The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2017 final rule with comment for Medicare’s hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system on November 1, 2016; policies in the final rule generally take effect on January 1, 2017. The final rule with comment also includes an interim final rule with comment that will pay certain off-campus provider-based departments a Medicare Physician Fee Schedule (MPFS) amount equal to 50 percent of the OPPS payment. The rule is scheduled for publication in the November 14th issue of the Federal Register. The 60-day public comment period ends at close of business on December 31st. Issues subject to comment:

1. The payment classifications assigned to new Level II HCPCS codes and recognition of new and revised Category I and III CPT codes in this final rule with comment period;
2. The 20-hour a week minimum requirement for partial hospitalization services in this final rule with comment period;
3. The potential limitation on clinical service line expansion or volume of services by nonexcepted off-campus PBDs in this final rule with comment period; and
4. The Medicare Physician Fee Schedule (MPFS) payment rates for nonexcepted items and services furnished and billed by nonexcepted off-campus provider-based departments of hospitals.

The final rule updates OPPS payment policies that apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children’s hospitals, and cancer hospitals, as well as for partial hospitalization services in community mental health centers (CMHCs). The document also includes updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Additional provisions in this final rule address implementation of section 603 of the Bipartisan Budget Act of 2015 pertaining to payment for certain off-campus departments; organ procurement organization (OPO) reporting and transplant outcome measures; the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, and the inpatient hospital Value-Based Purchasing (VBP) program.

1 Henceforth in this document, a year is a calendar year unless otherwise indicated.
Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

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APPENDIX: Table Reproduced from the Final Rule (page 120)

TABLE 52—ESTIMATED IMPACT OF THE FINAL 2017 CHANGES FOR
THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (p. 120)

I. Overview

Estimated Impact on Hospitals

CMS estimates that, compared to 2016, policies in the final rule will increase total payments under the OPPS by $773 million, 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 $5.0 billion; however, this figure does not include an estimated $50 million in program savings resulting from the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 (discussed in section X.A below). The final rule impact table indicates that Medicare makes payments under the OPPS to 3,906 facilities, including general acute care hospitals, children’s hospitals, cancer hospitals, and community mental health centers (CMHCs).

Payment rates under the OPPS will be increased by a conversion factor adjustment of 1.65 percent (1.55 percent in the proposed rule), based on the hospital inpatient market basket percentage increase of 2.7 percent (2.8 percent in the proposed rule) for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity adjustment of 0.3 percentage points (0.5 percentage points in the proposed rule), and minus an additional 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 1.65

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2 The OPPS percentage update is based on the IPPS market basket, as provided by statute.
percent, while hospitals that do not will be subject to the statutory reduction of 2.0 percentage points in the update factor. The reduction in payments for hospitals not meeting the quality reporting requirements is implemented by applying a reporting factor adjustment of 0.980 to the OPPS payments and copayments for all applicable services. Of the 3,266 hospitals that met eligibility requirements for the CY 2016 payment determination, CMS determined that 113 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Most of these hospitals (71 of the 113), chose not to participate in the Hospital OQR Program for the CY 2016 payment determination.

Table 52 in the final rule (reproduced in the Appendix to this summary) includes the estimated impact of the final rule by provider type. It shows a projected increase of 1.7 percent for all facilities and 1.8 percent for all hospitals (all facilities except cancer and children’s hospitals, which are held permanently harmless, and CMHCs). The following table shows components of the 1.7 percent total:

<table>
<thead>
<tr>
<th>Component</th>
<th>Percent change for all hospitals*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All changes</td>
<td>+1.75</td>
</tr>
<tr>
<td>Fee schedule increase factor</td>
<td>+1.65</td>
</tr>
<tr>
<td>Package unrelated laboratory tests</td>
<td>+0.04</td>
</tr>
<tr>
<td>Difference in pass through estimates for 2016 and 2017</td>
<td>+0.02</td>
</tr>
<tr>
<td>Difference from 2016 outlier payments (0.96%)</td>
<td>+0.04</td>
</tr>
</tbody>
</table>

*Excludes hospitals permanently held harmless and Community Mental Health Centers. In the 2017 final rule impact table reproduced as an Appendix to this summary, CMS shows this figure as 1.8 percent.

An adjustment of +0.04 percent increases the conversion factor to account for packaging unrelated laboratory tests in 2017 (discussed in item II.A.7 below). Pass-through spending for drugs, biologicals and devices for 2017 are estimated to total $150.6 million, or 0.24 percent of projected OPPS spending. The adjustment to the rates of +0.02 percent reflects the difference between this projection and the 0.26 percent estimate for 2016. In addition, CMS estimates that actual outlier payments in 2016 will represent 0.96 percent of total OPPS payments compared to the 1.0 percent set aside, for an estimated increase in 2017 payments of 0.04 percentage points.

Changes to the Ambulatory Payment Classification (APC) weights, wage indices, continuation of a payment adjustment for rural sole community hospitals (SCHs), including essential access community hospitals (EACHs), and the payment adjustment for IPPS-exempt cancer hospitals do not affect aggregate OPPS payments because these adjustments are budget neutral. However, these factors have differential effects on individual facilities.

Although CMS projects an overall increase of 1.7 percent for all hospitals, the final rule will have a differential effect on facilities. As shown in the table below and in the full impact analysis included in the appendix to this summary, the largest difference is that rural hospitals are estimated to have an increase of 2.2 percent; this difference from the overall increase of 1.7 percent reflects the impact on rural facilities of APC recalibration (+0.2) and the wage index.
(+0.3). Major teaching hospitals also will see a smaller increase than average of 1.5 percent due to APC recalibration (-0.2).

<table>
<thead>
<tr>
<th>All Hospitals</th>
<th>Projected 2017 Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Facilities (includes CMHCs and cancer and children’s hospitals)</td>
<td>+1.7%</td>
</tr>
<tr>
<td>Urban</td>
<td>+1.8%</td>
</tr>
<tr>
<td>Large Urban</td>
<td>+1.7%</td>
</tr>
<tr>
<td>Other Urban</td>
<td>+1.8%</td>
</tr>
<tr>
<td>Rural</td>
<td>+2.2%</td>
</tr>
<tr>
<td>Major Teaching</td>
<td>+1.5%</td>
</tr>
</tbody>
</table>

| Type of ownership:             |                      |
| Voluntary                      | +1.9%                |
| Proprietary                    | +1.8%                |
| Government                     | +1.6%                |
| CMHCs                          | -13.7%               |

Other than the rural categories, those in the impact table with a difference from the average of 0.5 percent or more (i.e., increase is ≤1.2 percent or ≥2.2 percent) are:

| Urban Mountain (206 hospitals) | +3.0% |
| Non-teaching/Non-DSH (10)      | -0.2% |
| DSH Patient Percent = 0 (10)   | -0.2% |

**Estimated Impact on Beneficiaries**

CMS estimates that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPPS in 2017. This reflects the requirement for beneficiaries to pay a 20 percent coinsurance after meeting the annual deductible. The final rule indicates “general system adjustments” along with the changes to the comprehensive APC payment policy result in the 18.5 percent aggregate coinsurance expected to be paid by beneficiaries. “General system adjustments” is not explained but presumably refers to the continuing transition for any APCs with a higher than 20 percent coinsurance continuing to transition to 20 percent. Coinsurance is the lesser of 20 percent of Medicare’s payment amount or the Part A inpatient deductible which accounts for the aggregate coinsurance percentage being less than 20 percent.

**II. Updates Affecting OPPS Payments**

**A. Recalibration of APC Relative Weights**

CMS is recalibrating the APC relative payment weights for 2017 using the same basic methodology used for many years. As discussed in succeeding sections of this summary, several changes are adopted, including expansion of packaging for lab services and the addition of 25 comprehensive APCs using the previously established criteria.
For the 2017 final rule, CMS uses hospital final action claims for services furnished from January 1, 2015 through December 31, 2015. Cost data are from the most recent filed cost reports, in most cases for cost reporting periods beginning in 2014. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the final rule payment rates, including the number of claims available at each stage of the process:

Continuing past years’ methodology, CMS calculates the cost of each procedure only from single procedure claims. CMS creates “pseudo” single procedure claims from bills containing multiple codes, using date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to “pseudo” single procedure claims. Through bypassing specified codes that CMS believes do not have significant packaged costs, CMS is able to use more data from multiple procedure claims.

For the 2017 final rule, CMS bypasses the 194 Healthcare Common Procedure Coding System (HCPCS) codes identified in Addendum N to the final rule. CMS indicates the list of bypass codes may include codes that were reported on claims in 2015 but were deleted for 2016. Addendum N is available from the CMS website at:

Table 1 of the final rule lists six HCPCS codes that CMS is deleting from the 2017 bypass list.

1. Calculation and use of cost-to-charge ratios

To convert billed charges on the outpatient claims to estimated costs, CMS multiplies the charges by a hospital-specific cost-to-charge ratio (CCR) associated with each revenue code and cost center. To calculate CCRs for 2017, CMS is employing the same basic approach used for APC rate construction for 2007 and each subsequent year. CMS applies the appropriate hospital-specific CCR to the hospital’s charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy, for each revenue code, of CCRs for estimating costs from charges. The current crosswalk is available for review and continuous comment on the CMS website:

CMS notes that no new revenue codes were added for 2015, which is the year of claims data used for the proposed 2017 payment rates.

CCRs are calculated for the standard and nonstandard cost centers accepted by the electronic cost report data base. Generally, the most detailed level used is the hospital-specific departmental level.
CMS received one comment asking that it continue to exclude CCRs for providers that use a “square foot” methodology to allocate costs associated with CT and MRI in CY 2018 and subsequent years; a policy it adopted on a transition basis for 2014-2017. CMS declined to continue the transition policy it adopted in the 2014 OPPS rule beyond 2017.

2. **Budget neutral weight scaler**

To make the APC reclassification and recalibration changes budget neutral, CMS compares the estimated aggregate weights calculated using the 2017 unscaled relative weights and service volume in the 2015 claims data to the aggregate weight calculated using the final 2016 scaled relative weights and the service volume using the same 2015 claims data. Based on this comparison, the final rule unscaled APC payment weights were adjusted by a weight scaler of 1.4208. CMS is continuing to include payments for “specified covered outpatient drugs” (SCODs) in the budget neutrality calculation for 2017.

3. **Recommendations of the Hospital Outpatient Payment Panel Regarding Data Development**

At the August 22, 2016 meeting of the Panel, CMS provided the Data Committee a list of APCs for CY 2017 for which geometric mean costs in the CY 2015 claims data varied significantly from the CY 2014 claims data used for the CY 2016 OPPS/ASC final rule with comment period. At the August 22, 2016 Panel meeting, the Panel made four recommendations related to the data process. CMS accepted the Panel’s four recommendations involving the data subcommittee:

- CMS will provide the data subcommittee a list of APCs fluctuating significantly in costs prior to each Panel meeting;
- The work of the data subcommittee will continue;
- The current Chair will remain; and
- CMS will provide the Data Subcommittee a presentation on the claims accounting process prior to each HOP Panel meeting.

4. **Calculation of single procedure APC criteria-based costs**

The calculation of geometric mean costs for some APCs follows various special rules, as described below.

**Blood and blood products.** For 2017, CMS is continuing, without change, to set payment rates for blood and blood products using the blood-specific CCR methodology that it has used since 2005. CMS calculated the procedure costs for setting the 2017 payment rates for blood and blood products using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and using a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

CMS is also continuing to include blood and blood products in the comprehensive APCs, which provide all-inclusive payments covering all services on the claim. When blood and blood
products appear on claims with services assigned to a comprehensive APC, their costs are included in calculating the overall costs of these comprehensive APCs, with such costs determined based on the blood-specific CCR methodology. Because the costs of blood and blood products are reflected in the overall costs of the comprehensive APCs – and thus the payment rates of the comprehensive APCs – beginning in 2015, no separate payment is made for blood and blood products when they appear on the same claims as services assigned to a comprehensive APC. CMS notes that Addendum B to the final rule is available on its website and includes the final payment rates for blood and blood products.

In the proposed rule, CMS invited comments on continuing these policies and also sought comments 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 codes provide for terms that 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 descriptors best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. The current set of active HCPCS P-codes that describe blood products can also be found in Addendum B to the final rule.

CMS received a variety of comments including a recommendation to convene a stakeholder group that includes representatives of hospitals, blood banks, the American Red Cross, and others to discuss a framework to systematically review and revise the HCPCS P-codes for blood products. CMS indicated that it will take the comments into consideration in the development of proposals to update the HCPCS P-codes that describe blood products.

Rapid Bacterial Testing for Platelets. The final rule announces a revision to the HCPCS code established in CY 2016 for pathogen-reduced platelets (HCPCS code P9072) to include the use of pathogen-reduction technology or rapid bacterial testing. The payment rate for HCPCS code P9072 is based on a crosswalk to HCPCS code P9037 (Platelets, pheresis, leukocyte reduced, irradiated, each unit). CMS will update the payment rate for P9072 when claims data become available using that data and the blood-specific CCR methodology. The revised HCPCS code descriptor and final payment rate for this service can be found in Addendum B of the final rule (link provided on page 1 of this summary).

Brachytherapy sources. The statute requires the Secretary to create additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., “brachytherapy sources” – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. In addition, separate groups are required for palladium-103 and iodine-125 sources, and for stranded and non-stranded devices. Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute.

The final rule for 2017 continues without change the policies used to set payment rates for brachytherapy sources; costs derived from the 2015 claims data were used to set 2017 payment
rates. The final payment rates appear in Addendum B to the final rule and are identified with status indicator “U.”

