital cost report. CMS directs interested parties to the Health Resources & Services Administration for questions relating to 340B eligibility. It notes that if the final CMS payment policies require a change for hospital cost reporting, it will issue sub-regulatory guidance.

Establishment of Payment Rates. CMS finalizes new PFS payment amounts for a new site of service, in non-excepted off-campus PBDs, for 2017. The payment mechanism established for 2017 is, at the Healthcare Common Procedure Coding System (HCPCS) code level, based on the relative payment rates and packaging and billing rules for those services furnished under the OPPS.

In developing this payment mechanism CMS analyzed hospital outpatient claims data from January through August 2016 that contained the "PO" modifier[2] for a limited number of services. The agency adopts, with some exceptions (as described below), a set of payment rates for 2017 that are based on a 50 percent reduction to the OPPS payment rates, inclusive of packaging, for items and services furnished by non-excepted off-campus PBDs. CMS arrived at the 50-percent reduction by comparing:

1. the payment differential between the OPPS and the ASC payment rates, noting that covered surgical procedures in ASCs are paid at 55 percent of the rate under the OPPS; and

2. the weighted average payment differential for overall payment under the OPPS and the PFS for a list of most frequently billed HCPCS codes reported with the "PO" modifier, arriving at 45 percent.

The agency believes that its 50 percent payment reduction does not underestimate the overall relativity between the OPPS and the PFS based on the limited data currently available. However, CMS emphasizes that it views this percentage reduction for 2017 as a transitional policy until it gathers more precise data.

CMS establishes several exceptions to the percentage reduction. That is, the agency will not reduce the payment rates for the following items and services:

- Services currently paid under the OPPS based on payment rates from other Medicare fee schedules (including the PFS) on an institutional claim will continue to be reported on an institutional claim and paid under the PFS, the clinical laboratory fee schedule (CLFS), or the Ambulance Fee Schedule without a payment reduction. These include services such as mammography, therapy services and various preventive services. These are items and services that are assigned status indicator “A” in Addendum B of this final rule.

- Drugs and biologicals that are separately payable under the OPPS will continue to be paid at their current rates, typically ASP + 6 percent, consistent with payment rules in the physician office setting. These drugs and biologicals are identified by status indicator “G” or “K” in Addendum B.

- Drugs and biologicals that are unconditionally packaged under the OPPS and are not separately payable will be bundled into the PFS payment and will not be separately paid to hospitals billing for non-excepted items and services. These drugs and biologicals are assigned status indicator of “N” in Addendum B.

PFS Relativity Adjuster. CMS notes that if it uses the IFC payment mechanisms for years after 2017, it would use the most recent Medicare claims data to develop a PFS

[2] The “PO” modifier is used to identify items and services billed by an off-campus PBD paid under the OPPS other than a remote location, a satellite facility, or a dedicated ED. The use of this modifier was optional in CY 2015 and mandatory in CY 2016.

relativity adjuster that incorporates the specific mix of services furnished in non-excepted off-campus PBDs. **CMS plans to study the issue and seeks comments on potential future refinements.**

Geographic Adjustments. CMS adopts hospital area wage index areas, as well as the actual hospital wage index values, for non-excepted off-campus PBDs to adjust the technical component rates in lieu of the PFS geographic practice cost indices.

Coding Consistency. CMS notes that the same HCPCS codes are used to describe services paid under both the PFS and the OPPS for most services. However, evaluation and management (E&M) services are reported under the OPPS using the single HCPCS code G0463 (Hospital outpatient clinic visit) while 10 Current Procedural Terminology (CPT) codes are used to describe these services under the PFS. The PFS payment rate for non-excepted off-campus PBDs furnishing E&M services in 2017 will be based on the rate for HCPCS code G0463 reduced by the 50-percent PFS relativity adjuster.

In addition, CMS established HCPCS Level II "G" codes for radiation treatment delivery services furnished in a physician's office. However, under the OPPS, CPT codes are used to described these services furnished in the hospital outpatient department (HOPD). CMS will require off-campus PBDs to bill for non-excepted items and services using the HCPCS "G" codes under the PFS to describe radiation treatment delivery services, and the off-campus PBD must append modifier "PN" to each applicable claim line for non-excepted items and services.

OPPS Payment Adjustments. CMS adopts the packaging payment rates and multiple procedure payment reduction percentage that apply under the OPPS to establish the PFS payment rates for items and services billed by non-excepted off-campus PBDs. The same claims processing logic that is used for OPPS payment for C-APCs, conditionally and unconditionally packaged items and services, and major procedures will be incorporated into the newly established PFS rates.

CMS notes that it is not adopting a number of OPPS payment adjustments under the IFC. These adjustments include outlier payments, the rural sole community hospital 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.

Partial Hospitalization Programs (PHPs). Under the proposed payment policy, off-campus PBDs would not have been paid for PHP services furnished at their facilities unless the entity enrolled and billed as a community mental health center (CMHC) for payment under the OPPS and it met all Medicare requirements and conditions of participation for CMHCs. The AHA and other commenters noted that this was not a viable option and that access to PHP services could be limited under the policy. Commenters requested that CMS develop a policy for payment for PHP services furnished by non-excepted off-campus PBDs.

Under the IFC, PHP services will be paid at the CMHC rate for APC 5853 (Partial Hospitalization (three or more services per day) for CMHCs). CMS believes that adopting the CMHC rate is appropriate since CMHCs are freestanding entities that are not part of a hospital but provide the same services as hospital-based PHPs.

Supervision Rules. CMS notes that the amendments made by Section 603 did not change the status of off-campus PBDs as provider-based departments, it only changed the manner in which they are reimbursed for their non-excepted items and services. Thus, the supervision rules applicable to all outpatient therapeutic services continue to apply to off-campus PBDs that furnish non-excepted items and services.

Beneficiary Cost-Sharing. CMS specifies that all beneficiary cost-sharing rules that apply under the PFS will continue to apply for all non-excepted items and services furnished by off-campus PBDs, regardless of the cost-sharing obligation under the OPPS.

2018, 2019 and Subsequent Years. CMS notes that unless it significantly modifies policies in response to comments to the IFC, it intends to continue to use the IFC payment mechanism in 2018. However, CMS restates that Section 603 was intended to remove Medicare payment incentives for hospitals to acquire physician practices and thus, CMS intends for its payment policies to ultimately equalize payment rates between non-excepted off-campus PBDs and physician offices to the greatest extent possible.

CMS states that it intends to implement the payment policy approach it specified in the 2017 OPPS/ASC proposed rule for 2019 and subsequent years. That is, CMS would pay non-excepted off-campus PBDs for their items and services at a PFS-based rate that the agency believes would reflect the relative resources involved in furnishing the services. Payment amounts under this approach would approximate the amount Medicare would pay under the PFS to cover facility overhead costs if the same services were furnished in a physician's office. CMS notes that:

- For most services, the PFS-based rate would equal the non-facility payment rate under the PFS minus the facility payment rate under the PFS for the service in question.
- For other services for which separate payment is not made under the PFS, if payment is made under OPPS, the PFS-based rate would equal the PFS non-facility rate[3].
- For other services, the technical component rate under the PFS would serve as the PFS-based rate.
- For services billable under OPPS but not under PFS, CMS would consider the relative resources involved in furnishing the service. It envisions a rate similar to the ASC rate for similar services.

[3] Please note that while the AHA restates this policy as articulated in the IFC, it is unclear how Medicare can make payment at the PFS non-facility rate for a service that does not receive separate payment under the PFS.

Implementing such a system would require substantial systems changes, and **CMS seeks comment on this approach.**

Alternatively, CMS seeks comment on the possibility of continuing to make payment using a methodology similar to that described under the IFC, or one similar to it, for future years. CMS notes that under this approach, the PFS relativity adjuster could be lower or higher than the percentage adopted in the IFC, and it would utilize billing data initially from CYs 2017 and 2018, to determine the appropriate percentage adjustment, and then update the percentage adjustment annually based on the most recently available data, for future years. However, CMS's goal would be to equalize payment rates between non-excepted off-campus PBDs and physician offices to the greatest extent possible. The agency acknowledges that the rates would not be equal on a procedure-by-procedure basis and raises concerns that specialty-specific patterns in payment differentials could incentivize hospitals to acquire certain types of physician practices, which Congress intended to avoid. However, under a continued IFC payment approach, hospitals could continue to bill through the facility claim form and there would be continuation of the packaging rules and cost report-based relative payment rate determinations under OPPS, which the agency believes are preferable to using the current valuation methodologies under the PFS for items and services furnished by non-excepted off-campus PBDs.

Audits. CMS notes that audits of hospital billing will examine whether off-campus PBDs are billing correctly for non-excepted items and services. The agency expects hospitals to maintain proper documentation showing which off-campus PBDs were billing Medicare prior to Nov. 2, 2015, and to make this documentation available to the agency and its contractors upon request.

Changes to the Inpatient-only List

Procedures Removed from the Inpatient-only List. CMS uses its established methodology to identify seven procedures (five spine procedure codes and two laryngoplasty codes) for removal from the inpatient-only list for CY 2017. These services include:

- CPT code 22585 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy, and decompression of spinal cord and/or nerve roots; each additional interspace (List separately in addition to code for primary procedure));
- CPT code 22840 (Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure));
- CPT code 22842 (Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 22845 (Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure));

- CPT code 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 code 31584 (Laryngoplasty; with open reduction of fracture); and
- CPT code 31587 (Laryngoplasty, cricoid split).

Possible Removal of Total Knee Arthoplasty (TKA) Procedure from the Inpatient-only List. CMS sought public comments on whether it should remove TKA or total knee replacement, CPT code 27447 (Arthroplasty, knee, condyle and plateau, medical and lateral compartment with or without patella resurfacing), from the inpatient-only list. In 2013, CMS had made a similar proposal, but did not finalize it. The AHA and most other commenters opposed the 2013 proposal, claiming that it would be unsafe to perform outpatient TKA for Medicare beneficiaries. CMS notes that recent innovations, such as minimally invasive techniques, improved perioperative anesthesia, alternative post-operative pain management and expedited rehabilitation protocols, have enabled surgeons to perform TKA on an outpatient basis on non-Medicare patients.

In the final rule, CMS reports that it received comments both in support of and opposed to removing TKA from the inpatient-only list and will consider those comments in developing future policy. The majority of the commenters supported removing TKA from the inpatient-only list, stating that they are currently performing TKA procedures on an outpatient basis in both the HOPD and ASC on non-Medicare patients. These commenters indicated that TKA on an outpatient basis was made possible by innovations such as less invasive surgical techniques, improved perioperative anesthesia, alternative postoperative pain management, expedited rehabilitation protocols and the similarity of the TKA procedure to other procedures currently being performed as outpatient services. A few commenters opposed the removal of a TKA procedure from the inpatient-only list on the basis that Medicare patients have comorbidities that require the need for intensive rehabilitation after a TKA procedure that preclude this procedure from being performed in the outpatient setting and most outpatient departments are not currently equipped to provide TKA procedures to Medicare beneficiaries. Other commenters were concerned about the implications that the removal of the TKA procedure from the inpatient-only list would have for the pricing methodologies, target pricing, and the reconciliation process of the procedure in certain Medicare payment models (that is, the Comprehensive Care for Joint Replacement and the Bundled Payments for Care Improvement models). They requested modifications to these models if the TKA procedure is removed from the inpatient-only list.

Recalibration and Scaling of APC Relative Weights

CMS recalibrates the relative APC weights using hospital claims for services furnished during CY 2015. As in the previous year, CMS 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 2017 to the estimated total relative payment weights in CY 2016 using the service volume in the CY 2015 claims data. Based on this comparison, the CY 2017 unscaled APC payment weights are adjusted by a weight scaler of 1.4208. The effect of the adjustment is to increase the unscaled relative weights by about 42 percent in order to ensure that the CY 2017 relative payment weights are budget neutral.

Comprehensive APCs

CY 2017 Comprehensive APCs (C-APCs). There are currently 37 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.

For CY 2017, CMS makes a slight modification to its current C-APC payment policy methodology related to how it applies the complexity adjustment. Otherwise, CMS continues to include in a single payment all covered outpatient department services on a hospital outpatient claim reporting a primary service that assigned to status indicator "J1." Further, CMS continues to use status indicator "J2," as finalized in 2016, to designate C-APCs to which assignment is based on specific combinations of services performed together rather the presence of a single primary service identified by status indicator "J1." The only services on a claim that are excluded from the C-APC payment are those that are not covered outpatient department services or that cannot, by law, be paid under the OPPS.

Using these criteria, CMS adds 25 new C-APCs in CY 2017, many of which are major surgery APCs within the various existing C-APC clinical families. The agency also adds three new clinical families to accommodate new C-APCs, including nerve procedures; excision, biopsy, incision and drainage procedures; and airway endoscopy procedures. In addition, as discussed below, CMS develops a C-APC and dedicated cost center for bone marrow transplants.

All C-APCs for 2017, including current and new C-APCs, are displayed in Table 1 below. Addendum J to the final rule contains data related to the C-APC payment policy methodology, including the list of complexity adjustments.

TABLE 1. 2017 COMPREHENSIVE APCs

C-APC	2017 APC Title	Clinical Family[4]	New C-APC[5]
5072	Level 2 Excision/Biopsy/Incision & Drainage	EBIDX	*
5073	Level 3 Excision/Biopsy/Incision & Drainage	EBIDX	*
5091	Level 1 Breast/Lymphatic Surgery & Related Procedures	BREAS	*
5092	Level 2 Breast/Lymphatic Surgery & Related Procedures	BREAS	*
5093	Level 3 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery & Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	*
5113	Level 3 Musculoskeletal Procedures	ORTHO	*
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	*
5154	Level 4 Airway Endoscopy	AENDO	*
5155	Level 5 Airway Endoscopy	AENDO	*
5164	Level 4 ENT Procedures	ENTXX	*
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5191	Level 1 Endovascular Procedures	VASCX	*
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5194	Level 4 Endovascular Procedures	VASCX	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	*
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	

[4] **C-APC Clinical Family Descriptor Key:** AENDO = Airway Endoscopy, AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices, BREAS = Breast Surgery, COCHL = Cochlear Implant, EBIDX = Excision, Biopsy, Incision and Drainage, ENTXX = ENT Procedures, EPHYS = Cardiac Electrophysiology, EXEYE = Extraocular Ophthalmic Surgery, GIXXX = Gastrointestinal Procedures, GYNXX = Gynecologic Procedures, INEYE = Intraocular Surgery, LAPXX = Laparoscopic Procedures, NERVE = Nerve Procedures, NSTIM = Neurostimulators, ORTHO = Orthopedic Surgery, PUMPS = Implantable Drug Delivery Systems, RADTX = Radiation Oncology, SCTXX = Stem Cell Transplant, UROXX = Urologic Procedures, VASCX = Vascular Procedures, WPMXX = Wireless PA Pressure Monitor.

[5] Asterisk (*) indicates new C-APC for CY 2017.

C-APC	2017 APC Title	Clinical Family[4]	New C-APC[5]
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	*
5302	Level 2 Upper GI Procedures	GIXXX	*
5303	Level 3 Upper GI Procedures	GIXXX	*
5313	Level 3 Lower GI Procedures	GIXXX	*
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	*
5361	Level 1 Laparoscopy & Related Services	LAPXX	
5362	Level 2 Laparoscopy & Related Services	LAPXX	
5373	Level 3 Urology & Related Services	UROXX	*
5374	Level 4 Urology & Related Services	UROXX	*
5375	Level 5 Urology & Related Services	UROXX	
5376	Level 6 Urology & Related Services	UROXX	
5377	Level 7 Urology & Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	*
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	*
5432	Level 2 Nerve Procedures	NERVE	*
5462	Level 2 Neurostimulator & Related Procedures	NSTIM	
5463	Level 3 Neurostimulator & Related Procedures	NSTIM	
5464	Level 4 Neurostimulator & Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	*
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	*
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	*
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

Allogeneic Hematopoietic Stem Cell Transplantation C-APC. Citing long-standing concerns raised by stakeholders regarding the accuracy of rate setting for allogeneic Hematopoietic Stem Cell Transplantation (HCST), CMS finalizes its proposal, with modifications, to create a new C-APC 5244 (Level 4 Blood Product Exchange and

Related Services). Consistent with the AHA's recommendations, CMS will only use the claims that include donor acquisition costs reported with both CPT code 38240 (Hematopoietic progenitor cell (HPC), allogeneic transplantation per donor) and revenue code 0819 (Organ Acquisition: Other Donor) in calculating the 2017 payment rate. The costs for all covered outpatient department services included on the claim, including donor acquisition services, is packaged into the new C-APC. The final rate for C-APC 5244 is $27,752.

For future rate setting, CMS will add a new standard cost center 77, "Allogeneic Stem Cell Acquisition" to Worksheet A (and applicable worksheets) with the standard cost center code of "07700" to be used to record any acquisition costs related to allogeneic stem cell transplants. Further, for 2017 and subsequent years, CMS will no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants. Instead, as recommended by the AHA, CMS will implement a code edit beginning in 2017 that will require a new revenue code 0815 (Allogeneic Stem Cell Acquisition Service) to be on a claim with CPT code 38240 to help ensure that donor acquisition costs are accurately recorded in the Medicare hospital cost report.

Changes to Packaging Policies

For CY 2017, CMS finalizes several changes to its packaging policies.

CY 2017 Laboratory Test Packaging. In CY 2014, CMS established a policy to conditionally package the costs of clinical diagnostic laboratory tests in the OPPS. Specifically, CMS pays separately for a laboratory test under the CLFS only when: (1) it is the only service provided to a beneficiary on a claim; (2) it is an unrelated test, meaning it is on the same claim as other outpatient services, but is ordered for a different diagnosis and by a different practitioner than the other OPPS services (hospitals are instructed to use an "L1" modifier to indicate when laboratory tests meet this exception for separate payment); (3) it is a molecular pathology test; or (4) it is considered a preventive test.

For CY 2017, CMS makes two changes to its laboratory packaging policy. The agency:

- *Discontinues the unrelated laboratory test exception (and the associated "L1" modifier that designates separate payment).* With this change, CMS packages all laboratory tests that appear on a claim with other outpatient department services. CMS believes that, in most cases, "unrelated" laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD. The agency claims that some hospitals have reported that the "unrelated" laboratory test exception is not useful because they cannot determine when a laboratory test has been ordered by a different physician and for a different diagnosis than the other services reported on the same claim. CMS notes that the discontinuation of the "L1" modifier does not affect the ability of hospitals to be paid separately for laboratory tests when these tests are the only services that are provided to the beneficiary. Such services are assigned status indicator "Q4"

(conditionally packaged laboratory tests) and will continue to be paid separately under the CLFS.

- *Expand the Molecular Pathology Exclusion to Include All Advanced Diagnostic Laboratory Tests (ADLTs).* CMS believes that ADLTs,[6] like molecular pathology tests, are relatively new and may have a different pattern of clinical use than more conventional laboratory tests. As a result, they may be less tied to a primary service in the outpatient department than other types of laboratory tests. Therefore, consistent with the AHA's recommendation, CMS finalizes a policy to assign status indicator "A" (separate payment under the CLFS) to laboratory tests designated as ADLTs under the CLFS.

Conditional Packaging Status Indicators "Q1" and "Q2." To identify packaged payment versus separate payment of items and services, CMS uses status indicators applied to CPT and HCPCS codes. There are several different indicators for conditional packaging, which means that, under certain circumstances, items and services are packaged and, under other circumstances, they are paid separately.