With respect to HCPCS code C2644 (Brachytherapy cesium-131 chloride) which became effective on July 1, 2014, CMS reports that this code was not reported on any 2015 claims, and it was unable to calculate a payment rate. CMS is assigning new status indicator “E2” (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644. Unlike new brachytherapy sources HCPCS codes, CMS says it will not consider external data to determine a payment rate for HCPCS code C2644 for CY 2017.

CMS indicated that the comments it received on Medicare payment for brachytherapy sources were similar to those it received in the past and addressed in prior rules. It is finalizing all its proposed policies with regard to the payment methodology for brachytherapy sources without change.

The final rule invites hospitals and other parties to submit recommendations to CMS for new HCPCS codes that describe new brachytherapy sources utilizing a radioactive isotope, including a detailed rationale to support recommended new sources. Recommendations should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. CMS will continue to add new brachytherapy source codes and descriptors to its payment systems on a quarterly basis through program transmittals.

5. Comprehensive APCs

CMS established and implemented a new policy for comprehensive APCs (C-APCs) in 2015 based on policies finalized in the 2014 final OPPS rule, with a delayed effective date of January 1, 2015, and modified in the 2015 final rule. A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in 2015; 10 additional C-APCs were finalized for 2016.

Current Policy for C-APCs

CMS selects HCPCS codes for primary services to be assigned to a C-APC and designates them by status indicator “J1” as listed Addendum B and Addendum J to the final rule. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are provided during the delivery of the comprehensive service and are integral, ancillary, supportive, dependent, and adjunctive to the primary service. Only services that are not covered OPD services or cannot by statute be paid for under the OPPS are excluded from Medicare’s C-APC payment.

Status indicator “J2,” new in 2016, designates C-APCs to which assignment is based on specific combinations of services performed in combination with each other rather than the presence of a single primary service identified by status indicator “J1.” Applying C-APC policies to these code
combinations means that other OPPS payable services and items reported on the claim are
treated as adjunctive to the comprehensive service. A single prospective payment is made for the
comprehensive service based on the costs of all reported services on the claim.

Services included under the C-APC payment packaging policy include:
- diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that
  assist in the delivery of the primary procedure;
- visits and evaluations performed in association with the procedure;
- uncoded services and supplies used during the service;
- durable medical equipment as well as prosthetic and orthotic items and supplies when
  provided as part of the outpatient service;
- outpatient department services that are similar to therapy and delivered either by
  therapists or non-therapists as part of the comprehensive service;
- all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs
  with pass-through payment status and drugs that are usually self-administered (SADs),
  unless they function as packaged supplies; and
- any other components reported by HCPCS codes that represent services which are
  provided during the complete comprehensive service, except the excluded services
  described below.

Services excluded from the C-APC payment policy include those that are not covered OPD
services; services excluded from the OPPS; and services that are required to be separately paid.
Addendum J to the final rule lists the following services that are excluded from the C-APC
payment policy:

- Ambulance services
- Brachytherapy
- Diagnostic and mammography screenings
- Physical therapy, speech-language pathology and occupational therapy services
  reported on a separate facility claim for recurring services
- Pass-through drugs, biologicals, and devices
- Preventive services defined in 42 CFR §410.2
- Self-administered drugs (SADs) - Drugs that are usually self-administered and do
  not function as supplies in the provision of the comprehensive service
- Services assigned to OPPS status indicator “F” (certain CRNA services, Hepatitis B
  vaccines and corneal tissue acquisition)
- Services assigned to OPPS status indicator “L” (influenza and pneumococcal
  pneumonia vaccines)
- Certain Part B inpatient services – Ancillary Part B inpatient services payable under
  Part B when the primary “J1” service for the claim is not a payable Medicare Part B
  inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries
  with Part B only).

For the minority of claims reporting more than one primary service with status indicator J1 or
multiple units, CMS identifies one J1 service as the primary service for the claim based on a
cost-based ranking of primary services using comprehensive geometric mean costs for single unit
J1 services. The multiple J1 procedure claims are assigned to the C-APC to which the service designated as the primary service is assigned:

- If the multiple J1 services reported on a claim map to different C-APCs, CMS designates the J1 service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim.
- If the reported multiple J1 services on a claim map to the same C-APC, CMS designates the costliest service (at the HCPCS code level) as the primary service for that claim.

CMS packages all add-on codes and assigns them status indicator “N” (unconditionally packaged). A set of these codes are evaluated for purposes of determining whether a complexity adjustment is appropriate. These are identified in Addendum J to the 2017 final rule. Addendum J can be found at:

**Complexity adjustments.** Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Specifically, qualifying J1 service code combinations or code combinations of J1 services and certain add-on codes are reassigned from the originating C-APC (i.e., the C-APC to which the designated primary service is initially assigned) to a higher paying C-APC in the same clinical family of comprehensive APCs. (For purpose of the C-APC policy, CMS defines a clinical family of comprehensive APCs as a set of clinically related comprehensive APCs that represent different resource levels of clinically comparable services.) After designating a service as the primary service for a claim, CMS evaluates that service in combination with each of the other procedure codes reported on the claim assigned to status indicator J1 (or certain add-on codes) to determine if they meet the complexity adjustment criteria. For new HCPCS codes, CMS determines initial C-APC assignments and complexity adjustments using the best data available, cross-walking the new HCPCS codes to predecessor codes if possible.

CMS is continuing to follow the criteria for determining which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment:

- Frequency of 25 or more claims reporting the code combination (i.e., the frequency threshold); and
- Violation of the 2 times rule, that is, the comprehensive geometric mean cost of the complex code combination exceeds the comprehensive geometric mean cost of the lowest significant HCPCS code assigned to the comprehensive APC by more than 2 times (the cost threshold).³

For code combinations satisfying the complexity criteria, CMS finalized a change as proposed to not apply the 2 times rule to the receiving APC when a code combination results in assignment to a higher cost C-APC. Currently, code combinations satisfying the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless (1) the APC reassignment is not clinically appropriate, (2) the reassignment would create a 2 times rule violation in the

³ In the 2015 final OPPS rule, CMS defined “significant HCPCS code” to mean frequency >1000 claims, or frequency > 99 claims and contributing at least 2 percent of the single major claims used to establish the originating comprehensive APC’s geometric mean cost, including the claims reporting the complex code pair.
receiving APC, or (3) the primary service is already assigned to the highest cost APC within the C-APC clinical family. CMS does not create new APCs with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

For 2017, CMS proposed to discontinue the requirement that a code combination also not create a 2 times rule violation in the higher level or receiving APC. CMS believes this requirement is not useful because the 2 times rule does not typically apply to complexity-adjusted code combinations. It says that most code combinations fall below the established frequency threshold for considering 2 times rule violations. Commenters generally agreed with CMS’ proposal although some asked for additional changes to the complexity criteria for assigning a primary service to a higher paying APC. CMS did not adopt any changes to the proposed policy in response to comments.

Addendum J to the 2017 final rule shows that 35,671 code combinations were evaluated for a complexity adjustment and that 376 code combinations qualified. The full Addendum J also includes cost statistics for all the code combinations which were evaluated for a complexity adjustment and the ranking of HCPCS codes within each C-APC based on the geometric mean cost of single J1 unit claims; this is the ranking used to determine the primary assignment of comprehensive HCPCS codes.

C-APC Payment Policy for 2017

CMS finalizes a total of 62 C-APCs to be paid under the existing C-APC payment policy in 2017. The final rule identifies 25 of these as new C-APCs beginning in CY 2017. However, Addendum A to the 2016 final rule shows 35 APCs with a status indicator of J1 or J2 indicating the APC is a C-APC; this suggests that CMS is creating 27 new C-APCs rather than 25 new C-APCs. However, CMS may not be counting four of the C-APCs (5094, 5116, 5194 and 5495) that did not exist in 2016 because the procedures that group to them were previously grouping to what was then the highest C-APC level in 2016. In addition, CMS incorrectly identifies two APCs as being new in 2017.4

While CMS received comments in support of the new C-APCs, several commenters requested that CMS delay the expansion of the C-APC policy and expressed concerns that the costs of procedures and services paid through a C-APC are not being accurately captured and C-APC payment rates do not adequately cover the costs associated with the primary and adjunctive services. Commenters also stated that more time is needed to analyze and assess the financial impact of the proposed C-APC policy changes; recommended that CMS establish a minimum cost threshold for assigning a procedure to a C-APC and that new codes not be assigned to C-APCs; and that CMS not finalize the C-APC for sinus surgery as it may involve several procedures in a single operative session.

CMS responded that sufficient information is available for stakeholders to comment in the time available as evidenced by the many stakeholders that submit public comments, including, for

45191 and 5113 (which is numbered as 5123 in 2016).
example, the analyses of the C-APC policy provided in the public comments. CMS does not believe that a cost threshold would help to differentiate primary from secondary or adjunctive services and notes that new codes are assigned to APCs and C-APCs based on predecessor code APC assignments, comparisons to similar codes, clinical comparability, and estimates of the resource intensity, as well as other relevant information. CMS rejected the comment requesting a C-APC for sinus surgery noting that if multiple surgical procedures are common as part of a single operative session, the C-APC will reflect those costs.

All C-APCs for 2017 are displayed in the table below.

<table>
<thead>
<tr>
<th>C-APC</th>
<th>2017 APC Title</th>
<th>Clinical Family</th>
<th>New C-APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>5072</td>
<td>Level 2 Excision/Biopsy/Incision and Drainage</td>
<td>EBIDX</td>
<td>*</td>
</tr>
<tr>
<td>5073</td>
<td>Level 3 Excision/Biopsy/Incision and Drainage</td>
<td>EBIDX</td>
<td>*</td>
</tr>
<tr>
<td>5091</td>
<td>Level 1 Breast/Lymphatic Surgery and Related Procedures</td>
<td>BREAS</td>
<td>*</td>
</tr>
<tr>
<td>5092</td>
<td>Level 2 Breast/Lymphatic Surgery and Related Procedures</td>
<td>BREAS</td>
<td>*</td>
</tr>
<tr>
<td>5093</td>
<td>Level 3 Breast/Lymphatic Surgery &amp; Related Procedures</td>
<td>BREAS</td>
<td></td>
</tr>
<tr>
<td>5094</td>
<td>Level 4 Breast/Lymphatic Surgery &amp; Related Procedures</td>
<td>BREAS</td>
<td>b</td>
</tr>
<tr>
<td>5112</td>
<td>Level 2 Musculoskeletal Procedures</td>
<td>ORTHO</td>
<td>*</td>
</tr>
<tr>
<td>5113</td>
<td>Level 3 Musculoskeletal Procedures</td>
<td>ORTHO</td>
<td>c</td>
</tr>
<tr>
<td>5114</td>
<td>Level 4 Musculoskeletal Procedures</td>
<td>ORTHO</td>
<td></td>
</tr>
<tr>
<td>5115</td>
<td>Level 5 Musculoskeletal Procedures</td>
<td>ORTHO</td>
<td></td>
</tr>
<tr>
<td>5116</td>
<td>Level 6 Musculoskeletal Procedures</td>
<td>ORTHO</td>
<td>b</td>
</tr>
<tr>
<td>5153</td>
<td>Level 3 Airway Endoscopy</td>
<td>AENDO</td>
<td>*</td>
</tr>
<tr>
<td>5154</td>
<td>Level 4 Airway Endoscopy</td>
<td>AENDO</td>
<td>*</td>
</tr>
<tr>
<td>5155</td>
<td>Level 5 Airway Endoscopy</td>
<td>AENDO</td>
<td>*</td>
</tr>
<tr>
<td>5164</td>
<td>Level 4 ENT Procedures</td>
<td>ENTXX</td>
<td>*</td>
</tr>
<tr>
<td>5165</td>
<td>Level 5 ENT Procedures</td>
<td>ENTXX</td>
<td></td>
</tr>
<tr>
<td>5166</td>
<td>Cochlear Implant Procedure</td>
<td>COCHL</td>
<td></td>
</tr>
<tr>
<td>5191</td>
<td>Level 1 Endovascular Procedures</td>
<td>VASCX</td>
<td>c</td>
</tr>
<tr>
<td>5192</td>
<td>Level 2 Endovascular Procedures</td>
<td>VASCX</td>
<td></td>
</tr>
<tr>
<td>5193</td>
<td>Level 3 Endovascular Procedures</td>
<td>VASCX</td>
<td></td>
</tr>
<tr>
<td>5194</td>
<td>Level 4 Endovascular Procedures</td>
<td>VASCX</td>
<td>b</td>
</tr>
<tr>
<td>5200</td>
<td>Implantation Wireless PA Pressure Monitor</td>
<td>WPMXX</td>
<td>*</td>
</tr>
<tr>
<td>5211</td>
<td>Level 1 Electrophysiologic Procedures</td>
<td>EPHYS</td>
<td></td>
</tr>
<tr>
<td>5212</td>
<td>Level 2 Electrophysiologic Procedures</td>
<td>EPHYS</td>
<td></td>
</tr>
<tr>
<td>5213</td>
<td>Level 3 Electrophysiologic Procedures</td>
<td>EPHYS</td>
<td></td>
</tr>
<tr>
<td>5222</td>
<td>Level 2 Pacemaker and Similar Procedures</td>
<td>AICDP</td>
<td></td>
</tr>
<tr>
<td>5223</td>
<td>Level 3 Pacemaker and Similar Procedures</td>
<td>AICDP</td>
<td></td>
</tr>
<tr>
<td>5224</td>
<td>Level 4 Pacemaker and Similar Procedures</td>
<td>AICDP</td>
<td></td>
</tr>
<tr>
<td>5231</td>
<td>Level 1 ICD and Similar Procedures</td>
<td>AICDP</td>
<td></td>
</tr>
<tr>
<td>5232</td>
<td>Level 2 ICD and Similar Procedures</td>
<td>AICDP</td>
<td></td>
</tr>
<tr>
<td>5244</td>
<td>Level 4 Blood Product Exchange and Related Services</td>
<td>SCTXX</td>
<td>*</td>
</tr>
<tr>
<td>5302</td>
<td>Level 2 Upper GI Procedures</td>
<td>GIXXX</td>
<td>*</td>
</tr>
<tr>
<td>5303</td>
<td>Level 3 Upper GI Procedures</td>
<td>GIXXX</td>
<td>*</td>
</tr>
</tbody>
</table>
## Final Rule 2017 C-APCs