Two of these status indicators indicate packaging of services furnished on the *same date*. Specifically, status indicator "Q1" packages items or services on the same date of service with services assigned status indicator "S" (Procedure or Service, Not Discounted When Multiple), "T" (Procedure or Service, Multiple Procedure Reduction Applies), or "V" (Clinic or ED Visit) and status indicator "Q2" packages items or services on the same date of service with services assigned status indicator "T." Other conditional packaging status indicators, such as "Q4" (Conditionally Packaged Laboratory Tests) and "J1"/"J2" (Hospital Part B Services Paid through a Comprehensive APC), package services on the *same claim*, regardless of the date of service.

For 2017, CMS finalizes a change to the logic for status indicators "Q1" and "Q2" so that packaging would occur at the claim level, instead of based on the date of service. CMS states that this aligns with other conditional packaging indicators and ensures that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies. This change increases the conditional packaging of items and services because conditional packaging will occur whenever a conditionally packaged item or service is reported on the same claim as a primary service without regard to the date of service. In comments, the AHA generally supported this policy but had urged CMS to consider the potential unintended consequences of claims level packaging on "Q1`" and "Q2" repetitive services, such as pulmonary rehabilitation services. In response to the AHA's concerns, CMS reassigned the status indicator for pulmonary rehabilitation service, HCPCS codes G0237, G0238, G0239, and G0424 to status indicator "S."

[6] An ADLT is a test that is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result.

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) 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 finalizes its proposal to continue this policy and use the final FY 2017 IPPS wage indices for calculating CY 2017 OPPS payments. For hospitals paid under the OPPS but not the IPPS, CMS will continue its longstanding policy for CY 2017 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 will be adjusted by the wage index.

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 2017, CMS sets the projected target for outlier payments at 1 percent of total OPPS payments – the same as in CY 2016 and previously.

The rule continues to include both a fixed-dollar and a percentage outlier threshold. But, in CY 2017, CMS increases the fixed-dollar threshold for outliers to $3,825, which is $575 more than in CY 2016, to ensure that outlier spending does not exceed the outlier target.

Thus, to be eligible for an outlier payment in CY 2017, the cost of a hospital outpatient service will have to exceed 1.75 times the APC payment amount (the percentage threshold), *and* at least $3,825 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.

In addition, CMS allocates 0.01 percent of outlier payments to CMHCs for PHP services. The agency also implements a CMHC outlier payment cap to be applied at the provider level. In any given year, an individual CMHC will receive no more than 8 percent of its CMHC total per diem payments in outlier payments.

Blood and Blood Products

For 2017, CMS continues to calculate the payment rates for blood and blood products using the blood-specific cost-to-charge ratio (CCR) methodology that it has used since 2005. CMS uses the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center to set the 2017 payment rates for blood and blood products.

CMS sought comments in the proposed rule regarding the adequacy and necessity of the current descriptors for the HCPCS P-codes describing blood products**.** For each of three main categories of blood products (red blood cells, platelets and plasma) the P-

codes describe various treatments or preparations of the blood products, with each, in several cases, represented individually and in combination. CMS noted that in some cases hospital costs are similar for blood products with different code descriptors, and wanted to know whether these P-code descriptors, with their associated granularity, best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. The AHA and other commenters agreed that a thorough examination of the current set of HCPCS P-codes for blood products is a necessary undertaking because the HCPCS P-codes were created several years ago. The AHA and other commenters also encouraged CMS to retain individual HCPCS P-codes for unique blood products with significant therapeutic distinctions, as opposed to creating modifiers to be applied to the existing HCPCS P-codes. CMS indicated that these comments will be taken into consideration in the development of proposals to update the HCPCS P-codes that describe blood products.

Device-intensive Procedures

For CY 2017, CMS makes several changes to its policies regarding device-intensive procedures.

Methodology for Assignment of Device-intensive Status. Currently, device-intensive procedures are those procedures assigned to a device-intensive APC, which are APCs with a device offset greater than 40 percent. The device offset amount for an APC is the portion of the APC payment amount that is associated with the cost of devices used in procedures assigned to the APC. The device portion of a device-intensive procedure's payment is the same in both the HOPD and ASC setting. With the recent reorganization of the APCs to include a greater number of procedures, some APCs contain procedures that have high device costs but do not meet the 40 percent device-intensive threshold. Given this outcome, CMS changes the device-intensive calculation methodology to calculate the device offset amount at the HCPCS code level rather than at the APC level so that device-intensive status is assigned to all device-intensive procedures that exceed the 40 percent threshold.

Changes to Device Edit Policy. For 2017, CMS will apply its device claims editing policy on a procedure level rather than APC level, consistent with its new policy to make device-intensive determinations at the HCPCS code level. For 2017 and subsequent years, CMS will apply the device coding requirements to the newly defined (individual HCPCS code-level device offset greater than 40 percent) device-intensive procedures. Therefore, any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, CMS creates HCPCS code C1889 to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS C-code. Reporting HCPCS code C1889 with a device intensive procedure will satisfy the edit requirement.

New Payment Policy for Low Volume Device-Intensive Procedures. CMS finalizes a policy that the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims for all procedures in the APC will be based on the median cost instead of the geometric mean cost. CMS believes that this approach will

mitigate significant year-to-year payment rate fluctuations while preserving accurate claims-data-based payment rates for low volume device-intensive procedures.

Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices. CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit using a value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS specifies a list of costly devices to which this APC payment adjustment would apply.

For 2017, CMS identifies the services to which the adjustment applies using the newly defined set of device-intensive procedures. That is, the adjustment applies to those procedures with an individual HCPCS level device offset greater than 40 percent, as described above.

Device Pass-through Applications

Device pass-through payments are intended to enable access to certain new medical devices. For CY 2016, CMS made changes to the OPPS device pass-through payment application process to improve transparency and stakeholder input. Specifically, in CY 2016, CMS adopted a policy to continue to accept and review device pass-through applications on a quarterly basis but to also include discussions of the preliminary pass-through applications in the next applicable OPPS proposed rule. For CY 2017, CMS evaluated three applications for device pass-through status. None of these applications were approved for device pass-through status.

Changes to Payment for Film X-ray

CMS implements a non-budget neutral provision of the Consolidated Appropriations Act of 2016, which reduces OPPS payment by 20 percent for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) furnished during 2017 and subsequent years. CMS establishes a new modifier, "FX" that hospitals will be required to use on claims for these imaging services beginning in CY 2017. The HCPCS codes describing these imaging services to which this policy will apply can be found in Addendum B to the final rule. CMS notes that when payment for an X-ray service taken using film is packaged into the payment for another item or service under the OPPS, no separate payment for the X-ray service taken using film is made. Accordingly, the payment reduction in this instance would be 0 percent (that is, 20 percent of $0).

The act also reduces payment for imaging services that are X-rays using computed radiography (including the X-ray component of a packaged service). Such imaging services furnished in 2018 through 2022 will receive a reduction of 7 percent in payment and in 2023 and subsequent years a 10 percent reduction.

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. CMS addressed the initial component of the AUC program, including specifying applicable AUC and establishing CMS authority to identify clinical priority areas for making outlier determinations in the 2016 PFS final rule. The program's criteria and requirements are established and updated through PFS rulemaking.

CMS notes that ordering practitioners will be required to consult AUC at the time of ordering advanced diagnostic imaging, and imaging suppliers will be required to report information related to such consultations on claims, for all applicable advanced diagnostic imaging services paid under the PFS, OPPS and ASC payment system. The 2017 PFS final rule includes requirements and processes for the second component of the Medicare AUC program: the specification of qualified clinical decision support mechanisms (CDSMs) under the program. The CDSM is the electronic tool through which the ordering practitioner consults AUC. The 2017 PFS final rule also includes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. Please see the CY 2017 PFS final rule for further details.

Payment Changes for Drugs, Biologicals & Radiopharmaceuticals

Changes to Transitional Pass-through Period for All Pass-through Drugs, Biologicals and Radiopharmaceuticals. By law, transitional pass-through payments for drugs, biologicals and radiopharmaceuticals (hereafter referred to as "drugs") are made for a period of at least two years, but not more than three years, beginning on the first date on which pass-through payment was made for the product. CMS accepts pass-through applications and begins pass-through payments for new pass-through drugs on a quarterly basis. Pass-through status, however, currently expires on a calendar-year basis, through notice-and-comment rulemaking, when at least two years of pass-through payments have been made, regardless of the quarter in which it was initially approved. Thus, the duration of the pass-through eligibility for a particular drug depends on the quarter of initial eligibility for pass-through payment.

Therefore, CMS finalizes its proposal that beginning with pass-through drugs newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status to afford a pass-through period that is as close to a full three years as possible for all pass-through payment drugs.

Packaging Policy for "Threshold-Packaged" and "Policy-Packaged" Drugs, Biologicals and Radiopharmaceuticals. The payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status that will be effective Jan. 1, 2017, will be based on third quarter of 2016 ASP data. Updates to the ASP-based rates will be published quarterly and posted on CMS's website through CY 2017.

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 2017, CMS sets the packaging threshold for "threshold-packaged" drugs, including nonimplantable biologicals and therapeutic radiopharmaceuticals, at $110 per day, $10 more than in CY 2016. Therefore, drugs costing less than $110 will have their cost packaged in the procedure with which they are billed, such as a drug administration procedure. Drugs costing more than $110 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 diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure (e.g., skin substitutes), regardless of whether they meet the $110 per day threshold. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this final rule.

Payment for Drugs and Biologicals without Pass-through Status that are not Packaged. For CY 2017, CMS continues its current policy and pays for separately payable drugs and biological 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.

Payment for Biosimilar Biological Products. The ACA authorized an abbreviated pathway for the licensing of biosimilar biological products. For 2017, CMS continues the policies it finalized in 2016. That is, it extends pass-through payment eligibility to biosimilar biological products and applies the same payment methodology to biosimilar biologic products as it does to other pass-through drugs and biologicals. In addition, as it finalized in 2016, the agency will pay for non-pass-through biosimilar biological products in the same way that other drugs and biological products are paid, using the ASP plus 6 percent payment methodology, subject to the threshold-packaging policy.

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 48 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 one set is subject to the multiple procedure payment reduction (T) and the other set not subject to the multiple procedure payment reduction (S).

CMS expands the new technology APC groups by adding three more levels with two parallel status indicators, Levels 49 through 51. These new levels range from the cost band assigned to proposed APC 1901 (New Technology – Level 49 ($100,001 - $120,000)) through the highest cost band assigned to proposed APC 1906 (New Technology – Level 51 ($140,001 - $160,000)). CMS establishes this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to another new technology APC. The payment rates for these New Technology APCs are included in Addendum A to the rule. Table 10 in the final rule includes the complete list of the additional six new technology APC groups for CY 2017.

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 2017, CMS projects that pass-through payments will be 0.24 percent of total OPPS payments, or $150.6 million. This includes $112.7 million in pass-through payments for devices and $37.9 million for drugs and biologicals. These payments are implemented in a budget-neutral manner.

Rural Adjustment for Sole-community Hospitals

CMS will continue to increase 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.

Cancer Hospital Adjustment

CMS will continue its cancer hospital update policy finalized in the CY 2012 OPPS final rule. Using the most recently submitted or settled cost report data, this policy will increase *each* of the 11 "exempt" cancer hospitals' OPPS payments by the percentage difference between its individual payment-to-cost ratio (PCR) and the weighted average PCR of the other hospitals paid under the OPPS (0.91). The adjustment is made at cost report settlement and is budget neutral.

Partial Hospitalization Program Payment

CMS currently uses four separate APCs to pay for PHP services, including two APCs for services furnished in hospital-based PHPs and two APCs for services furnished in a CMHC. For each setting there is currently an APC that describes the payment for a PHP day with three services and a separate APC that describes the payment for a PHP day with four or more services. Payments for hospital-based PHP services are

calculated using only hospital data, and payment for CMHC PHP services are calculated using only CMHC claims data.

For 2017, CMS calculates the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, CMS is replacing the existing two-tiered APC structure for PHPs with a single APC by provider type for providing three or more services per day. CMS believes that this changes will provide more predictable PHP per diems, particularly given the small number of CMHCs, and will generate more appropriate payments for these services by avoiding the cost inversions that hospital-based PHPs experienced in the CY 2016 OPPS/ASC final rule and that would have again occurred in 2017 under the previous APC structure.

The resulting PHP geometric mean per diem costs and final payment rates for CY 2017 are in Table 2 below.

TABLE 2. CY 2017 PHP GEOMETRIC MEAN PER DIEM COSTS AND PAYMENT

2017 APC	Group Title	CY 2017 PHP APC Geometric Mean Per Diem Cost	CY 2017 PHP APC Payment Rate
APC 5853	Partial Hospitalization (three or more services per day) for CMHCs	$124.92	$121.48
APC 5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$213.14	$207.27

* Note: APC 5853 replaces existing CMHC APCs 5851 and 5852. APC 5863 replaces existing hospital-based PHP APCs 5861 and 5862.

PHP Eligibility Requirements. CMS expresses concern that providers may inappropriately provide too few services to beneficiaries enrolled in PHPs. The agency notes 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. The agency plans to monitor PHP claims beginning in January 2017 to determine whether PHP participants are receiving at least 20 hours per week in PHP services as well as to determine whether there is an increase in three-service days. CMS states that payments for claims will not be affected now, but it is working expeditiously to implement claims edits to ensure beneficiaries are receiving the intense level of services required under the statute and regulations. CMS seeks comments on what facility types, treatment patterns and other indicators are most important to monitor to ensure adequate provision of PHP services.

CMS also is concerned by the low frequency of individual therapy in PHP services. It believes that appropriate treatment for PHP patients includes individual therapy, and it

will monitor the extent to which individual therapy is provided. The agency notes that it is considering clarifications to its regulations during the 2018 rulemaking cycle to more strongly tie a beneficiary's receipt of at least 20 hours per week of PHP services to payment for those services. CMS also wants providers to review their admissions procedures to ensure that patients receiving PHP services are truly eligible for them. The agency seeks comments on the advantages, disadvantages and challenges of strengthening the tie between payment and furnishing at least 20 hours of PHP services per week to eligible beneficiaries.

Beneficiary Coinsurance

CMS decreases beneficiary liability for coinsurance for outpatient services. As required by law, CMS maintains last year's maximum beneficiary coinsurance rate of 40 percent of the total payment to the hospital for that service. Under Medicare law, the cap on coinsurance rates is to be reduced gradually until all services have a coinsurance rate of 20 percent of the total payment.

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 in order 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 adopts a total of seven new measures for the CY 2020 OQR program – hospital admissions and ED visits for outpatient chemotherapy patients, hospital visits following outpatient surgery and five measures derived from a new Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey. Detailed specification for the two hospital visit measures can be found on CMS's website, while details on the OAS CAHPS are available here. A list of finalized OQR measures can be found in Appendix A of this advisory.

The AHA is concerned that only one of the seven newly adopted measures has been endorsed by the National Quality Forum (NQF), providing little insight into whether the measures are accurate and fair representations of hospital performance. We will continue to urge the agency to seek and obtain NQF endorsement of these measures before they are implemented in the OQR program. In addition, the AHA will strongly urge CMS to assess all seven proposed measures for the impact of sociodemographic factors on performance, and incorporate adjustments where needed.

Admissions and ED Visits for Chemotherapy Patients (OP-35). For the CY 2020 OQR program, CMS adopts OP-35, which calculates the rates of inpatient admissions and ED visits within 30 days for patients receiving chemotherapy treatment in the HOPD setting. CMS calculates separate rates for inpatient admissions and ED visits, and does not combine them into a single score. Those patients experiencing both an inpatient admission and ED visit are counted toward the inpatient admission rate. Rather than being an "all-cause" measure, OP-35 only includes inpatient admissions and ED visits

for the following 10 conditions – anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia and sepsis.

OP-35 is calculated using Medicare claims data, and does not require hospitals to collect and submit data. The measure includes Medicare fee-for-service patients 18 years and older with a diagnosis of any cancer – except leukemia – during the measure performance period. OP-35 excludes leukemia patients because of concerns that hospital visits for leukemia reflect the relative toxicity of the treatment and frequent recurrence of the disease, rather than shortcomings in quality of care.

For the purposes of calculating OP-35, CMS attributes visits to the hospital where patients received chemotherapy treatment. If a patient receives treatment at two different hospitals within the 30-day timeframe covered by the measure, then the patient would be attributed to **both** hospitals.

Similar to other hospital admission and readmission measures, OP-35 is adjusted for patient clinical factors (i.e., co-morbid conditions and pre-existing conditions) that contribute to the likelihood of hospital visits. However, measure results would not be adjusted for the socioeconomic status of patients or communities. Moreover, the measure is not endorsed by the NQF.

Hospital Visits after Outpatient Surgery (OP-36). OP-36 calculates the rate of hospital visits – including inpatient admissions, ED visits and observation stays – occurring in the seven days after "same day" surgeries in an HOPD. In contrast to OP-35, CMS calculates a single rate for OP-36 encompassing all of the hospital visit types listed above. The measure is endorsed by the NQF.

OP-36 is calculated by CMS using Medicare claims data, and includes all patients 65 years and older undergoing a "substantive surgery or procedure" included on Medicare's list of covered ASC procedures. CMS believes the use of the ASC procedure list is appropriate because they want the measure to assess hospital visits for "surgeries that have a low to moderate risk profile and are safe to be performed as same-day surgeries." Moreover, the list is annually reviewed and includes a public commenting process. The list of covered ASC procedures for 2016 is posted on CMS's website (refer to Addendum AA). CMS excludes patients undergoing eye surgeries because it believes the risk of adverse outcomes is significantly lower than that of other procedures assessed in the measure.

Similar to other hospital admission and readmission measure, OP-36 is adjusted for patient clinical factors (i.e., co-morbid conditions and pre-existing conditions) that contribute to the likelihood of hospital visits. However, measure results would not be adjusted for the socioeconomic status of patients or communities.

OAS CAHPS Survey Measures (OP-37a – 37e).

OAS CAHPS Overview. For the CY 2020 OQR program, CMS adopts five measures derived from the 37-item OAS CAHPS patient experience of care survey. The survey has been under development for several years, and is part of the same family of

surveys as the Hospital CAHPS (HCAHPS) that is required for both the hospital inpatient quality reporting (IQR) and hospital VBP programs. However, the OAS CAHPS will be administered only to patients receiving surgeries and certain other procedures in the HOPD setting. In finalizing the measure, CMS states that the use of the OAS CAHPS would promote alignment of patient experience measurement across inpatient and outpatient settings, and fill a perceived measurement gap.

CMS will require the collection and submission of OAS CAHPS on a quarterly basis, starting with procedures on Jan. 1, 2018. Hospitals will be required to use CMS-approved survey vendors to collect and submit survey data. A list of approved vendors is available at http://oaschaps.org. On Jan. 1, 2016, CMS initiated a voluntary national reporting program for OAS CAHPS. The agency encourages hospitals to begin submitting survey data on voluntary basis before January 2018 to gain familiarity with the survey.

The AHA has long been supportive of rigorously designed surveys of patient experience of care, including the HCAHPS survey. However, we will continue to urge CMS to delay implementation of the OAS CAHPS for a number of reasons. First, the OAS CAHPS survey measures are not endorsed by the NQF, which significantly limits the hospital field's insight into whether the measures portray hospital performance in a fair and accurate manner. Given the significant resources needed to collect the survey, we believe the measures should be NQF endorsed before OAS CAHPS is required of hospitals. Additionally, we are concerned that the CAHPS program already includes multiple overlapping survey tools. The inclusion of yet another survey may lead to confusion among patients about which provider is being assessed, and excessive survey administration burden.