<table>
<thead>
<tr>
<th>C-APC</th>
<th>2017 APC Title</th>
<th>Clinical Family</th>
<th>New C-APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>5313</td>
<td>Level 3 Lower GI Procedures</td>
<td>GIXXX</td>
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</tr>
<tr>
<td>5331</td>
<td>Complex GI Procedures</td>
<td>GIXXX</td>
<td></td>
</tr>
<tr>
<td>5341</td>
<td>Abdominal/Peritoneal/Biliary and Related Procedures</td>
<td>GIXXX</td>
<td>*</td>
</tr>
<tr>
<td>5361</td>
<td>Level 1 Laparoscopy &amp; Related Services</td>
<td>LAPXX</td>
<td></td>
</tr>
<tr>
<td>5362</td>
<td>Level 2 Laparoscopy &amp; Related Services</td>
<td>LAPXX</td>
<td></td>
</tr>
<tr>
<td>5373</td>
<td>Level 3 Urology &amp; Related Services</td>
<td>UROXX</td>
<td>*</td>
</tr>
<tr>
<td>5374</td>
<td>Level 4 Urology &amp; Related Services</td>
<td>UROXX</td>
<td>*</td>
</tr>
<tr>
<td>5375</td>
<td>Level 5 Urology &amp; Related Services</td>
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</tr>
<tr>
<td>5376</td>
<td>Level 6 Urology &amp; Related Services</td>
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<tr>
<td>5377</td>
<td>Level 7 Urology &amp; Related Services</td>
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<tr>
<td>5414</td>
<td>Level 4 Gynecologic Procedures</td>
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<tr>
<td>5415</td>
<td>Level 5 Gynecologic Procedures</td>
<td>GYNXX</td>
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<tr>
<td>5416</td>
<td>Level 6 Gynecologic Procedures</td>
<td>GYNXX</td>
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</tr>
<tr>
<td>5431</td>
<td>Level 1 Nerve Procedures</td>
<td>NERVE</td>
<td>*</td>
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<tr>
<td>5432</td>
<td>Level 2 Nerve Procedures</td>
<td>NERVE</td>
<td>*</td>
</tr>
<tr>
<td>5462</td>
<td>Level 2 Neurostimulator &amp; Related Procedures</td>
<td>NSTIM</td>
<td></td>
</tr>
<tr>
<td>5463</td>
<td>Level 3 Neurostimulator &amp; Related Procedures</td>
<td>NSTIM</td>
<td></td>
</tr>
<tr>
<td>5464</td>
<td>Level 4 Neurostimulator &amp; Related Procedures</td>
<td>NSTIM</td>
<td></td>
</tr>
<tr>
<td>5471</td>
<td>Implantation of Drug Infusion Device</td>
<td>PUMPS</td>
<td></td>
</tr>
<tr>
<td>5491</td>
<td>Level 1 Intraocular Procedures</td>
<td>INEYE</td>
<td>*</td>
</tr>
<tr>
<td>5492</td>
<td>Level 2 Intraocular Procedures</td>
<td>INEYE</td>
<td></td>
</tr>
<tr>
<td>5493</td>
<td>Level 3 Intraocular Procedures</td>
<td>INEYE</td>
<td></td>
</tr>
<tr>
<td>5494</td>
<td>Level 4 Intraocular Procedures</td>
<td>INEYE</td>
<td></td>
</tr>
<tr>
<td>5495</td>
<td>Level 5 Intraocular Procedures</td>
<td>INEYE</td>
<td>b</td>
</tr>
<tr>
<td>5503</td>
<td>Level 3 Extraocular, Repair, and Plastic Eye Procedures</td>
<td>EXEYE</td>
<td>*</td>
</tr>
<tr>
<td>5504</td>
<td>Level 4 Extraocular, Repair, and Plastic Eye Procedures</td>
<td>EXEYE</td>
<td>*</td>
</tr>
<tr>
<td>5627</td>
<td>Level 7 Radiation Therapy</td>
<td>RADTX</td>
<td></td>
</tr>
<tr>
<td>5881</td>
<td>Ancillary Outpatient Services When Patient Dies</td>
<td>N/A</td>
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</tr>
<tr>
<td>8011</td>
<td>Comprehensive Observation Services</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

*New C-APC for CY 2017.
a: These C-APCs have been renumbered (from 5123-5125).
b: Addenda A and B show that these C-APCs are comprised of procedure codes moving from the highest-intensity C-APC in the family in 2016 to a higher-level C-APC newly created for 2017.
c: Final rule in Table 2 incorrectly lists this C-APC as new. Addendum A of the 2016 final rule shows this as a C-APC for 2016.

**Clinical Family Descriptor Key:**
- C-APC Clinical Family Descriptor Key:
  - AENDO = Airway Endoscopy
  - AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
  - BREAS = Breast Surgery
  - COCHL = Cochlear Implant
  - EBDIX = Excision/ Biopsy/ Incision and Drainage
  - ENTXX = ENT Procedures
  - EPHYS = Cardiac Electrophysiology
  - EXEYE = Extraocular Ophthalmic Surgery
New Allogeneic Hematopoietic Stem Cell Transplantation APC. Reviewing long-standing concerns raised by stakeholders regarding the accuracy of ratesetting for allogeneic Hematopoietic Stem Cell Transplantation (HSCT), CMS finalized with modification its proposal to create a new C-APC 5244 (Level 4 Blood Product Exchange and Related Services). Procedures described by CPT code 38240 (hematopoietic progenitor cell; allogeneic transplantation per donor) will be assigned to this C-APC and a “J1” status indicator assigned to this code. The costs for all covered OPD services included on the claim, including donor acquisition services, would be packaged into the C-APC rate. CMS would also analyze these costs using its comprehensive cost accounting methodology to establish future C-APC rates. CMS establishes a 2017 payment rate for C-APC 5244 of $15,267.

For future ratesetting, CMS will update the Medicare hospital cost report (CMS-2552-10) to include a new cost center (112.50) for “Allogeneic Stem Cell Acquisition.” CMS notes that acquisition charges only apply to transplants for which stem cells are obtained from a donor; autologous transplants involve services to a beneficiary for which the hospital can bill and receive payment. In addition to the new cost center, CMS will use the newly created revenue code 0815 (Allogeneic Stem Cell Acquisition Services) to identify hospital charges for stem cell acquisition for allogeneic bone marrow/stem cell transplants. Specifically, for 2017 and subsequent years, hospitals will be required to identify stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately in Field 42 on Form CMS-1450 (or UB-04), when an allogeneic stem cell transplant occurs. Revenue code 0815 charges should include all services required to acquire stem cells from a donor and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes. The new revenue code 0815 would map to new line 112.50 (with the cost center code of “11250”) on the Form CMS-2552-10 cost report. In addition, for 2017 and subsequent years, CMS is instructing hospitals to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants.

The final payment rate for new C-APC 5244 is $27,752 for CY 2017. CMS adopted changes in the final rule in response to public commenters that were concerned that the C-APC for HSCT remained underpaid despite the changes CMS was making in the proposed rule. Of specific note is that CMS will use only the claims with both the CPT code for the transplant (CPT code 38240) and the revenue code for the donor acquisition costs (revenue code 0819) to calculate the

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5 This code was approved by the National Uniform Billing Committee in 2016 for use beginning January 1, 2017.
payment rate for this service under the new C-APC. CMS indicates that it is departing from its general practice and will use only the subset of claims that include both codes because hospitals were specifically instructed in the CMS Internet Only Manual and in prior final rule preamble language to use revenue code 0819 to report donor acquisition costs. Further, CMS is implementing a code edit beginning in CY 2017 that will require revenue code 0815 to be on a claim with CPT code 38240 to ensure that donor acquisition costs for allogeneic HSCT are reported with the appropriate revenue code and that these costs are accurately recorded in the Medicare hospital cost report.

6. Calculation of composite APC criteria-based costs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS is not proposing new composite APCs for 2017, but would continue composite policies for low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services.

**LDR Prostate Brachytherapy Composite APC (APC 8001).**

For 2017, CMS proposed to continue the composite APC policy that has been employed since 2008 for LDR Prostate Brachytherapy. Under this policy, the OPPS provides a single payment when the composite service, identified by CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), is furnished in a single hospital encounter. CMS bases the payment for composite APC 8001 on the cost derived from claims that contain both CPT codes 55875 and 77778 for the same date of service and that do not contain other separately-paid codes which are not on the bypass list. When these services are billed individually, hospitals receive separate payments for the individual services.

Using the CY 2015 claims data available for this CY 2017 final rule with comment period, CMS was able to use 224 claims (202 in the proposed rule) that contained both CPT codes 55875 and 77778 to calculate the geometric mean cost of approximately $3,598 ($3,581 in the proposed rule) for these procedures upon which the final CY 2017 payment rate for composite APC 8001 is based.

**Mental Health Services Composite APC (APC 8010)**

For 2017, CMS finalized without change its proposal to continue its longstanding payment policy of limiting the combined payment for specified less intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which the agency considers to be the most resource intensive of all outpatient mental health treatments. Using the claims processing software, when the total payment for the individual services for specified mental health services – based on the payment rates associated with those APCs – provided by one hospital to a single beneficiary on one date of service exceeds the maximum per diem partial hospitalization payment, those specified mental health services are assigned to APC 8010 (Mental Health Services Composite) at the same payment rate that it is establishing for APC
5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the code editor would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5862 for all of the specified mental health services furnished by the hospital on that single date of service. CMS did not receive any public comments on this proposal which is being finalized without change. Further information can be found in section XIII regarding CMS’ policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC.

**Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)**

For 2017, CMS is continuing the multiple imaging composite APC policies that it has applied since 2009. Under the multiple imaging policy payment is based using five composite APCs:
- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and Computed tomographic angiography (CTA) without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and magnetic resonance angiography (MRA) without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

One composite APC payment is made when a hospital bills more than one procedure described by HCPCS codes within an OPPS imaging family (per imaging family designations provided in each year’s regulation) on a single date of service. If the hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital would receive payment for the “with contrast” composite APC. CMS assigns the status indicator “S” to the composite APCs, thus signifying that payment for the APC is not reduced when appearing on the same claim with other significant procedures. When the conditions for a composite APC payment do not apply, CMS makes payment according to the standard OPPS methodology through the standard (sole service) imaging APCs; this rule applies when a single imaging procedure is performed, or when the imaging procedures performed have HCPCS codes assigned to different OPPS imaging families.

CMS continues current billing practices whereby hospitals use the HCPCS codes to report imaging services and the integrated outpatient code editor determines when combinations of imaging procedures qualify for composite APC payment or map to standard APCs for payment. CMS did not receive any public comments on these proposals and is finalizing its policy without change.

Table 3 of the final rule lists the HCPCS codes that CMS is making subject to the multiple imaging composite policy for 2017 and their respective families and approximate composite APC geometric mean costs for 2017 based on claims data for 2015. For the CY 2017 final rule with comment period, CMS identified approximately 635,363 “single session” claims out of an estimated 1.7 million potential claims for payment through composite APCs from its ratesetting
claims data, which represents approximately 37 percent of all eligible claims, to calculate the final CY 2017 geometric mean costs for the multiple imaging composite APCs.

7. Changes to packaged items and services

For 2017, CMS finalized modifications to its packaging policies and to package the costs of two drugs that function as supplies in a surgical procedure.

**Clinical Diagnostic Laboratory Test Packaging Policy**

Under current policy, certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged in the OPPS as integral, ancillary, supportive, dependent or adjunctive to the primary service or services provided in the OPD. Laboratory tests are conditionally packaged and only paid separately when 1) they are the only services provided to a beneficiary on a claim; 2) they are unrelated tests, meaning they are on the same claim as other OPD services but are ordered for a different diagnosis and by a different practitioner; 3) they are molecular pathology tests; or 4) they are considered preventive.

For 2017, CMS made two changes to the laboratory test packaging policy:

- Discontinue the unrelated laboratory test exception (and the associated “L1” modifier that designates separate payment). With this change, CMS proposed to package any and all laboratory tests that appear on a claim with other OPD services. CMS believes that in most cases, “unrelated” laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD. It says that multiple 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 also believes that the “different physician, different diagnosis” criteria do not necessarily correlate with whether a laboratory test is related to other HOPD services, and has concluded that the criteria do not clearly distinguish laboratory tests that are integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services provided to the beneficiary during the hospital stay.

- Expand the molecular pathology test exception to include all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. CMS agrees with past commenters who maintain that other tests that are relatively new also may have a different pattern of clinical use than more conventional laboratory tests, which results in making them less tied to a primary service in the OPD. Under the proposal CMS would assign status indicator “A” (separate payment under the CLFS) to laboratory tests designated as ADLTs under the CLFS.

CMS is finalizing the above policies as proposed that were largely supported by commenters. CMS declined to expand the molecular pathology/ADLT exception to all multi-analyte with algorithmic analysis tests as requested by commenters.