OAS CAHPS Survey Requirements. Hospitals will be required to collect the OAS CAHPS on a random sample of eligible patients on a monthly basis, and submit it to CMS on a quarterly basis. Patients eligible to be included in the sampled patient population will be identified using sets of billing codes:

- **CPT Codes** in the range from 10021 to 69990, which include a variety of procedures done on an outpatient basis. These include colonoscopy, hernia repair and injections for pain management.

- **The following G-codes:**
  - G0104 – Colorectal cancer screening; flexible sigmoidoscopy
  - G0105 – Colorectal cancer screening; colonoscopy on individual at high risk
  - G0121 – Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
  - G0260 – Injection procedure for sacroiliac joint; provision of anesthetic, steroid

The OAS CAHPS survey can be administered using three modes – mail-only, telephone-only and "mixed mode" (i.e., mail with telephone follow up for non-respondents). Additional details on these survey modes are available on the OAS

CAHPS website. Vendors will be required to give patients the OAS CAHPS survey using the above modes no later than 21 days after the month in which a patient receives the procedure. To count as a "complete survey," the data must be collected within six weeks of when the patient is initially provided the survey. CMS expects survey vendors to make multiple attempts to reach the patient, unless the patient refuses to complete the survey, or the hospital learns the patient is ineligible for the survey.

Consistent with the HCAHPS survey requirements, hospitals will be required to collect at least 300 completed surveys over each 12 month reporting period (i.e., an average of 25 completed surveys per month). Smaller hospitals that cannot collect 300 completed surveys in a 12-month period will be required to collect as many surveys as possible during the time period. However, those hospitals that treat fewer than 60 survey-eligible patients in the year preceding the data collection period will be allowed to request an exemption from OAS CAHPS reporting.

OAS CAHPS Survey Content. Of the 37 items on the OAS CAHPS survey, 24 items are "core" survey questions assessing patient perspectives on care access, communications with providers, experience at the facility and interactions with facility staff. There also are two "global" survey items asking patients to give the facility an overall rating of zero to 10 and to indicate how strongly they would recommend the facility to others. Lastly, there are nine items asking patients to report their own health status and demographic information (e.g., race/ethnicity, education level, language). Responses to these nine items are used to risk adjust hospital performance on the survey measures.

The responses to the "core" survey questions have various rating scales. Some ask patients for one of three possible responses (i.e., yes definitely, yes somewhat or no), while others have only two responses (i.e., yes or no). The global overall rating item asks for a response on a scale of 0 to 10, while the recommendation of facility question has four responses (i.e., definitely yes, probably yes, probably no or definitely "no").

OAS CAHPS Measures. CMS will calculate a total of five measures from OAS CAHPS results – three "composite" survey measures that aggregate the results of several related questions into a single score, and two "global" measures that ask the patient to rate their overall experience at the facility. The measures are:

- Composite:
    - OP-37a: OAS CAHPS – About Facilities and Staff
    - OP-37b: OAS CAHPS – Communication About Procedure
    - OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
- Global:
    - OP-37d: OAS CAHPS – Overall Rating of Facility
    - OP-37e: OAS CAHPS – Recommendation of Facility

To calculate performance on the three composite measures, CMS will determine the proportion of "top box" scores (i.e., proportion of patients answering "Yes" or "Definitely Yes") on individual questions, and average them into a composite. For the two global measures, CMS will calculate the proportions of patients providing high-value

responses (i.e., a rating of 9 or 10 on OP-37d, and an answer of "definitely yes" on OP-37e). CMS will adjust the survey scores for patient characteristics. However, CMS does not indicate whether it will adjust survey results for the mode of survey administration.

Extraordinary Circumstances Exception (ECE) Process. In previous rulemaking, CMS adopted an ECE process in which a hospital affected by natural disasters and other extraordinary events affecting its ability to report quality data could request an exemption from reporting quality data for a particular time period. Under existing policy, hospitals would have 45 days from the date of the event to request an ECE. CMS will extend this timeframe to 90 days in order to align the OQR's ECE process with that for other hospital quality reporting and pay-for-performance programs.

REMOVAL OF HCAHPS PAIN QUESTIONS FROM VBP SCORES

Starting with FY 2018 program year, CMS will no longer consider hospital performance on the three pain management questions currently included in the HCAHPS survey when calculating value-based purchasing VBP program scores. However, CMS will continue to collect and publicly report the results of the HCAHPS pain management questions while the agency works on developing new questions that may be added to VBP in the future. The AHA had urged CMS to suspend these questions in the VBP program due to concerns over their perceived potential to encourage or pressure clinicians to prescribe powerful pain medications as the U.S. experiences a devastating opioid overdose epidemic. Delinking the pain questions from payment calculations sends the right message that CMS encourages clinicians to prescribe opioids judiciously.

CHANGES FOR THE CY 2017 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

Updating the ASC Relative Payment Weights for CY 2017. 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 2017, CMS uses an ASC scaler of 0.9000.

Updating the ASC Conversion Factor. 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)) must be reduced by a productivity adjustment. For CY 2017, the CPI-U update is projected to be 2.2 percent. As required by the ACA, this update is reduced by a productivity adjustment, which is 0.3 percentage point, resulting

in a net 1.9 percent update for CY 2017. CMS further applies a 0.9996 ASC wage index budget-neutrality adjustment in calculating the CY 2017 ASC conversion factor. The net CPI-U update, together with the wage adjustment for budget neutrality, results in a CY 2017 ASC conversion factor of $45.030. In contrast, the CY 2017 OPPS conversion factor is $75.001.

ASC-covered Surgical Procedures. CMS adds 10 surgical procedures to the list of ASC-covered surgical procedures, which are listed in Table 51 of the final rule. Three of the eight proposed additions to the list of ASC covered surgical procedures are procedure codes that are proposed for removal from the OPPS inpatient-only list.

Surgical Procedures Designated as Office-based. Office-based procedures are procedures that CMS determines are performed predominantly (more than 50 percent of the time) in physicians' offices. They are paid at the lower of the Medicare PFS non-facility practice expense relative value unit amount or the amount calculated using the ASC standard rate-setting methodology for the procedure.

For CY 2017, CMS designates one additional covered surgical procedures as an office-based procedure (see Table 47 in the final rule). In addition, CMS retains the temporary office-based status of all eight procedures assigned this designation in the CY 2016 final rule (see Table 48 in the final rule). Finally, CMS assigns temporary office-based status to two new CY 2017 codes for ASC-covered surgical procedures (see Table 49 in the final rule).

ASC-covered Surgical Procedures Designated as Device-intensive. CMS currently applies a modified payment methodology for ASC-covered procedures eligible for payment according to the device-intensive procedure payment methodology. That policy is in place to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in these procedures. In CY 2015, CMS implemented a comprehensive APC policy under the OPPS under which comprehensive APCs replaced most of the then-current device-dependent APCs. CMS did not, however, implement comprehensive APCs in ASCs because the ASC payment system was not configured to accommodate this type of payment.

CMS will continue using the standard OPPS APC rate-setting methodology to calculate the device offset percentage for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs. CMS defines an ASC device-intensive procedure as one that is assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC rate setting methodology.

However, CMS believes that it is no longer appropriate to designate ASC device-intensive procedures based on APC assignment, because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity. Therefore, for 2017, a procedure with a HCPCS code-level device offset of greater than 40 percent of the APC costs when calculated according to the standard OPPS APC rate setting methodology would be designated as an ASC device-intensive procedure.

For 2017, CMS also updates the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology, consistent with its revised definition of device-intensive procedures. The list of these procedures and related information is included in Addendum AA on CMS's ASC website.

ASC Quality Reporting (ASCQR) 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.

For the CY 2020 ASCQR program, CMS adopts the same five OAS CAHPS measures that it proposes for the OQR program. Please see the OQR section of this advisory for additional information about the OAS CAHPS measures and reporting requirements. In addition, CMS adopts two other measures for the ASCQR program, both of which would be chart-abstracted and submitted using CMS's web-based tool on QualityNet:

- **ASC-13 – Normothermia outcome**, which assesses the percentage of patients undergoing surgical procedures under general or neuraxial anesthesia whose body temperatures are normal within 15 minutes of arrival in post-anesthesia care units; and

- **ASC-14 - Unplanned victrectomy**, which assesses the percentage of cataract surgery patients who undergo unplanned anterior victrectomies (i.e., unplanned repairs of the mainly liquid portion of the eye).

A list of ASCQR measures can be found in Appendix B of this advisory.

CHANGES TO THE MEDICARE AND MEDICAID ELECTRONIC HEALTH RECORD INCENTIVE PROGRAMS

In the rule, CMS finalizes: (1) changes to the EHR Incentive Program objectives and measures for eligible hospitals (EHs) and CAHs for Modified Stage 2 and Stage 3, starting with the EHR reporting periods in CY 2017; (2) changes to the EHR reporting period in CY 2016 and CY 2017 for EHs, CAHs and eligible providers (EPs); (3) a revised reporting period for EHs, CAHs and EPs that are new program participants in CY 2017; (4) policy that clarifies measure calculations for actions outside the EHR reporting period; and (5) a one-time significant hardship exception from the 2018 payment adjustment for new EPs in the EHR Incentive Program in CY 2017 that are transitioning to the Merit-Based Incentive Payment System (MIPS) in CY 2017.

CMS finalizes the proposal that changes to the objectives and measures or measure thresholds will not apply to EHs and CAHs attesting under the Medicaid EHR Incentive Program, which means that Medicaid-only hospitals will face separate and more difficult requirements. Hospitals that participate in both the Medicare and Medicaid EHR Incentive Programs that attest to CMS will attest based on the objectives and measures

for Modified Stage 2 and Stage 3 that CMS finalizes. CMS states its ability to adopt modifications to the Medicare and Medicaid EHR Incentive Programs remains constrained by the HITECH Act.

CMS did not delay the mandatory start of Stage 3 in 2018 or reduce the reporting period from a full year in 2018.

Removal of Medicare EHR Incentive Program Objectives

Removal of Objectives. For Modified Stage 2 in CY 2017 and Stage 3 in CY 2017 and 2018, CMS finalizes the removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and associated measures. CMS states that removing these objectives and measures will reduce the reporting burden on providers for measures already achieving widespread adoption and will reduce administrative burden. CMS adds that the technology requirements for CDS and CPOE will remain required functionality in certified EHRs.

Proposed Changes to Medicare Modified Stage 2 Measures

Revision of Measure Thresholds. For the Modified Stage 2 Patient Electronic Access objective, CMS finalizes a revised measure that at least one unique patient (or patient-authorized representative) discharged from the EH or CAH inpatient or ED (POS 21 or 23) views, downloads or transmits to a third party his or her health information during the EHR reporting period. The threshold is lower than the previous 5 percent threshold in Modified Stage 2. The threshold reduction also applies to dual-eligible hospitals that attest to CMS for both the Medicare and Medicaid EHR Incentive Programs. CMS states that reducing thresholds would decrease administrative burdens and support health care provider focus on providing more quality patient care and updating and optimizing certified EHR functionalities to prepare for Stage 3.

The AHA is pleased to see CMS finalize a less stringent requirement for 2017.

CMS finalizes the continuation of a measure exclusion for any EH or CAH in a county where 50 percent of more of the housing units lack 4Mbps broadband availability on the first day of the EHR reporting period.

Appendix C lists the Modified Stage 2 objectives and measures for CY 2017.

Changes to Medicare Stage 3 Measures

Revision of Measure Thresholds. For CY 2017 and 2018, CMS finalizes the modification of seven measure thresholds included in Stage 3. **The AHA appreciates this reduction in the Stage 3 reporting requirements for EHs and CAHs but remains concerned that unrealistic requirements remain.**

Patient Electronic Access Objective.

Patient Access Measure. CMS finalizes that, for more than 50 percent of all unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23): (1) the patient

(or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application program interface (APIs) in the provider's certified EHR. The final threshold is lower than the 80 percent threshold included in the Stage 3 final rule. CMS states that reducing the threshold to greater than 50 percent provides EHs and CAHs increased flexibility and additional time to communicate and educate patients on how and why to access their medical information. CMS also states that EHs and CAHs need to fully enable the API functionality in such a way that any application chosen by a patient would enable them to gain access to their individual health information. The information provided in the application should be configured to meet the technical specifications of the API. EHs and CAHs may continue providing patients with paper-based educational materials and information, if they deem it beneficial and useful to the patient but CMS will no longer require or allow providers to manually count and report on these paper-based exchanges beginning in Stage 3.

Patient-specific Education Measure. CMS finalizes that for more than 10 percent of unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, the EH or CAH must use clinically relevant information from the certified EHR to identify patient-specific educational resources and provide electronic access to those materials. The final threshold is lower than the 35 percent threshold in the Stage 3 final rule. CMS states the reduced threshold will provide EHs and CAHs the ability to meet the needs of their patients while allowing additional time for modifications to make patient-educational materials available electronically after discharge. EHs and CAHs may continue to provide patients with paper-based educational materials and information, if they deem it beneficial and useful to the patient but CMS will no longer require or allow providers to manually count and report on these paper-based exchanges beginning in Stage 3.

Coordination of Care through Patient Engagement Objective.

View/Download/Transmit Measure. CMS finalizes that at least one unique patient (or patient-authorized representative) who is discharged from the EH or CAH inpatient or ED (POS 21 or 23) actively engage with the EHR made accessible by the provider through one of the following actions: (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified EHR; or (3) a combination of (1) and (2). The final threshold is lower than the 10 percent threshold in the Stage 3 final rule. CMS states that the reduction will allow additional time for providers to teach patients the importance of accessing their health information while increasing participation.

Secure Messaging Measure. CMS finalizes that for more than 5 percent of all unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of certified EHR to the patient (or the patient-authorized representative), or sent in response to a secure message sent by the patient (or the patient-authorized

representative). The final threshold is lower than the 25 percent threshold in the Stage 3 final rule. CMS declined to eliminate this measure for hospitals because they believe that there is value in communication between members of the care team and a patient post discharge.

Health Information Exchange Objective.

Send a Summary of Care Record Measure. CMS finalizes that for more than 10 percent of transitions of care and referrals, the EH or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using certified EHR and (2) electronically exchanges the summary of care record. The final threshold is lower than the 50 percent threshold in the Stage 3 final rule. CMS states that the majority of hospitals are engaging in health information exchange and the advancement in health information exchange will increase trading partners and expand the ability for hospitals to meet the threshold.

Request/Accept Summary of Care Measure. CMS finalizes that for more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH incorporates into the patient's EHR an electronic summary of care document. The final threshold is lower than the 40 percent threshold in the Stage 3 final rule. CMS states that a lower threshold will allow additional time for focus on interoperability and an increase in trading partners.

Clinical Information Reconciliation Measure. CMS finalizes that for more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH performs a clinical information reconciliation for three clinical information sets: (1) Medications, including a review of the name, dosage, frequency and route of each medication; (2) Medication allergies; and (3) Current Problem list, including the patient's current and active diagnoses. The final threshold is lower than the 80 percent threshold in the Stage 3 final rule. CMS states that the success of the medication reconciliation measure, as shown in their data, will transcend to the Clinical Information Reconciliation measure because it builds on the medication reconciliation measure and allows for the provider’s clinical judgment on what information is included in the process.

The AHA appreciates the reduction in the seven Stage 3 threshold reporting requirements for EHs and CAHs for CY 2017 and 2018. However, the changes do not sufficiently align the hospital requirements with the information exchange requirements facing physicians under the Advancing Care Information category in the Medicare Access and CHIP Reauthorization Act (MACRA) final rule. The AHA also remains concerned about requirements for providers to provide third-party access to their systems through application program interfaces without evidence that a relevant standard is ready for nationwide use and despite concerns that this will create security risks.

Measure Exclusions

CMS finalizes the continuation of an exclusion for each of the seven measures for any EH or CAH in a county where 50 percent of more of the housing units lack 4Mbps broadband availability on the first day of the EHR reporting period. For the Request/Accept Summary of Care Measure, CMS also finalizes an exclusion for any EH or CAH with fewer than 100 total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient.

Appendix D lists the final Stage 3 objectives and measures for CYs 2017 and 2018.

Medicare Stage 3 Measures That Remain Unchanged

For CYs 2017 and 2018, CMS finalizes that several measure thresholds will remain unchanged for Stage 3.

Protect Electronic Health Information Objective.

Security Risk Analysis Measure. The measure remains unchanged and will require EHs and CAHs to conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the EH's or CAH's risk management process.

Electronic Prescribing Objective.

e-Prescribing Measure. The measure remains unchanged and will require that more than 25 percent of EH or CAH discharge medication orders for permissible prescriptions (new and changed) are queried for a drug formulary and transmitted electronically using certified EHR. CMS clarifies that providers have flexibility to include or exclude controlled substances in the denominator for the Stage 3 electronic prescribing objective and measure.

Coordination of Care through Patient Engagement Objective.

Patient Generated Health Data Measure. The measure remains unchanged and will require the incorporation of patient-generated data or data from a non-clinical setting into the certified EHR for more than 5 percent of all unique patients.

The AHA is disappointed that CMS finalizes the retention of several unrealistic Stage 3 requirements and did not revise additional Stage 3 measure thresholds, specifically e-prescribing and patient-generated health data.

Revision of Public Health and Clinical Data Registry Measures Reported. To meet the Public Health and Clinical Data Registry Reporting objective, for CYs 2017 and 2018, CMS finalizes that the EH or CAH attest to active engagement with any three public

health and clinical data registry reporting options from the six available. The final measure threshold is lower than the requirement to attest to active engagement with four public health and clinical data registry reporting options in the Stage 3 final rule.

Changes to the CY 2016 and CY 2017 Reporting Periods

Revised CY 2016 Reporting Period. CMS finalizes the change to the EHR reporting period for 2016 to any continuous 90 day period for all EHs, CAHs and EPs. In connection with this proposal, CMS also finalizes a reporting period of any continuous 90 days for electronic clinical quality measures (eCQMs) in 2016 for all EHs, CAHs and EPs. eCQMs may be reported by attestation or electronically reported. CMS states that eCQM data submitted via attestation can be submitted for a different 90 day period than the EHR reporting period for meaningful use objectives and measures. **The AHA is pleased that CMS finalizes a reporting period of any continuous 90 days for 2016.**

Revised CY 2017 Reporting Period. CMS finalizes the change to the EHR reporting period for 2017 to any continuous 90-day period for EPs, EHs and CAHs. CMS states that a 90-day reporting period allows more time for implementing new requirements without negatively affecting clinician workflow. CMS also states disagreement with the recommendation for a permanent 90-day EHR reporting period. **The AHA is pleased that CMS finalizes a reporting period of any continuous 90 days for 2017.**

Revised the Reporting Period for New EHs, CAHs and EP in CY 2017. CMS finalizes that EHs and EPs new to the EHR Incentive Program in CY 2017 that seek to avoid the 2018 payment adjustment or any CAH new to the EHR Incentive Program in CY 2017 that seeks to avoid the 2017 payment adjustment attest to Modified Stage 2 objectives and measures. CMS finalizes that the attestation deadline for the new participants is Oct. 1, 2017. The requirement to attest to Modified Stage 2 includes participants in the Medicaid EHR Incentive Program.

CMS states that it is not technically feasible for EHs, CAHs and EPs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest to the Stage 3 objectives and measures in CY 2017 in the EHR Incentive Program Registration and Attestation System. The agency adds that in early 2018, returning EHs and CAHs will be transitioned to other reporting systems to attest for CY 2017. CMS also states that providers using 2014 Edition, 2015 Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 would have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

Clarify Measure Calculations Outside of the EHR Reporting Period. CMS finalizes actions included in the numerator for meaningful use measures must occur within the EHR reporting period if that period is a full calendar year. If the reporting period is less than a full calendar year, the actions must occur within the calendar year in which the EHR reporting period occurs. CMS states this is intended to address the open-ended timeframe implied in CMS Frequently Asked Question 8231, which states that actions may fall outside of the EHR reporting period but must take place no earlier than the start of the reporting period and no later than the date of attestation.