*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: status indicator “Q1,” which 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 Emergency Department Visit); and status indicator “Q2,” which packages items or services on the same date of service with services assigned status indicator “T.” Other conditional packaging status indicators, “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 finalized without change a proposal to change 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 says this would align with other conditional packaging indicators and would ensure 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. CMS notes that its proposal would increase the conditional packaging of items and services because conditional packaging would 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.

CMS is finalizing the proposal without change. The majority of commenters opposed the proposal because of a general opposition to packaging in the OPPS. Other commenters supported the proposal and acknowledged CMS’ efforts to promote consistency in the OPPS by not having differential packaging policies depending on how a service is billed.

**B. Conversion Factor Update**

The OPPS conversion factor for 2017 is $75.001. CMS began with the 2016 conversion factor of $73.725 and adjusted it by the fee schedule increase factor and various budget neutrality factors. (Neither the proposed or final rule discuss the 2.0 percent reduction built into the 2016 conversion factor and, thus, into the base for the 2017 update resulting from the CMS actuaries’ determination of excess packaged payment for laboratory tests associated with a policy change made in the OPPS 2014 final rule.) As discussed earlier, the fee schedule increase factor equals the hospital inpatient market basket percentage increase, which is 2.7 percent, reduced by a multifactor productivity adjustment (MFP) of 0.3 percentage points as required by the ACA, and further reduced by an additional 0.75 percentage points as also required by the ACA. This provides for a fee schedule increase factor of 1.65 percent.

Hospitals that fail to meet the reporting requirements of the hospital Outpatient Quality Reporting program (OQR) are subject to a reduction of 2.0 percentage points, as discussed in section XIII below.

The following additional adjustments are applied in calculating the 2017 conversion factor: a wage index budget neutrality factor of 0.9999 and budget neutrality adjustment of 1.0003 for the
cancer hospital adjustment. The rural adjustment factor also is 1.000 – and therefore does not affect the conversion factor – because CMS makes no change in the rural adjustment policy. CMS estimates that 2017 pass-through spending for drugs, biological and devices will be $148.3 million, or 0.24 percent of total spending, compared with CMS’ estimate that pass-through spending in 2016 would represent about 0.26 percent of total payments. The increase in projected pass-through spending for 2016 therefore results in an increase in the conversion factor of 0.02 percentage points. Finally, the policy to package all unrelated laboratory tests described in II.A.7 above) results in a conversion factor adjustment of +0.04 percent (or 0.01 percentage points higher than CMS proposed) to make the change budget neutral.

CMS raised the budget neutrality adjustment for packing of laboratory services from 1.0003 to 1.0004. Public commenters suggested the adjustment for the additional packaging of laboratory services should be $40 million rather than $22 million. CMS’ response suggests that the adjustment amount should be based on $22 million even though $40 million is the amount used for setting the relative weights. While there is insufficient detail in the final rule to understand that point, CMS nevertheless raised the adjustment by 0.01 percentage point which is consistent with what public commenters were seeking.

The table below shows the calculation of the conversion factor for 2017.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$73.725</td>
<td>1.0002</td>
<td>0.9999</td>
<td>1.0003</td>
<td>1.0004</td>
<td>1.0165</td>
<td>$75.001</td>
</tr>
<tr>
<td></td>
<td>$73.740</td>
<td>$73.732</td>
<td>$73.754</td>
<td>$73.784</td>
<td>$75.001</td>
<td>$75.001</td>
</tr>
</tbody>
</table>

The combined effect of these factors yields a 2017 conversion factor of $75,001 for hospitals satisfying the requirements of the quality reporting program. To calculate the 2017 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the OQR, the final rule applies a reduced fee schedule increase factor such that the conversion factor for hospitals that do not report quality data is 0.98 of the conversion factor for hospitals that do report quality data. The 2017 final rule conversion factor for hospitals that do not report quality data is $73.501. (Note: This conversion factor is slightly less than if a 2 percentage point reduction was applied to the 1.65 percent increase factor for hospitals that report quality data. If an update of -0.35 percent was applied (1.65 – 2.0), the conversion factor for hospitals that do not report quality data would be $73.526 or about 2.5 cents higher).

C. Wage Index Changes

CMS is continuing its policy of adopting the final fiscal year IPPS post-classified wage index as the OPPS calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. The 2017 OPPS final rule wage index is based on the FY 2017 IPPS final rule post-classified wage index. This includes adoption of revisions to several labor market areas made by the Office of Management and Budget (OMB) in OMB Bulletin No. 15-
01 issued on July 15, 2015. The wage index tables are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html.

For non-IPPS hospitals paid under the OPPS, CMS is continuing its policy 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.

The final rule retains the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2017 and notes that the wage index adjustment is made in a budget neutral manner.

CMS is continuing its policy to implement the wage index adjustments called for in the ACA in the same manner as it has since 2011. That includes the “frontier state” adjustment requiring a wage index floor of 1.0 in certain cases if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality adjustment) is less than 1.0. In the case of an OPD affiliated with a multi-campus hospital system, the OPD will continue to receive the wage index value of the specific inpatient hospital with which it is associated. If that hospital is in a frontier state, the frontier state wage index adjustment for that hospital will apply to the OPD.

CMS is retaining its policy allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a county designated as an out-migration county under section 505 of the MMA. Those counties eligible for this out-migration adjustment, as well as the non-IPPS hospitals, are available in Addendum L (link to Addenda is on page 1 of this summary.)

In the 2015 final OPPS rule, CMS adopted a 3-year transition period for hospitals paid under the OPPS but not under the IPPS that were currently located in urban counties that become rural under the new OMB delineations. Such hospitals will maintain the wage index of the CBSA in which they are physically located in FY 2014 for three years. Thus, for the 2017 OPPS, consistent with the FY 2017 IPPS rule, the 3-year transition will continue for its final year.

In the FY 2017 IPPS final rule CMS is continuing the extension of the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2017. For purposes of the 2017 OPPS, CMS will also continue to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS.

For CMHCs, CMS will to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, the 2015 final OPPS rule established policies to use a 3-year transition period for CMHCs, ending December 31, 2017. The final rule notes, that consistent with its current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and the rural floor adjustment, but does not include the out-migration adjustment, which only applies to hospitals.
D. Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for rate-setting, CMS uses overall hospital-specific CCRs calculated from the hospital’s most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. Default CCRs are used for hospitals for which the MACs cannot calculate a valid CCR, including certain hospitals that are new, hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR, and hospitals whose most recent cost report reflects all-inclusive rate status, until a hospital’s MAC is able to calculate the hospital’s actual CCR from its most recently submitted Medicare cost report.

The final rule updates the default ratios for 2017 using the most recent cost report data and CMS’ standard method for calculating this update; for Maryland, CMS continues to use an overall weighted average CCR for all hospitals in the nation.

Table 4 in the final rule sets out the statewide default CCRs for urban and rural areas in each state for 2017 and the comparable default CCRs for 2016. The CCRs represent the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital’s most recently submitted cost report, weighted by Medicare Part B charges. Most CCR changes shown in Table 4 are small. The five largest changes are those for rural Utah (-0.144), rural Alaska (-0.139), rural Washington (-0.078), Puerto Rico (-0.063) and urban Minnesota (-0.058).

E. Adjustment for Rural SCHs and EACHs under Section 1833(t)(13)(B)

For 2017, CMS is continuing to apply a 7.1 percent payment adjustment for rural SCHs, including Essential Access Community Hospitals (EACH), for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

F. OPPS Payments to Cancer Hospitals

Medicare law exempts 11 cancer hospitals meeting statutory classification criteria for exclusion from payment under the IPPS. Since the inception of the OPPS, Medicare has paid these hospitals under the OPPS for covered outpatient hospital services. The ACA requires a budget neutrality adjustment to the extent that the Secretary determines that the 11 cancer hospitals’ OPPS costs are greater than other OPPS hospitals’ costs, including consideration of the cost of drugs and biologicals. Cancer hospitals remain eligible for transitional outpatient payments, which are not budget neutral, and outlier payments, which are budget neutral.

For 2017, CMS is continuing the cancer adjustment policy used since 2012 to make additional payments to the 11 cancer hospitals sufficient to bring each hospital’s payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals. Rather than a claims-based adjustment, CMS makes an aggregate payment, as necessary, to each cancer hospital at cost report settlement. CMS determines the cancer hospital’s PCR (before a cancer hospital payment
adjustment) and determines the lump sum amount necessary (if any) to make the cancer hospital’s final PCR equal to the weighted average PCR (or “target PCR”) for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of the final rule. If a cancer hospital’s PCR (before the cancer hospital payment adjustment) is above the target PCR, the cancer hospital payment adjustment equals zero.

CMS recalculates the payment adjustment annually, in part because it believes that the ACA’s expansion of the 340B drug purchasing program to cancer hospitals may lower their drug acquisition costs in the future. The target PCR is set in advance and is calculated using the same extract of cost report data from HCRIS as is used for OPPS rate-setting. For the 2017 final rule, CMS updated its calculations to determine the target PCR using the latest available cost data (cost report periods with fiscal year ends ranging from 2014 to 2015) and determined that 0.91 is the correct target PCR.

Table 5 in the final rule, copied below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2017 ranging from 14.0 percent to 58.7 percent. As noted, the actual amount of the 2017 cancer hospital payment adjustment for each cancer hospital is determined at cost report settlement and depends on each hospital’s 2017 payments and costs.

The 2017 final rule budget neutrality adjustment to the OPPS conversion factor is 1.0000 for the cancer hospital adjustment reflecting CMS’ projection that aggregate cancer hospital adjustments would be largely unchanged in 2017 compared to 2016.

**TABLE 5.—FINAL ESTIMATED 2017 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT**

<table>
<thead>
<tr>
<th>Provider Number</th>
<th>Hospital Name</th>
<th>Estimated Percentage Increase in OPPS Payments for 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>050146</td>
<td>City of Hope Comprehensive Cancer Center</td>
<td>25.8%</td>
</tr>
<tr>
<td>050660</td>
<td>USC Norris Cancer Hospital</td>
<td>14.0%</td>
</tr>
<tr>
<td>100079</td>
<td>Sylvester Comprehensive Cancer Center</td>
<td>32.4%</td>
</tr>
<tr>
<td>100271</td>
<td>H. Lee Moffitt Cancer Center &amp; Research Institute</td>
<td>27.3%</td>
</tr>
<tr>
<td>220162</td>
<td>Dana-Farber Cancer Institute</td>
<td>49.8%</td>
</tr>
<tr>
<td>330154</td>
<td>Memorial Sloan-Kettering Cancer Center</td>
<td>50.4%</td>
</tr>
<tr>
<td>330354</td>
<td>Roswell Park Cancer Institute</td>
<td>30.0%</td>
</tr>
<tr>
<td>360242</td>
<td>James Cancer Hospital &amp; Solove Research Institute</td>
<td>37.9%</td>
</tr>
<tr>
<td>390196</td>
<td>Fox Chase Cancer Center</td>
<td>16.6%</td>
</tr>
<tr>
<td>450076</td>
<td>M.D. Anderson Cancer Center</td>
<td>52.3%</td>
</tr>
<tr>
<td>500138</td>
<td>Seattle Cancer Care Alliance</td>
<td>58.7%</td>
</tr>
</tbody>
</table>
G. Hospital Outpatient Outlier Payments

The OPPS makes outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2017, CMS is continuing to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It calculates the fixed-dollar threshold using the same methodology that was used to set the threshold for 2016 and previously.

For the 2017 final rule, CMS provides that the outlier threshold would be met when a hospital’s cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a $3,825 fixed-dollar threshold (same as the proposed rule and compared to $3,250 in 2016). CMS is continuing to set the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold ($3,825) are met.

CMS is adopting as final its proposal that a portion of the 1.0 percent outlier pool, specifically an amount equal to less than 0.01 percent of outlier payments, be allocated to CMHCs for partial hospitalization program outlier payments. This is in contrast with amounts of 0.49 percent for 2016 and 0.47 percent for 2015. CMS is continuing its policy that if a CMHC’s cost for partial hospitalization services paid under APC 5853 (Partial Hospitalization for CMHCs) exceeds 3.40 times the payment rate for APC 5853, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals failing to satisfy the quality reporting requirements, CMS is continuing its policy that a hospital’s costs for the service are compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied the hospital-specific overall ancillary CCRs available in the July 2016 update to the Outpatient Provider-Specific File after adjustment (using a CCR inflation adjustment factor of 0.9688 to approximate 2017 CCRs) and to charges on 2015 claims. CMS is using the 1-year average annualized rate-of-change in charges per case for two years of 1.0984 to approximate 2017 charges. The inflation adjustment factors for CCRs and charges are the same as were used for the FY 2017 IPPS final rule.

H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

This section provides step by step instructions for calculating an adjusted Medicare payment from the national unadjusted Medicare payment amounts shown in Addenda A and B to the final rule. The steps show how to determine the APC payments that would be made under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status
indicator assignments: “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “Q4,” “R,” “S,” “T,” “U,” or “V” (as defined in Addendum D1 to the final rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of “Q1” and “Q2”) qualify for separate payment. CMS notes that, although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

I. Beneficiary Coinsurance

Medicare law provides that the maximum coinsurance rate for any service is 40 percent of the total OPPS payment to the hospital and the minimum coinsurance is 20 percent. The statute also limits a beneficiary’s actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,288 in 2016. The inpatient hospital deductible limit is applied to the actual co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPS payment rate Addenda A and B to the final rule do not reflect application of the hospital deductible limit.

Although the last statutory reduction in the maximum coinsurance rate occurred in 2006, the methodology for calculating coinsurance rates ensures that beneficiary coinsurance amounts will continue to decrease gradually relative to the payment rates until all services have a coinsurance rate of 20 percent of the payment amount for the service.