Significant Hardship Exceptions for New EPs Transitioning to MIPS in CY 2017.

CMS finalizes that EPs are allowed to apply for a significant hardship exception from the 2018 payment adjustment if they have not successfully demonstrated meaningful use in a prior year, intend to attest to meaningful use for an EHR reporting period in CY 2017 by Oct. 1, 2017 to avoid the 2018 payment adjustment, and intend to transition to MIPS and report on measures specified for the advancing care information performance category under the MIPS in CY 2017. CMS states that this proposed significant hardship exception is based on 2017 as the first performance period for MIPS per the MACRA proposed rule.

CHANGES TO THE MEDICARE REQUIREMENTS FOR TRANSPLANT CENTERS AND ORGAN PROCUREMENT ORGANIZATIONS

Observed to Expected Rates

In 2007, CMS established Conditions of Participation (CoPs) for solid organ transplant programs. Among the outcome requirements described in the CoPs, a transplant program will be noncompliant with patient and graft survival standards if it crosses three specific thresholds: (1) the observed to expected (O/E) ratio of patient deaths and graft failures exceeds 1.5; (2) the results are statistically significant ($p<.05$); and (3) the results are numerically meaningful (if the number of observed events minus the expected number surpasses 3).

In the final rule, CMS changed the numerical value defining the first performance threshold from 1.5 to 1.85 for all organ types. In the proposed rule, CMS had noted that the expected number of events is based on the national average, which has improved over time. Therefore, the agency believes that it has become more difficult for transplant centers to meet the first of the three thresholds. CMS was concerned that transplant centers are discouraged from using certain organs that could adversely affect their outcomes metrics. CMS hopes that changing the threshold will "encourage transplant centers to use more of the increasing number of viable organs."

Mitigating Factors Review: Timeframes for Notification/Data Submission

The CoPs allow CMS to consider select "mitigating factors" in some circumstances when approving or reapproving a transplant center. Currently, transplant centers are required to notify CMS of the intent to request mitigating factors approval within 10 days after a formal written notice of a condition-level deficiency. In addition, transplant centers have 120 days to submit to CMS the relevant materials for consideration of mitigating factors. **In the final rule, CMS extended the notification period from 10 days to 14 calendar days. CMS also clarified that the timeframe to submit mitigating factors materials is 120 calendar days.** Currently, the regulation does not specify whether the timeframe is calendar or business days.

Systems Improvement Agreements (SIAs)

The agency also revised regulations related to SIAs. Specifically, CMS clarifies that a signed SIA remains in place even if a subsequent report by the Scientific Registry of Transplant Recipients (SRTR) signifies that the transplant program has met the CoPs. However, CMS may shorten the SIA timeframe or allow other modifications.

Organ Procurement Organizations (OPO)

CMS also finalizes several changes to the requirements for OPOs. Among the changes, the agency clarified the amount of paper documentation that must be sent to a receiving transplant center. The new policy states that blood type source documentation (blood type and blood subtype if used for allocation) and infectious disease testing results are the only records required to be physically sent in hard copy with the organ and provides specific standards for how to package and send the documentation. CMS believes that other required data can be accessed electronically.

NEXT STEPS

The AHA strongly encourages members to submit comments to CMS responding to the agency's request for feedback on specified issues, particularly regarding the policies for implementing the site-neutral payment cuts under Section 603 in CY 2017 and beyond.

Comments are due to CMS by Dec. 31 and may be submitted electronically at http://www.regulations.gov. Follow the instructions for "Comment or Submission." Attachments can be in Microsoft Word, WordPerfect or Excel; however, CMS prefers Microsoft Word. CMS also accepts written comments via regular or overnight/express mail.

Via regular mail:
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1656-FC or CMS-1656-IFC (as appropriate)
P.O. Box 8013
Baltimore, MD 21244-1850

Via overnight or express mail:
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1656-FC or CMS-1656-IFC (as appropriate)
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

FURTHER QUESTIONS

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

Appendix A: Hospital OQR Program Measures, CY 2016 – 2020 Payment Determination

Measure	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Cancer Care (Chart-abstracted, reported by hospitals via QualityNet web-based tool)					
OP-33: External beam radiotherapy (EBRT) for bone metastases			X	X	X
Cardiac Care (Chart-abstracted, collected by hospitals via CART / vendor, submitted via QualityNet[#])					
OP-1: Median time to fibrinolysis	X	X	X	X	X
OP-2: Fibrinolytic therapy received within 30 minutes	X	X	X	X	X
OP-3: Median time to transfer to another facility for acute coronary intervention	X	X	X	X	X
OP-4: Aspirin at arrival	X	X	X	X	X
OP-5: Median time to electrocardiogram (ECG)	X	X	X	X	X
Cataract Surgery (Chart-abstracted, reported by hospitals via QualityNet web-based tool)					
OP-31: Cataracts—Improvement in patient's visual function within 90 days following cataract surgery	Suspended[2]	Voluntary reporting	Voluntary reporting	Voluntary reporting	Voluntary reporting
ED (Chart-abstracted. OP-18, OP-19 and OP-20 collected by hospitals via CART / vendor. [#] OP-22 reported via QualityNet web-based tool)					
OP-18: Median time from ED arrival to ED departure for discharged ED patients	X	X	X	X	X
OP-20: Door to diagnostic evaluation by a qualified medical professional	X	X	X	X	X
OP-22: ED Left without being seen	X	X	X	X	X
Endoscopy (Chart-abstracted, reported by hospitals via QualityNet web-based tool)					
OP-29: Appropriate follow-up interval for normal colonoscopy in average risk patients	X	X	X	X	X
OP-30: Colonoscopy interval for patients with a history of adenomatous polyps—Avoidance of inappropriate use	X	X	X	X	X
Healthcare Associated Infections (Collected by hospitals, submitted via National Healthcare Safety Network)					
OP-27: Influenza vaccination coverage among health care personnel (HCP)	X	X	X	X	X
Hospital Visit Rates (Claims-based, calculated by CMS)					
OP-32: Facility 7-Day risk-standardized hospital visit rate after outpatient colonoscopy			X	X	X
OP-35: Admissions and ED visits for patients receiving outpatient chemotherapy					X[1]

Measure	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
OP-36: Hospital visits after outpatient surgery					X[1]
Imaging Efficiency (Claims-based, calculated by CMS)					
OP-8: MRI lumbar spine for low back pain	X	X	X	X	X
OP-9: Mammography follow-up rates	X	X	X	X	X
OP-10: Abdomen CT – Use of contrast material	X	X	X	X	X
OP-11: Thorax CT – Use of contrast material	X	X	X	X	X
OP-13: Cardiac imaging for preoperative risk assessment for non-cardiac low risk surgery	X	X	X	X	X
OP-14: Simultaneous use of brain CT and sinus CT	X	X	X	X	X
Pain Management (Chart-abstracted, collected by hospitals via CART or vendor, submitted via QualityNet[#])					
OP-21: ED – Median time to pain management for long bone fracture	X	X	X	X	X
Patient Experience of Care (Based on OAS CAHPS** survey collected and submitted by survey vendors)					
OP-37a: OAS CAHPS – About facilities and staff					X[1]
OP-37b: OAS CAHPS – Communication about procedure					X[1]
OP-37c: OAS CAHPS – Preparation for discharge and recovery					X[1]
OP-37d: OAS CAHPS – Overall rating of facility					X[1]
OP-37e: OAS CAHPS – Recommendation of facility					X[1]
Stroke (Chart-abstracted, reported by hospitals via CART or vendor, submitted via QualityNet[#])					
OP-23: Head CT scan results for acute ischemic stroke or hemorrhagic stroke who received head CT scan interpretation within 45 minutes of arrival	X	X	X	X	X
Surgery (Chart-abstracted, collected by hospitals via CART or vendor, submitted via QualityNet[#])					
OP-6: Timing of antibiotic prophylaxis	X				
OP-7: Prophylactic antibiotic selection for surgical patients	X				
Structural Measure (Submitted by hospitals via QualityNet web-based tool)					
OP-12: The ability for providers with health information technology (HIT) to receive laboratory data electronically directly into their qualified/certified EHR system as discrete searchable data	X	X	X	X	X

Measure	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
OP-17: Tracking clinical results between visits	X	X	X	X	X
OP-25: Safe Surgery Checklist use	X	X	X	X	X
OP-26: Hospital outpatient volume data on selected outpatient surgical procedures	X	X	X	X	X

 # CART is the CMS Abstraction and Reporting Tool. Hospitals may also elect to have measure collection and submission performed by third-party vendors.
*** OAS CAHPS is the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems*
[1] Adopted in the CY 2017 OPPS final rule
[2]Per CMS announcement on April 2, 2014.