For 2017, CMS is determining the copayment amounts for new and revised APCs using the methodology that was first implemented in 2004. CMS refers readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458) for a full description of this methodology, which is summarized in the 2017 final rule. Also, for 2016 as in prior years, CMS is reducing the beneficiary co-payment proportionately to the 2 percentage point conversion factor reduction when services are rendered in a hospital that does not report the required quality measures, or that reported them unsatisfactorily.

The final rule estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2017 will be 18.5 percent, a decrease from the 19.3 percent estimated for 2016 in the 2016 OPPS final rule.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

Table 6 (copied below from the final rule) summarizes the process CMS uses for updating codes through the OPPS quarterly update Change Requests (CRs), seeking public comment, and finalizing the status and payment of these codes under the OPPS.
TABLE 6: COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

<table>
<thead>
<tr>
<th>OPPS Quarterly Update CR</th>
<th>Type of Code</th>
<th>Effective Date</th>
<th>Comments Sought</th>
<th>When Finalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1, 2016</td>
<td>Level II HCPCS Codes</td>
<td>April 1, 2016</td>
<td>CY 2017 OPPS/ASC proposed rule</td>
<td>CY 2017 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td>July 1, 2016</td>
<td>Level II HCPCS Code</td>
<td>July 1, 2016</td>
<td>CY 2017 OPPS/ASC proposed rule</td>
<td>CY 2017 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td></td>
<td>Category I (certain vaccine codes) and Category III CPT codes</td>
<td>July 1, 2016</td>
<td>CY 2017 OPPS/ASC proposed rule</td>
<td>CY 2017 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td>October 1, 2016</td>
<td>Level II HCPCS Codes</td>
<td>October 1, 2016</td>
<td>CY 2017 OPPS/ASC final rule with comment period</td>
<td>CY 2018 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td>January 1, 2017</td>
<td>Level II HCPCS Codes</td>
<td>January 1, 2017</td>
<td>CY 2017 OPPS/ASC final rule with comment period</td>
<td>CY 2018 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td></td>
<td>Category I and Category III CPT Codes</td>
<td>January 1, 2017</td>
<td>CY 2017 OPPS/ASC proposed rule</td>
<td>CY 2017 OPPS/ASC final rule with comment period</td>
</tr>
</tbody>
</table>

1. Treatment of New 2016 Level II HCPCS Codes and CPT Codes Effective April 1 and July 1, 2016

In the April 2016 OPPS quarterly update, CMS made effective 10 new Level II HCPCS codes and assigned them to interim OPPS status indicators and APCs (see Table 7 on page 210 of the display copy of the final rule). In the July 2016 OPPS quarterly update, CMS made effective 9 new Level II HCPCS codes and 9 new Category III CPT codes and assigned them to interim OPPS status indicators and APCs (see Table 8 on page 213 of the display copy of final rule). The payment rates, where applicable, can be found in Addendum B to the final rule. CMS solicited public comments on the proposed status indicators, APC assignments and payment rates for these new codes. CMS finalized status indicators, APC assignments and payment rates for these codes as proposed. It received one public comment on the proposed APC assignment for Category III CPT codes 0440T, 0441T, and 0442T. CMS responded to this comment in section III.D. of the final rule with comment period.
2. Process for New Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 Which CMS Will Be Soliciting Public Comments in the 2017 Final Rule with Comment Period

CMS is continuing its practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for new Level II HCPCS codes that will be effective October 1, 2016 or January 1, 2017 in Addendum B to the 2017 final rule. These codes will be flagged with comment indicator “NI” in Addendum B, indicating that CMS has assigned the codes an interim OPPS payment status for 2017. CMS invites public comment in the 2017 OPPS/ASC final rule about the status indicators, APC assignments, and payment rates for these codes and this information would be finalized in the 2018 OPPS/ASC final rule with comment period.


CMS received the new and revised 2017 Category I and III CPT codes from the AMA in time for inclusion in the proposed rule. The final status indicators, APC assignments, and payment rates for the new CPT codes that will be effective January 1, 2017, can be found in Addendum B to this final rule with comment period. CMS responded to comments on the status indicators and APC assignments for these codes in section III.D. of this CY 2017 OPPS/ASC final rule with comment period. Because the CPT code descriptors in Addendum B are short descriptors, CMS included the long descriptors for the new and revised CPT codes in Addendum O.

B. OPPS Changes – Variations within APCs

1. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost item or service within an APC group is more than 2 times greater than the lowest cost item or service within that same group. In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers only those HCPCS codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant.

2. APC Exceptions to the 2 Times Rule

CMS may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria to decide whether to propose exceptions: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for upcoding and code fragments. CMS notes that in cases in which a recommendation by the Panel appears to result in or a violation of the 2 times rule, CMS generally accepts the Panel’s recommendations because the Panel’s recommendations are based on explicit consideration of resource use,
clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 9 in the proposed rule listed 4 APCs that CMS proposed to except from the 2 times rule for 2016 based on established criteria and based on claims data from January 1, 2015, through December 31, 2015 and processed on or before December 31, 2015. For the final rule, CMS uses claims data for dates of service from January 1, 2015 and December 31, 2015 that were processed on or before June 30, 2016 and updated CCRs, if available.

Based on the updated final rule CY 2015 claims data, CMS found 7 APCs with violations of the 2 times rule. CMS identified 4 additional APCs that meet the criteria for exception to the 2 times rule for this final rule with comment period that did not meet the criteria using proposed rule claims data.

After considering the public comments, CMS adopted its proposals with modifications. Table 9 found of the final rule lists 7 APCs that CMS is excepting from the 2 times rule for CY 2017.

C. New Technology APCs

1. Additional New Technology APC Groups

Currently, there are 48 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of “S” (S = Significant procedure, not discounted when multiple) and the other set with a status indicator of “T” (T = Significant procedure, multiple reduction applies). The New Technology APC levels range from the cost band assigned to APC 1491 (New Technology – Level 1A ($0 - $10)) through the highest cost band assigned to APC 1599 (New Technology – Level 48 ($90,001 - $100,000)). Payment for each APC is made at the mid-point of the APC’s assigned cost band.

CMS proposed to expand the New Technology APC groups by adding 3 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 proposed this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to another New Technology APC. CMS did not receive any comments on this proposal and is finalizing it without change. Table 10 on page 231 of the display copy of the final rule includes the new New Technology APC numbers, titles and cost bands.

2. Procedures Assigned to New Technology APC Groups for 2017

CMS is continuing its current policy to retain services within New Technology APC groups until it obtains sufficient claims data to justify reassignment of the service to a clinically appropriate APC. CMS notes, that in cases where it determines, based on additional information, that the initial New Technology APC assignment is no longer appropriate it will reassign the procedure or service to a different New Technology APC that more appropriately reflects its costs.
Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis. The retinal prosthesis device that is used in the procedure described by CPT code 0100T is described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components). Pass-through status was granted for HCPCS code C1841 beginning October 1, 2013 and expired on December 31, 2015. For 2016, the procedure described by C1841 was assigned to OPPS status indicator “N” (the payment for the procedure is packaged) and CPT code 0100T was assigned to APC 1599 (New Technology – Level 48 ($90,001 - $100,000)) with a 2016 OPPS payment of $95,000. This payment includes both the surgical procedure (CPT code 0100T) and the retinal prosthesis (HCPCS code C1841).

For 2017, CMS proposed to reassign the procedure described by CPT code 0100T from APC 1599 to APC 1906 (New Technology – Level 51 ($140,001 - $160,000) which has a proposed payment rate of approximately $150,000. CMS notes this proposal is based on both OPPS claims data and its further understanding of the retinal prosthesis implant procedure (the Argus® II procedure). Commenters generally supported CMS’ proposal related to the Argus® II New Technology APC assignment and CMS is finalizing the proposal without change.

D. OPPS APC-Specific Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups and their relative payment weights to take into account various factors including changes in medical practices, changes in technology, the addition of new services and new cost data. The Secretary is also required to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Panel recommendations for specific services for the 2017 OPPS and CMS’ responses are discussed throughout the final rule.

Addendum B to the final rule identifies with a comment indicator “CH” those HCPCS codes for which CMS is making a change to the APC assignment or status indicator. CMS states that in many cases, the reassignments and associated APC reconfigurations for 2017 are related to changes in costs of services that were observed in the 2015 claims data used for 2017 rate setting. CMS is also changing the status indicators for some codes because, based on new policies, CMS believes another status indicator more accurately describes their payment status. In addition, CMS is renaming existing APCs or creating new clinical APCs to complement HCPCS code reassignments.

1. Imaging Services

In 2016, as part of the comprehensive reviews of the structure of APCs, CMS restructured the APCs groupings for imaging services to better reflect the costs and clinical characteristics of the procedures within each APC. CMS agrees with recommendations from stakeholders and proposed further restructuring of the OPPS imaging APCs. The proposed restructuring would...
consolidate the imaging APCs from 17 APCs to 8 APCs. (Table 11 of the proposed rule showed the 2016 imaging APCs and Table 12 of the proposed rule showed the proposed 2017 imaging APCs.) The specific APC assignments for each service grouping were listed in Addendum B of the proposed rule. CMS noted that some of the imaging procedures are assigned to APCs that are not listed in tables in the proposed rule (e.g. vascular procedures APCs). In addition, nuclear medicine services APCs are not included in this proposal.

In the final rule, CMS modified its proposal in response to public comment by changing the title of the diagnostic radiology series of APCs to “Level […] Imaging” (either without contrast or with contrast) instead of “Diagnostic Radiology.” In addition, CMS received many code-specific comments requesting a different reassignment than CMS proposed. CMS changed the APC assignment for some of these codes but not for others. The final APC assignment for individual HCPCS codes can be found in Addendum B of the final rule.

In general, CMS responded to comments concerned that its APC reorganization would group clinically dissimilar procedures together by stating that the outpatient imaging procedure is generally performed by a technician (sometimes aided by a physician) who captures the images by operating one of the types of equipment used for x-ray, ultrasound, CT, or MR and it is not relevant to the structure of the APC groupings that physicians of different specialties interpret certain tests. APC groupings in general do not necessarily correspond to groupings of procedures that are performed by a given physician specialty. Some of the APC groupings resemble to some extent traditional physician specialty classifications (for example, the urology series of APCs), but many others do not. CMS believes that imaging services, which are diagnostic tests including x-rays, ultrasounds (including echocardiography), CT scans, and MRIs, are sufficiently clinically similar for APC grouping purposes.

Table 19 (page 293 of the display copy of the final rule) is a list of services requested to be reassigned to the next higher level imaging APC. The table shows the proposed and final 2017 APC and whether or not CMS agreed with the request. Table 20 (page 296 of the display copy of the final rule) is a list of services requested to be reassigned to non-imaging APCs. The table shows the proposed and final 2017 APC and whether or not CMS agreed with the request. Table 21 (page 301 of the display copy of the final rule) shows the final 2017 imaging APCs (number and title; 5521 – 5524 corresponding to Level 1–4 Imaging APCs without contrast and 5571 - 5573 corresponding to Level 1–3 Imaging APCs with contrast).

2. Strapping and Cast Application (APCs 5101 and 5102)

Based on review of procedures assigned to these APCs, CMS proposed to revise their status indicator assignment from “S” (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment) to “T” (Procedure or Service, Multiple Procedure Reduction Applies; Paid under OPPS; separate APC payment). CMS states that because the procedures assigned to APCs 5101 and 5102 are primarily associated with surgical treatments, it believes the proposed reassignment of these procedures to status indicator “T” is appropriate. CMS finalized its proposal without modification.
Public commenters generally opposed the status indicator reassignment from “S” to “T” stating that CMS did not provide substantive information for the proposed change; National Correct Coding Initiative (NCCI) guidelines prevent the reporting of casting/strapping services when performed as part of a surgical procedure; AMA CPT code instructions indicate that CPT codes 29700 through 29799 are only reported when the service is for a replacement procedure following a period of follow-up, or when the service is performed as the primary treatment without an associated restorative treatment or procedure(s).

CMS responded that the NCCI Policy Manual specifies that for payment under the OPPS, if a hospital treats a fracture, dislocation, or injury with a cast, splint, or strap as an initial service without any other definitive procedure or treatment, the hospital should report the appropriate casting/splinting/strapping CPT code. CMS further indicated that it does not discuss all APC coding changes in the preamble to the proposed rule but the changes are available to all public commenters in Addendum B of the final rule on the CMS website.

3. Transprostatic Urethral Implant Procedure

The procedure described by HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) is one of two procedure codes associated with the UroLift System, which is used to treat patients with benign prostatic hyperplasia (BPH). The procedure was assigned to the New Technology APC 1564 on April 1, 2014. For 2016, CMS assigned HCPCS code C9740 to New Technology APC 1565 (New Technology – Level 28 ($5,000 - $5,500) with a payment rate of $5,250).

For the 2017 update, the review of claims data for HCPCS code C9740 shows a geometric mean cost of approximately $6,312 based on 585 single claims. Based on this information, CMS proposed to reassign C9740 from APC 1565 to APC 5376 (Level 6 Urology and Related Services), which has a geometric mean cost of approximately $7,723.

Commenters generally supported CMS’ proposed policy and CMS finalized it without modification.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. CMS’ established policy is to base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device. (See below in this section for discussion of CMS’ finalized policy to base pass-through status expiration for a device category on the first date on which pass-through payment is made under the OPPS.) Further, except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the
costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates.

CMS finalizes the following device categories will continue to be eligible for pass-through payments in 2017:

- HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) was established effective April 1, 2015;
- HCPCS code C2613 (Lung biopsy plug with delivery system) was established effective July 1, 2015; and
- HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system) was established effective January 1, 2016.

For 2017, CMS will package the costs of the device described by HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) into the costs related to the procedures with which the device is reported in the hospital claims data.

2. New Device Pass-Through Applications

   a. Background

Criteria for New Device Pass-Through Applications

Existing regulations at §419.66(b)(1) through (b)(3) specify that, to be eligible for transitional pass-through payment under the OPPS a device must meet the following criteria:

1. If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meets another appropriate FDA exemption from premarket approval or clearance; and the pass-through application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in the US market availability in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

2. The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury to improve the functioning of a malformed body part; and

3. The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to §419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following:

1. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual; or

2. A material or supply furnished incident to a service (e.g. a suture, customized surgical kit, or a clip, other than a radiological site marker).
Separately, CMS also uses the following criteria established at §419.66(c) to determine whether a new category of pass-through devices should be established:

- Not appropriately described by an existing category or any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Has an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated as determined under §419.66(d) by demonstrating:
  1. The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices;
  2. The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and
  3. The difference between the estimated average reasonable cost of the device in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoblation, exempted from the cost requirements at §419.66(c)(3) and §419.66(e); and
- Demonstrates a substantial clinical improvement: substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

In 2016, CMS changed the OPPS device pass-through payment evaluation and determination process. Under the revised application process for device pass-through payments, applications are still submitted through the quarterly subregulatory process, but the applications will be subject to the notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. The current deadline for device pass-through payment applications continues to be the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the calendar year involved. CMS notes that the decision on an application that is submitted by the first business day in March would likely be presented in that calendar year’s OPPS proposed rule. Decisions on applications received after the first business day in March would be included in the OPPS proposed rule for the following calendar year. The process changes became effective January 1, 2016.

More details on the requirements for device pass-through applications are included in the application form on the CMS Web site at: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments?HospitalOutpatientPPS/passthrough_payment.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments?HospitalOutpatientPPS/passthrough_payment.html). CMS notes it is also available to meet with applicants or potential applicants to discuss research trial design in advance of submitting any application.

b. Applications Received for Device Pass-Through Payments for 2017

CMS received three applications by the March 1, 2016 quarterly deadline, the last quarterly deadline in time for the 2017 OPPS/ASC proposed rule. Applicants received for the remaining
2016 quarters (June 1, September 1, and December 1) will be presented in the 2018 OPPS/ASC proposed rule.

CMS does not approve device pass-through payment status for 2017 for the three applicants:
1. **BioBag®** (Larval Debridement Therapy in a Contained Dressing)
2. **Encore™ Suspension System**
3. **Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit**

The summary below provides a high level discussion of each application; readers are advised to review the final rule for more detailed information.

1. **BioBag® (Larval Debridement Therapy in a Contained Dressing)**

BioMonde US, LLC submitted an application for the BioBag® (Larval Debridement Therapy in a Contained Dressing), a biosurgical wound treatment consisting of disinfected, living larvae in a polyester net bag. The larvae remove dead tissue from wounds; BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds. The other similar product is “free-range” or uncontained larvae.

With respect to the newness criterion, the applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 38, 2013 and its March 1, 2016 application was within 3 years of FDA clearance. Although the applicant claims BioBag® is an integral part of wound debridement and is used for only one patient, in the proposed rule, CMS was concerned that BioBag® is a surgical supply similar to a surgical dressing that facilitates debridement and therefore, it would not be eligible for device pass-through payments.

In response to the manufacturer’s comments explaining that BioBag® is a treatment for active and physical wound debridement, but more like a sharp debridement, surgical debridement or water jet, CMS no longer considers the BioBag® as an ineligible supply for pass-through status. CMS also notes it has not identified an existing pass-through payment category that describes BioBag®.

With respect to the cost criterion, the applicant stated that BioBag® would be reported with CPT code 97603. This CPT code is assigned to APC 5051 with a payment rate of $117.83 and the device offset is $1.18. The price of BioBag® varies with the size of the bag ($375 to $435 per bag) and the bag size selected is based on the wound size. As discussed in the final rule, BioBag® meets all the three cost significance tests and satisfies the cost significance criterion.

With respect to the substantial clinical improvement criterion, CMS discusses the 18 articles submitted relating to wound debridement and comments it received. CMS concludes that it is not able to determine that BioBag® provides a substantial clinical improvement over other treatments for wound debridement.

2. **Encore™ Suspension System**

Siesta Medical, Inc. submitted an application for the Encore™ Suspension System, a kit of surgical instruments and implants that are used to perform an adjustable hyoid suspension. The Encore™ System is designed for hyoid bone suspension to the mandible bone using bone screws.
and suspension lines and is used for the treatment of mild or moderate sleep apnea and/or snoring, when the patient is unable to tolerate continuous positive airway pressure.

With respect to the newness criterion, the Encore™ System received FDA clearance through the section 510(k) process on March 24, 2014. In the proposed rule, CMS discussed how it considered several components of the Encore™ System to be either instruments or supplies, which are not eligible for pass-through. CMS noted that the only implantable devices in the kit are the bone screws, which are described by the existing HCPCS code C1713.

After consideration of the comments submitted by the manufacturer, CMS continues to believe that several components of the system are not eligible for pass-through and the implantable devices in the kit are described by the existing HCPCS code C1713.

With respect to the cost criterion, the applicant stated that the Encore™ System would be used in the procedure described by CPT code 21685. CPT code 21685 is assigned to APC 5164 with a 2016 payment rate of $1616.90 and the device offset is $15.85. The price of the Encore™ System is $2,200. As discussed in the proposed rule, based on the costs submitted by the applicant, the device meets all the three cost significance tests and satisfies the cost significance criterion. CMS was concerned, however, that the cost criterion would not be met “if based only on the kit components that are not supplies, not instruments, and not described by an existing category (if any)”. No comments were received related to the cost criterion, and CMS continues to have concerns that the cost criterion are not met.

With respect to the substantial clinical improvement criterion, in the proposed rule, CMS noted that the applicant did not provide any specific data addressing the substantial clinical improvement criterion. CMS was also concerned that based on information in the application, the Encore™ System is similar to the Medtronic AirVance System, another surgical kit used with CPT code 21685. CMS concluded that the clinical data provided by the applicant is insufficient to demonstrate substantial clinical improvement and invited comments.

CMS notes that commenters provided support for the system but did not provide any actual empirical clinical evidence. CMS continues to believe that there is insufficient evidence to demonstrate that the Encore™ System represents a substantial clinical improvement.

3. Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing Kit

Endophys Holdings, LLC submitted an application for the Endophys PSS, a stand-alone catheterization sheath that is inserted percutaneously during intravascular diagnostic or interventional procedures. The Endophys PSS is an introducer sheath with an integrated fiber optic pressure transducer for blood pressure monitoring; it is used with the Endophys Blood Pressure Monitor to display blood pressure measurements.

With respect to the newness criterion, the Endophys PSS received FDA clearance through the section 510(k) process on January 7, 2015. According to the applicant, the Endophys PSS is an integral part of several endovascular procedures, is used for one patient only, comes in contact with human skin, and is surgically implanted. Based on review of the application, CMS believes
that the device may be described by HCPCS code C1894 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser), which is consistent with the FDA section 510(k) Summary Product Description which describes the Endophys PSS as an introducer sheath with an integrated fiber optic pressure transducer. In the proposed rule, CMS concluded the Endophys PSS was described by the previously existing category of HCPCS code C1894 established for transitional pass-through payments.

One commenter, the manufacturer, disagreed with CMS’ conclusion that the Endophys PSS was described by C1894. The commenter also noted that the FDA had assigned a new product code to the Endophys PSS. In response, CMS notes that a new product code from the FDA, which is used by the FDA to classify and track a medical device, is not relevant to whether or not a device is described by an existing HCPCS C-code. CMS concludes that the Endophys PSS is appropriately described by the existing C-code.

With respect to the cost criterion, according to the applicant the Endophys PSS would be reported with CPT code 36620. CPT code 36620 is assigned status indicator “N” (which means its payment is packaged under the OPPS). The applicant also stated that its device can be used in many endovascular procedures that are assigned to APCs 5188, 5191, 5526, 5183, 5181, 5182, and 5291. CMS used APC 5291 for the cost calculations, which has a 2016 payment rate of $199.80 and the device offset of $3.38. According to the applicant, the cost of the Endophys PSS is $2,500. As discussed in the proposed rule, Endophys PSS met all the three cost significance tests and satisfies the cost significance criterion.

CMS continues to believe the Endophys PSS meets the cost criterion.

With respect to the substantial clinical improvement criterion, in the proposed rule CMS noted that the applicant provided minimal direct clinical data to support substantial clinical improvement.

CMS acknowledges the submission of a new study by the manufacturer and public comments supporting the technology. CMS believes that additional trials are needed to demonstrate the reduction of complication rates with the use of the Endophys PSS and does not believe the submitted study supports a definitive conclusion that the device provides substantial clinical improvement.

3. Beginning Eligibility Date for Device Pass-Through Payment Status

The pass-through payment eligibility period currently begins on the date CMS establishes a category of devices. CMS finalizes its proposal to amend § 419.66(g) to provide that the pass-through eligibility period would begin on the first date on which pass-through payment is made. It notes that this change is unlikely to affect the pass-through expiration date, but could result in an expiration date that is later than it otherwise would have be in cases of significant delay from the date of establishment of a pass-through category to the date of the first pass-through payment. CMS notes this policy allows for more robust data collection for the purposes of setting future APC rates to accurately include the device costs. Commenters agreed.
4. Making the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Devices and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

By statute, transitional pass-through payments are made for a period of at least 2 years, but not more than 3 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 devices on a quarterly basis. Pass-through status, however, currently expires on a calendar-year basis through notice-and-comment rulemaking. Device pass-through status expires at the end of a calendar year when at least 2 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 device depends on the quarter of initial eligibility for pass-through payment. A new pass-through device with pass-through status effective on April 1 would receive 2 years and 3 quarters of pass-through status while a pass-through device with pass-through status effective on October 1 would receive 2 years and 1 quarter of pass-through status.

CMS finalizes its proposal, beginning with pass-through devices newly approved in 2017, to allow for a quarterly expiration of pass-through status for devices to provide for a pass-through period that is as close to a full 3 years as possible for all pass-through payment devices. Under this policy pass-through status would expire on September 30, 2020 for a device with pass-through payment first effective on October 1, 2017.

In response to a commenter’s concerns that CMS would adjust payment rates mid-year, CMS notes it does not generally adjust payment rates mid-year and doesn’t anticipate doing so under this policy. CMS explains that while the device maintains pass-through payment status, it reduces the APC payment by the device offset and adds the device pass-through payments. When a device pass-through payment status expires, hospitals will bill for and receive the full APC payment, which includes packaged device costs. In response to commenters requesting CMS to implement the proposed policy retroactively, CMS notes the policy will apply to pass-through devices newly approved in 2017.

5. Changes to Cost-to-Charge Ratios (CCRs) That Are Used to Determine Device Pass-Through Payment

Currently, transitional pass-through payments for devices are calculated by taking the hospital charges for each billed device, reducing them to cost by use of the hospital’s average CCR across all outpatient departments, and subtracting an amount representing the device cost contained in the APC payments for procedures involving that device (65 FR 18481 and 65 FR 67809). To address the effects of charge compression, in the FY 2009 IPPS final rule CMS created a cost center for “Medical Supplies Charged to Patients,” which includes primarily low cost supplies, and another cost center for “Implantable Devices Charged to Patients,” which typically includes high-cost implantable devices.

Responding to a request to consider using the “Implantable Devices Charged to Patients” CCR in the calculation of device pass-through payment, CMS analysis found that about two-thirds of providers report an “Implantable Devices Charged to Patients” CCR and that these hospitals
have a median “Implantable Devices Charged to Patients” CCR of 0.3911 compared to a median hospital-wide CCR of 0.2035. Based on this finding, CMS proposed to use the more specific “Implantable Devices Charged to Patients” CCR instead of the less specific average hospital-wide CCR to calculate transitional pass-through payments for devices, beginning with device pass-through payments in 2017.

After consideration of public comments, CMS finalizes its proposal to use the “Implantable Devices Charged to Patients CCR instead of the average hospital-wide CCR to calculate transitional pass-through payments for devices beginning with device pass-through payments in 2017. If the CCR for the “Implantable Devices Charged to Patients” CCR is not available for a particular hospital, CMS will use the hospital-wide CCR to calculate pass-through payments.


As required by statute to avoid duplicative payment, CMS deducts from the charges adjusted to cost for the device, an amount that reflects the portion of the APC payment amount that it determines is associated with the cost of the device, defined as the device APC offset amount. To determine the offset amount for the eligible device, CMS uses claims data from the period for the most recent recalibration of the APC rates. CMS updates the applicable device APC offset amounts for eligible pass-through device categories through transmittals that implement the quarterly OPPS updates.

For 2017, CMS finalizes its proposal to calculate the device offset amounts for each device-intensive procedure at the HCPCS code level rather than at the APC level (which is an average of all codes assigned to an APC). This policy is discussed in section IV.B below. The list of device offsets for all device procedures will be posted on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

B. Device-Intensive Procedures

Device-intensive APCs are defined as APCs with a device offset greater than 40 percent (79 FR 66795); the device costs of all procedures within the APC are calculated as well as their geometric mean device offset, which must exceed 40 percent. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs (see discussion below). CMS requires that procedures assigned to certain APCs (formerly device-dependent) require the reporting of a device code on the claim.