Appendix B: ASCQR Program Measures, CY 2016 – 2020 Payment Determination

Measure	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Reported by ASCs through the inclusion of Quality Data Codes (QDCs) on Medicare Part B Claims, and subsequently calculated by CMS					
ASC-1: Patient burns	X	X	X	X	X
ASC-2: Patient falls	X	X	X	X	X
ASC-3: Wrong site, wrong side, wrong patient, wrong procedure, wrong implant	X	X	X	X	X
ASC-4: Hospital transfer / admission	X	X	X	X	X
ASC-5: Prophylactic intravenous antibiotic timing	X	X	X	X	X
Cataract Surgery (Chart-abstracted, submitted by ASCs via QualityNet web-based tool)					
ASC-11: Cataracts—Improvement in patient's visual function within 90 days following cataract surgery	Suspended [2]	Voluntary Reporting	Voluntary Reporting	Voluntary Reporting	Voluntary Reporting
ASC-14: Unplanned anterior vitrectomy					X[1]
Complications from anesthesia (Chart-abstracted, submitted by ASCs via QualityNet web-based tool)					
ASC-13: Normothermia outcome					X[1]
Endoscopy (Chart-abstracted, submitted by ASCs via QualityNet web-based tool)					
ASC-9: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X
ASC-10: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use	X	X	X	X	X
Healthcare Associated Infection (Collected and submitted by ASCs via NHSN)					
ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel	X	X	X	X	X
Hospital Visit Rates (Claims-based, calculated by CMS)					
ASC-12: Facility 7-Day risk – Standardized hospital visit rate after outpatient colonoscopy			X	X	X
Patient Experience of Care (Based on OAS CAHPS** survey collected and submitted by survey vendors)					
ASC-15a: OAS CAHPS – About facilities and staff					X[1]
ASC-15b: OAS CAHPS – Communication about procedure					X[1]
ASC-15c: OAS CAHPS – Preparation for discharge and recovery					X[1]
ASC-15d: OAS CAHPS – Overall rating of facility					X[1]
ASC-15e: OAS CAHPS – Recommendation of facility					X[1]

Measure	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Structural Measures (Collected and submitted by ASCs via QualityNet web-based tool)					
ASC-6: Safe Surgery Checklist Use	X	X	X	X	X
ASC-7: ASC Facility Procedural Volumes on Selected ASC Procedures	X	X	X	X	X

*** OAS CAHPS is the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems*

[1] Adopted in CY 2017 Outpatient PPS Final Rule

[2] Per CMS announcement on April 2, 2014.

Appendix C: Medicare EHR Incentive Program
Modified Stage 2 Objectives and Measures in CY 2017

Modified Stage 2 Objective	Current Modified Stage 2 Measures	Final Rule Change Modified Stage 2
Protect electronic health information	Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of electronic protected health information created or maintained in Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EH's or CAH's risk management process.	No change.
Clinical decision support	Measure 1: Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EH's or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. Measure 2: The EH or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	Objective and Measures removed
Computerized Provider Order Entry (CPOE)	Measure 1: More than 60 percent of medication orders created by authorized providers of the EH's or CAH's inpatient or ED place of service ((POS) 21 or 23)) during the EHR reporting period are recorded	Objective and Measures removed

Modified Stage 2 Objective	Current Modified Stage 2 Measures	Final Rule Change Modified Stage 2
	using CPOE. Measure 2: More than 30 percent of laboratory orders created by authorized providers of the EH's or CAH's inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. Measure 3: More than 30 percent of radiology orders created by authorized providers of the EH's or CAH's inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	
e-Prescribing	Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology.	No change.
Health information exchange	Measure: The EH or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses Certified EHR Technology to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.	No change.
Patient-specific education	Measure: More than 10 percent of all unique patients admitted to the EH's or CAH's inpatient or ED (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.	No change.

Modified Stage 2 Objective	Current Modified Stage 2 Measures	Final Rule Change Modified Stage 2
Medication reconciliation	Measure: The EH or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the EH's or CAH's inpatient or ED (POS 21 or 23).	No change.
Patient electronic access (view, download and transmit)	Measure 1: More than 50 percent of all patients who are discharged from the inpatient or ED (POS 21 or 23) of an EH or CAH are provided timely access to view online, download, and transmit to a third party their health information. Measure 2: More than 5 percent of unique patients discharged from the inpatient or ED (POS 21 or 23) of an EH or CAH (or patient-authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period.	No change to Measure 1. Change to Measure 2: View/Download/Transmit Measure: At least 1 patient (or patient authorized representative) who is discharged from the inpatient or ED (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her health information during the EHR reporting period
Public health EHs and CAHs must report on three of the four measure options.	Immunization Registry Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system. Syndromic Surveillance Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an	No change.

Modified Stage 2 Objective	Current Modified Stage 2 Measures	Final Rule Change Modified Stage 2
	emergency or urgent care department for EHs and CAHs (POS 23). Specialized Registry Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit data to a specialized registry. Electronic Reportable Laboratory Result Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.	

Appendix D: Proposed Medicare EHR Incentive Program Stage 3 Objectives and Measures

Stage 3 Objective	Current Stage 3 Measures	Final Rule Change Stage 3
1. Protect electronic health information: Protect electronic protected health information (ePHI) created or maintained by the certified electronic health record technology (certified EHR) through the implementation of appropriate technical, administrative and physical safeguards.	Measure: Conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR) in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the EH's or CAH's risk management process.	No change.
2. Electronic prescribing: Eligible hospitals (EHs) and critical access hospitals (CAHs) must generate and transmit permissible discharge prescriptions electronically (eRx).	More than **25 percent** of EH or CAH discharge medication orders for permissible prescriptions (new and changed) are queried for a drug formulary and transmitted electronically using certified EHR.	No change.
3. Clinical decision support (CDS): Implement CDS interventions focused on improving performance on high-priority health conditions.	Measure 1: Implement five CDS support interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. Measure 2: Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	Objective and Measures Removed.

Stage 3 Objective	Current Stage 3 Measures	Final Rule Change Stage 3
4. Computerized Provider Order Entry (CPOE): Use CPOE for medication, laboratory and diagnostic imaging orders.	Measure 1: CPOE for medication – More than 60 percent of medication orders created by authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. Measure 2: CPOE for labs – More than 60 percent of laboratory orders created by the authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. Measure 3: CPOE for diagnostic imaging – More than 60 percent of diagnostic imaging orders created by the authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	Objective and Measures Removed.
5. Patient electronic access to health information: Use the certified EHR functionality to provide patient access health information or patient-specific educational resources.	Measure 1: For **more than 80 percent** of unique patients, either: (i) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information - **and** (ii) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's certified EHR.	Objective remains unchanged. Specified name for measures – Provide Patient Access Measure: For **more than 50 percent** of all unique patients discharged from the EH or CAH inpatient or ED (POS 21or 23): (1) the patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; **and** (2) the provider ensures the patient's health

Stage 3 Objective	Current Stage 3 Measures	Final Rule Change Stage 3
	Measure 2: Use certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients.	information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the APIs in the provider's certified EHR. Patient-Specific Education Measure: The EH or CAH must use clinically relevant information from the certified EHR to identify patient-specific educational resources and provide electronic access to those materials to **more than 10 percent** of unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period.
6. Coordination of Care through Patient Engagement: Use certified EHR functionality to engage with patients or their authorized representatives. EH and CAH must attest/report the numerators/denominators for all three measures and must meet thresholds for two out of three measures.	Measure 1: **More than 10 percent** of all unique patients (or their authorized representatives) discharged from the EH or CAH inpatient or ED (POS 21 or 23) actively engage with the EHR made accessible by the provider. Measure to be met by patient is one of the following (i) view, download, or transmit to a third parity their health information, (ii) access their health information through the use of an API that can be used by applications chosen by the patient and configured to	Objective remains unchanged. Specified name for measures-View/Download/Transmit Measure: **At least one** unique patient (or patient-authorized representative) who is discharged from the EH or CAH inpatient or ED (POS 21 or 23) actively engage with the EHR made accessible by the provider and one of the following: (1) view,

Stage 3 Objective	Current Stage 3 Measures	Final Rule Change Stage 3
	the API in the provider's certified a combination of (i) and (ii).	download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified EHR; or (3) a combination of (1) and (2).
	Measure 2: For **more than 25 percent** of all unique patients or patient's authorized representative discharged from EH or CAH inpatient or ED (POS 21 or 23), certified EHR was used to send a secure message to the patient or used in response to a secure message sent by the patient.	Secure Messaging Measure: For **more than 5 percent** of all unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of certified EHR to the patient (or the patient-authorized representative), or sent in response to a secure message sent by the patient (or the patient-authorized representative.
	Measure 3: Patient generated data or data from a non-clinical setting is incorporated into the certified EHR for more than five percent of all unique patients.	Patient Generated Health Data Measure: No Change
7. Health information exchange: provide a summary of care record when	Measure 1: For **more than 50 percent** of transitions of care and referrals, a summary of care	Objective remains unchanged. Specified name for measures – Send a

Stage 3 Objective	Current Stage 3 Measures	Final Rule Change Stage 3
transitioning or referring their patient to another setting of care, or retrieve a summary of care record upon the first patient encounter with a new patient. EH/CAH must attest/report the numerators/denominators for all three measures. Must meet threshold on two of three measures.	record is created and sent electronically.	Summary of Care Measure: For **more than 10 percent** of transitions of care and referrals, the EH or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using certified EHR and (2) electronically exchanges the summary of care record.
	Measure 2: For **more than 40 percent** of transitions and referrals received and patient encounters in which the provider has never before encountered the patient, incorporate into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.	Request/Accept Summary of Care Measure: For **more than 10 percent** of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH incorporates into the patient's EHR an electronic summary of care document.
	Measure 3: For **more than 80 percent** of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH, CAH or EP performs a clinical information reconciliation that includes medications, medication allergy and current problem list.	Clinical Information Reconciliation Measure: For **more than 50 percent** of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH performs a clinical information reconciliation for three clinical information sets: medications, medication

Stage 3 Objective	Current Stage 3 Measures	Final Rule Change Stage 3
		allergies; and current problem list.
8. Public health and clinical data registry reporting: EH or CAH is in active engagement with a public health agency (PHA) or clinical data repository (CDR) to submit electronic public health data in a meaningful way using certified EHR, except where prohibited and in accordance with applicable law.	Immunization Registry Reporting. The EH or CAH is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS). Syndromic Surveillance Reporting. The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. Electronic Case Reporting. The EH or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions. Public Health Registry Reporting. The EH or CAH is in active engagement with a public health agency to submit data to public health registries. Clinical Data Registry Reporting. The EH or CAH is in active engagement to submit data to a clinical data registry. Electronic Reportable Lab Result Reporting. The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.	No change. Change in the number of measures reported: EHs and CAHs report to three of the registries or claim exclusions. The registry measures may be counted more than once if multiple registries are supported.