1. HCPCS Code-Level Device-Intensive Determination

CMS adopts its proposal to assign device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. All procedures requiring the implantation of a medical device and having an individual HCPCS code-level device offset of greater than 40 percent would be identified as device-intensive and would be subject to the device edit and no cost/full credit and partial credit device policies.
For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, CMS finalizes applying a device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. CMS also finalizes that in certain rare instances, such as in the case of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.

In response to comments, CMS notes that additional information for CMS to use for its consideration of an offset percentage higher than the default of 41 percent, such as pricing data or invoices from a device manufacturer, should be sent to the Division of Outpatient Care or electronically to outpatientpps@cms.hhs.gov. Additional information can also always be submitted in response to a OPPS/ASC proposed rule. In response to a commenter raising concerns about devices that did not have a specific HCPCS code, CMS notes it is creating a new category HCPCS C-code (described below in this section) for providers to report when a device implantation or insertion procedure uses a device that is not described by a specific C-code in order for these device intensive procedures to satisfy the device edit policy.

The full listing of device-intensive procedures is posted at the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

2. Changes to Device Edit Policy

In the 2015 OPPS/ASC final rule, CMS relaxed its device claims processing edits to require simply that any device code used in prior device-to-procedure edits be included on a claim whenever a procedure code assigned to any of the APCs (formerly device-dependent APCs) identified by CMS were reported on a claim. For 2016, CMS further revised its policy and applied the device code reporting requirements to procedures assigned to all APCs that meet the device-intensive definition, not just the subset of such APCs that also were previously device-dependent APCs.

For 2017, CMS finalizes its proposal to apply the device claims editing policy on a procedure level rather than APC level, consistent with its finalized 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.

In addition, after consideration of a comment, CMS is creating HCPCS code C1889 to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. Any device code, including C1889, when reported on a claim with a device-intensive procedure, will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

3. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

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6 Division of Outpatient Care, Mail Stop C4-01-26, CMS, 7500 Security Boulevard, Baltimore, MD 21244-1850
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 in the amount portion for 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 also limits the total amount of the device offset when the “FD” value code appears on a claim. CMS specifies a list of costly devices to which this APC payment adjustment would apply. For 2017, CMS will continue the existing policy of reducing OPPS payment when a hospital furnishes a specified device without cost or with a full or partial credit.

In 2015 and prior years, CMS specified a list of costly devices to which this APC payment adjustment applied. For 2016, CMS applied the APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC (listed in Table 42 of the 2016 OPPS/ASC final rule) when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device. For 2017, CMS finalizes its proposal to identify the services to which the adjustment would apply using the newly defined set of device-intensive procedures – i.e., procedures with an individual HCPCS level device offset greater than 40 percent, as described above.

CMS will also continue using the three criteria established in the 2007 OPPS/ASC final rule for determining the procedures to which the 2017 device-intensive policy will apply. Specifically, for 2017, (1) all procedures must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient’s body after the conclusion of the procedure (at least temporarily); and (3) the procedure must be device-intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the procedure’s mean cost.

4. Payment Policy for Low Volume Device-Intensive Procedures

For 2016, CMS used its equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost rather than the geometric mean cost to calculate the payment rate for the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal or crystalline lens or intraocular lens prosthesis). The procedure is the only code assigned to APC 5494 (Level 4 Intraocular Procedure). CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs), and CMS concluded that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. The median cost for 2016 of the procedure described by CPT code 0308T is $18,365 and the geometric mean cost is $13,833.

CMS finalizes its proposal that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC will be calculated using the median cost instead of the geometric mean cost.
For 2017, CMS reassigns the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). CMS notes it will be the only procedure code assigned to APC 5495 and it will continue to determine the payment rate using median cost. The final 2017 payment rate, calculated using the median cost, is approximately $18,984.

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals and Radiopharmaceuticals

1. Making the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Expire Pass-Through Status on a Quarterly Rather Than Annual Basis

By statute, transitional pass-through payments are made for a period of at least 2 years, but not more than 3 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 devices on a quarterly basis. Pass-through status, however, currently expires on a calendar-year basis through notice-and-comment rulemaking. As with devices, pass-through status for drugs, biologicals, and radiopharmaceuticals expires at the end of a calendar year when at least 2 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, biological, or radiopharmaceutical depends on the quarter of initial eligibility for pass-through payment. A new pass-through item with pass-through status effective on January 1 would receive 3 years of pass-through payment; one effective on April 1 would receive 2 years and 3 quarters of pass-through payment; while one with pass-through status effective on October 1 would receive 2 years and 1 quarter of pass-through payment.

As described in section IV.A.4. above for devices, CMS proposed, beginning with pass-through drugs, biologicals, and radiopharmaceuticals newly approved in 2017, to allow for a quarterly expiration of pass-through status for devices to provide for a pass-through period that is as close as possible to a full 3 years all pass-through payment drugs, biologicals, and radiopharmaceuticals. Under the proposal, pass-through status would expire on September 30, 2020 for a drug, biological, or radiopharmaceutical with pass-through payment first effective on October 1, 2017. CMS invited public comment on this proposal.

Public commenters supported the proposal. CMS finalized this proposal without modification. The new policy will apply to all drugs, biologicals and radiopharmaceuticals that are newly approved in 2017 for pass-through status. CMS declined a commenters’ request to apply the new policy to drugs, biologicals and radiopharmaceuticals already receiving pass-through payment as of January 1, 2017.

2. Drugs and Biologicals with Expiring Pass-Through Payment Status in 2017

CMS finalized it proposal to terminate the pass-through payment status for the 15 drugs and biologicals effective January 1, 2017. By that date, all of these drugs and biologicals will have
received OPPS pass-through payment for at least 2 years and not more than 3 years. These items were approved for pass-through status on or before January 1, 2015. Except for the policy-packaged drugs, which are drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS makes a separate payment if the product’s estimated per day cost exceeds the OPPS drug packaging threshold, which will be $110 for 2017. The “policy-packaged drugs” are: 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).

CMS did not receive any public comments on its proposal. Table 35 of the final rule includes a list of those drugs and biologicals with expiring pass-through payment status in 2017. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the final rule (which is available on the CMS website).

3. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in 2017

CMS finalized its proposal with modification to continue pass-through status in 2017 for 38 drugs, biologicals and radiopharmaceuticals. None of these products will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2016.

For 2017, CMS will continue to pay for drugs and biologicals with pass-through status at average sales price plus 6 percent (ASP+6). For purposes of pass-through payment, CMS considers radiopharmaceuticals to be drugs under the OPPS and therefore also sets the payment rate for them at ASP+6; if ASP data are not available for a radiopharmaceutical, CMS provides pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, CMS provides payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

CMS will continue to update the list of pass-through drugs on a quarterly basis on the CMS website during 2017 to reflect newly approved pass-through drugs and biologicals as well as to adjust payment rates for pass-through drugs as necessary based on later quarter ASP submissions (or more recent WAC or AWP information, as applicable).

CMS will continue its policy that the pass-through payment portion of the total drug payment is the difference between the pass-through payment rate of ASP+6 percent and the 2017 payment rate that CMS sets for non-pass-through, separately payable drugs. Except for the policy-packaged drugs, the pass-through portion is zero since CMS pays both pass-through and non-pass-through drugs at ASP+6 percent. For policy-packaged drugs, their pass-through payment amount would be equal to ASP+6 percent for 2017 because, if not for having pass-through status, payment for these products would be packaged into the associated procedure. Public comments supported CMS’ proposals. One commenter requested that CMS make additional payments to radiopharmaceuticals. CMS did not adopt this request.
Table 36 of the final rule lists the items, which were approved for pass-through status between January 1, 2014 and July 1, 2016. Pass-through drugs and biologicals are identified by status indicator “G” in Addenda A and B.

4. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

When non-pass-through drugs, biologicals, and radiopharmaceuticals function as supplies for a diagnostic test or procedure, they are packaged under the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Similarly, when non-pass-through drugs and biologicals function as supplies in a surgical procedure, such as skin substitutes and other surgical-supply drugs and biologicals, they are packaged under the OPPS.

Therefore, a payment offset is necessary in order to provide an appropriate transitional pass-through payment since the statute specifies that the transitional pass-through payment amount is the difference between the amount paid under section 1842(o) of the Act (i.e., ASP + 6 percent) and the otherwise applicable OPD fee schedule amount. CMS deducts from the pass-through payment for policy packaged drugs, biologicals, and radiopharmaceuticals an amount – the payment offset – reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals.

For 2017, CMS finalized its proposal to continue to apply the current offset policies for all of the “policy-packaged” drugs, biologicals, and radiopharmaceuticals. CMS refers readers to the discussion in the 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432) for a full description of the payment offset policy.

CMS will continue to post annually on the its website a file with the APC offset amounts to be used for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts. See [https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/2017-OPPS-HCPCS-Device-Offset.zip](https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/2017-OPPS-HCPCS-Device-Offset.zip)

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: packaged into the payment for the associated service; or separate payment (individual APCs). Hospitals do not receive a separate payment for packaged items and hospitals may not bill beneficiaries separately for any packaged items: these

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7 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).
costs are recognized and paid within the OPPS payment rate for the associated procedure or service.

Cost Threshold for Packaging of “Threshold-Packaged Drugs”

CMS finalizes its proposed policy without modification. As background, “threshold-packaged drugs” under the OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug’s average cost per day exceeds the annually determined packaging threshold, it is separately payable and, if not, it is packaged. For 2016, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status is $100.

To calculate the final rule 2017 threshold, CMS used the most recently available four quarter moving average Producer Price Index (PPI) forecast levels for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from the CMS’ Office of the Actuary (OACT) to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2017 and rounded the resulting dollar amount ($111.65) to the nearest $5 increment, which yielded a figure of $110. Based on this calculation, CMS is finalizing a packaging threshold for 2017 of $110.

For the final rule, CMS determined 2017 packaging status for all non-pass-through drugs and biologicals that are not policy packaged (with the exception of those drugs and biologicals with multiple HCPCS codes described below). Using 2015 claims data processed before January 1, 2016, CMS calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called “threshold-packaged” drugs) that had a HCPCS code in 2015 and were paid (either as packaged or separate payment) under the OPPS.

To calculate the per day cost, CMS used an estimated payment rate of ASP+6 percent for each HCPCS code. CMS used the manufacturer-submitted ASP data from the fourth quarter of 2015 (data that were used for payment purposes in the physician’s office setting effective April 1, 2016). For products that do not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS used their mean unit cost derived from the 2015 hospital claims data. CMS is packaging products with a per day cost of less than or equal to $110 and pay separately for items with a per day cost greater than $110 in 2017.

CMS continues to use quarterly ASP updates as follows:

- 4th quarter of 2015: budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2017 OPPS proposed rule;
- 1st quarter of 2016: budget neutrality estimates, packaging determinations, and impact analyses for the 2017 OPPS final rule;
- 2nd quarter of 2016: payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the 2017 OPPS final rule; and
3rd quarter of 2016: payment rates effective January 1, 2017 for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B; these are the same ASP data used to calculate payment rates effective January 1, 2017 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings are updated quarterly using quarterly reported ASP data with a two-quarter lag, and these updates are available on the CMS website. CMS proposed to continue its policy of making an annual packaging determination for a HCPCS code for the OPPS final rule and not updating that code’s packaging status during the year. Only HCPCS codes which are identified as separately payable in this final rule are subject to quarterly updates.

As in past years, CMS is continuing to apply the following policies to determine the 2017 final rule packaging status of a threshold-packaged drug when the drug’s packaging status as calculated for the final rule using more current data, differs from its status in the proposed rule.

- HCPCS codes that were separately payable in 2016 and were proposed for separate payment in 2017 are separately payable in 2017 even if the updated data used for the 2017 final rule indicate per day costs equal to or less than the $110 threshold.
- HCPCS codes that were packaged in 2016, proposed for separate payment in 2017, and have per day costs equal to or less than $110 based on the updated data used for the 2017 final rule are packaged in 2017.
- HCPCS codes for which CMS proposed packaged payment in 2017 but have per day costs greater than $110 based on the updated data used for the 2017 final rule are separately payable in 2017.

CMS received similar public comments that it has in the past specifically requesting that particular items be exempted from policy packaging (Lexiscan®, Omidria®, and Cysview). CMS explained why it believes these items meet the criteria for policy packaging and, as stated above, is finalizing its proposed policy without change.

**High/Low Cost Threshold for Packaged Skin Substitutes**

In the 2014 OPPS final rule, CMS unconditionally packaged skin substitute products into the associated surgical procedures, including a methodology that divided skin substitutes into a high-cost group and a low-cost group for packaging purposes. Skin substitutes in the high-cost category are reported with the skin substitute CPT codes and skin substitutes in the low-cost category are reported with the analogous skin substitute HCPCS C-codes. CMS continued this policy, with modifications, in 2015 and 2016. For a discussion of the 2016 high cost/low cost methodology, CMS refers readers to the 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435).

For 2017, as in 2016, CMS finalized as proposed without a policy to determine the high/low cost status for each skin substitute product based on either a product’s geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product’s per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of
days) exceeding the PDC threshold. Based on 2015 claims data available for the proposed rule, CMS calculated a proposed 2017 MUC threshold of $25 per cm\(^2\) (rounded to the nearest $1) and a proposed 2017 PDC threshold of $729 (rounded to the nearest $1). The final CY 2017 MUC threshold is $33 per cm\(^2\) (rounded to the nearest $1) and the final CY 2017 PDC threshold is $716 (rounded to the nearest $1).

CMS continues to assign skin substitutes with pass-through payment status to the high cost category. Skin substitutes with pricing information but without claims data to calculate a MUC or PDC are assigned to either the high cost or low cost category based on the product’s ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, CMS uses WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. New skin substitutes without pricing information are assigned to the low-cost category until pricing information is available to compare to the 2016 MUC threshold.

Table 37 in the 2017 final rule shows the high/low cost status for each skin substitute product in 2017. CMS assigns a skin substitute to the high cost group for 2017 if it was assigned to the high cost group in 2016 and exceeds either the MUC or PDC in the 2017 proposed rule even if it no longer exceeds the MUC or PDC 2017 thresholds based on updated claims data and pricing information used in the 2017 final rule. CMS received a public comment that the proposed rule MUC threshold was incorrect. CMS agreed with the comment and recalculated the MUC threshold but disagreed with the commenter that a product incorrectly assigned to the high-cost category in the proposed rule because of the error should be moved to the low-cost in the final rule. CMS’ response indicates that such an action would be inconsistent with the policy rule described above. CMS makes no changes in the final rule based on public comments.

**Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages**

For 2017, CMS continues its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, in the case of multiple HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy applies, and their packaging status, are listed in Table 38 of the final rule.

2. **Payment for Drugs and Biologicals without Pass-Through Status that Are Not Packaged**

For 2017, CMS finalized as proposed its policy to continue to pay separately payable drugs and biologicals at ASP+6 percent. This payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. CMS also will continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler). Following established policy, it does not, however, apply the budget neutral weight scaler in determining payments for these separately paid drugs and biologicals due to the statutory requirement that their payments are to be based on acquisition costs.

The payment rates shown for drugs and biologicals in Addenda A and B of the final rule will be updated through the quarterly update process to reflect the actual payment rates that will be used
beginning January 1, 2017. Payment rates effective January 2017 will be released near the end of December 2016 and will be based on ASP data submitted by manufacturers for the third quarter of 2016 (July 1, 2016 through September 30, 2016). Payment rates for drugs and biologicals in Addenda A and B to this final rule for which there was no ASP information available for October 2016 are based on mean unit cost in the available 2015 claims data. If ASP information becomes available for payment for the quarter beginning in January 2017, CMS will price payment for these drugs and biologicals based on the newly available ASP information. For drugs and biologicals that have ASP information available for this final rule (reflecting October 2016 ASP data) that do not have ASP information available for the quarter beginning in January 2017, payment will be paid based on mean unit cost data derived from 2015 hospital claims.

### Biosimilar Biological Products

For 2017, CMS is continuing its established policies for biosimilar biological products without change. For 2016, CMS established policies pertaining to biosimilar biological products under the OPPS: 1) to pay for biosimilar biological products under the OPPS based on the payment allowance of the product as determined under section 1847A(b)(8) of the Act, as provided by the Affordable Care Act; 2) to determine the packaging status of non-pass-through biosimilar biological products using the threshold-packaged drug policies as they apply to other products; and 3) to extend pass-through payment eligibility to biosimilar biological products and to establish the pass-through payment amount applying the policies applicable to other pass-through drugs, biologicals and radiopharmaceuticals. For 2016, CMS also proposed and finalized a policy that HCPCS coding and modifiers for biosimilar biological products would be based on policy established under the 2016 MPFS rule.

3. **Payment Policy for Therapeutic Radiopharmaceuticals**

As proposed for 2017, CMS is continuing to pay for all non-pass-through, separately payable therapeutic radiopharmaceuticals under the same ASP methodology that is used for separately payable drugs and biologicals, i.e. ASP+6 percent, when all manufacturers of a product submit the necessary ASP information for a “patient ready” dose. The payment rate is updated quarterly using the most recently available ASP data reported by manufacturers. Reporting ASP information remains optional for manufacturers. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS will determine 2017 payment rates based on 2015 geometric mean unit cost data derived from 2015 hospital claims data.

4. **Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources**

For 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources for a time period not to exceed 5 years (77 FR 68323). CMS indicated that it would evaluate annually the continuing need and amount of this transitional payment. For the 2017 proposed and now final rule, CMS reassessed the $10 additional payment amount and did not identify any new information to cause a payment change. Thus, CMS will continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources. In response to a comment, CMS indicated it does not provide for an annual
inflation update to its $10 payment for radioisotopes produced by non-HEU sources because it does not have any data or basis upon which to determine an inflation update.

5. Payment for Blood Clotting Factors

As proposed for 2017, CMS is continuing to pay for blood clotting factors using the same methodology that it uses to pay other non-pass-through separately payable drugs and biologicals under the OPPS, i.e. ASP+6 percent. CMS will update the 2016 furnishing fee ($0.202 per unit) based on the percentage increase in the Consumer Price Index (CPI) for medical care following the same methodology it has used since 2008. For 2017, the updated amount will be based on the percentage increase in the CPI for medical care for the 12-month period ending in June 2016. Because this information was not available in the final rule, CMS will announce the actual fee through program instructions and will post the updated rate on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee.html.

When blood clotting factors are provided in physicians’ offices under Medicare Part B and in other Medicare settings, a furnishing fee also is applied to the payment.

6. Payment for Non-pass-through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPPS Hospital Claims Data

As proposed for 2017, CMS is continuing to use the same payment policy as in 2016 for non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. The 2017 payment status of each of the non-pass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to the final rule, which is available on the CMS website.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

The final rule estimate for total pass-through spending for drug and device pass-through payments during 2017 is approximately $150.6 million, or 0.24 percent of total OPPS projected payments for 2017, which is less than the applicable pass-through payment percentage statutory limit of 2.0 percent.

A. Devices

Using its established methodology, CMS projects $112.7 million in pass-through spending attributable to device categories in 2017. CMS’ estimates did not change from the proposed rule and there were no public comments on them. The final rule estimate for the first group of items (i.e., those device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in 2017) is $102.7 million as follows:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Code Descriptor</th>
<th>Effective Date</th>
<th>Total (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Code Descriptor</td>
<td>Effective Date</td>
<td>Total (in millions)</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>C2623</td>
<td>Catheter, transluminal angioplasty, drug-coated, non-laser</td>
<td>4/1/2015</td>
<td>$97</td>
</tr>
<tr>
<td>C2613</td>
<td>Lung biopsy plug with delivery system</td>
<td>7/1/2015</td>
<td>$4.7</td>
</tr>
<tr>
<td>C1822</td>
<td>Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system</td>
<td>1/1/2016</td>
<td>$1.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>$102.7</strong></td>
</tr>
</tbody>
</table>

CMS estimates $10 million for the second group of device categories which consists of those device categories CMS knows or projects may be approved for pass-through status in 2017, and includes contingent projections for new device categories in 2017. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for the second group.

**B. Drugs and Biologicals**

For the final rule, CMS calculates a pass-through spending estimate of $37.9 million in 2017 attributable to drugs and non-implantable biologicals in the two groups described below. CMS considers radiopharmaceuticals as drugs for pass-through purposes and includes them in their estimates for drugs and biologicals.

The estimate for the first group of drugs and non-implantable biologicals is $20.2 million. The first group consists of drugs and biologicals recently eligible for pass-through payments that will continue for 2017. CMS projects utilization based on the most recent Medicare physician claims data, information in pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information.

The estimate for the second group of drugs and non-implantable biologicals is $17.7 million. The second group consists of those drugs and biologicals CMS knows or projects could be approved for pass-through status in 2017, and includes contingent projections for new drugs and non-implantable biologicals that could initially be eligible in 2017. CMS projects utilization for this group using estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity. CMS also considers recent OPPS experience in approving new pass-through drugs and biologicals.

Because CMS pays for most non-pass-through separately payable drugs and biologicals and all pass-through drugs and biologicals at the same rate (ASP+6 percent), its estimates for this group of items is zero. However, the estimate of pass-through payment amounts for diagnostic radiopharmaceuticals and contrast agents with pass-through status is not zero because they are paid at ASP+6 percent in lieu of being packaged into associated procedures as is the case for non-pass-through radiopharmaceuticals and contrast agents. Additionally, if CMS determines that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated
with the drug receiving pass-through payment, it will offset the amount of pass-through payment for the policy-packaged drug or biological and also provide for a corresponding reduction in the estimate of pass-through payments for those drugs or biologicals.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

CMS proposed no changes to the current clinic and emergency department (ED) hospital outpatient visits payment policies, described in the 2016 OPPS/ASC final rule (80 FR 70448) or to the payment policy for critical care services also described in that rule (80 FR 70449). CMS did not receive any public comments requesting changes to its OPPS rates for hospital outpatient visits and critical care services.

VIII. Payment for Partial Hospitalization Program (PHP) Services

A. PHP APC Update for 2017

For 2017, CMS finalizes its proposals for the calculation of the partial hospitalization program (PHP) APC per diem payment rates for Community Mental Health Centers (CMHCs) and for hospital-based PHPs. Specifically, for PHP services furnished in 2017, CMS combines the Level 1 and Level 2 PHP APCs for CMHCs and the Level 1 and Level 2 APCs for hospital-based PHPs. For CMHCs, APC 5853 replaces APCs 5851 and 5852, and for hospital-based PHPs, APC 5863 replaces APCs 5861 and 5862. Thus, the payment rate by provider type will be the same whether the provider furnishes 3 or 4 or more PHP services per day.

CMS believes that this policy best reflects actual geometric mean per diem costs going forward, given the small number of CMHCs, and it will generate more appropriate payments for these services by avoiding the cost inversions that hospital-based PHPs experienced in the 2016 OPPS/ASC final rule (80 FR 70459). The agency also believes the statute and regulations support the single APC policy to ensure that PHP services are paid appropriately based on actual provider costs. CMS calculates the PHP APC per diem payment rates for 2017 based on geometric mean per diem costs using updated 2015 final claims data for each provider type.

CMS reiterates that the cost inversions between PHP APC Level 1 and Level 2 service days in the hospital-based PHP claims data and the small number of CMHCs are the two primary reasons for its policy to replace the two-tiered PHP APCs with a single PHP APC for each provider type. A cost inversion exists when the Level 1 PHP APC geometric mean per diem cost for providing exactly 3 services per day exceeds the Level 2 PHP APC geometric mean per diem cost for providing 4 or more services per day. This issue occurred in the calculation of the 2016 OPPS/ASC rates for hospital-based PHP providers, for which CMS made an adjustment, and would have occurred in 2017, if the 2016 policy was maintained. By combining these levels, CMS believes this will reduce cost fluctuations and provide more stability in the geometric mean per diem costs.

The final costs are contained in Table 41 of the final rule (reproduced below).
TABLE 41. 2017 PHP APC GEOMETRIC MEAN PER DIEM COSTS

<table>
<thead>
<tr>
<th>2017 APC</th>
<th>Group Title</th>
<th>PHP APC Geometric Mean Per Diem Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>5853</td>
<td>Partial Hospitalization (3 or more services per day) for CMHCs</td>
<td>$124.92</td>
</tr>
<tr>
<td>5863</td>
<td>Partial Hospitalization (3 or more services per day) for hospital-based PHPs</td>
<td>$213.14</td>
</tr>
</tbody>
</table>

Note: The final CMHC geometric mean per diem cost is lower than that calculated for the proposed rule ($135.30), but the final hospital-based geometric mean per diem cost is higher than that calculated for the proposed rule ($192.57).

Some commenters worried that the combined PHP APCs might create an incentive to reduce services with providers providing only 3 services per day but receiving a payment more heavily weighted towards 4 services per day. CMS responds that it monitored utilization of 3-service days and found them to be "appropriately infrequent". For example, 2015 claims data show that only 5 percent of CMHC paid days and 12 percent of hospital-based PHP paid days show that exactly 3 services were provided. CMS also notes what it refers to as its longstanding eligibility requirement under §§410.43(a)(3) and (c)(1) that PHP beneficiaries require a minimum of 20 hours per week in services per the plan of care. CMS has stated in several earlier regulations that a typical PHP includes 5 to 6 hours per day (e.g., 70 FR 68548, 71 FR 67999, 72 FR 66671, and 73 FR 68687). CMS plans to monitor PHP claims beginning in January 2017 to determine whether PHP participants are receiving at least 20 hours per week in partial hospitalization services as well as to determine whether there is an increase in 3-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 is also 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. CMS also intends to work with its MACs to better educate providers on PHP requirements. CMS 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; **it 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.**

For 2017, the outpatient mental health treatment cap will equal the combined hospital-based PHP rate under APC 5863. The outpatient mental health treatment cap limits the maximum payment for a day of individually billed outpatient mental health services. CMS' rationale for this policy is that the costs of administering a PHP represent the most resource-intensive of all outpatient
mental health treatment services; thus it would be inappropriate to pay more for a day of individually billed outpatient mental health services.

CMS considered several other alternatives to its proposal. CMS did not believe that maintaining the 2016 policy was appropriate given the potential cost inversion issues. Further, CMS considered combining only the two-tiered PHP APC structure for the provider type with inverted data, but it believes that providers would prefer the predictability of knowing whether they are paid using a single PHP APC or using two-tiered PHP APCs for Level 1 and Level 2 services. CMS also considered whether to apply an adjustment if cost inversion occurs, but it believes that providers prefer predictability rather than ad hoc adjustment.

Commenters requested that CMS delay implementation of the 2017 per diem payment rates or freeze the rates at the 2016 level; CMS declines to do so. Some commenters noted that the lack of a standardized PHP cost center on the Medicare cost report may be creating some cost-finding issues. CMS agrees that if PHP costs are combined with other less intensive outpatient mental health treatment costs in the same cost center, the CCR could be diluted; it will analyze the issue further and consider adding a cost center to the hospital cost report uniquely for PHP costs.

CMS completed an extensive analysis of PHP claims and cost data using final 2015 data, including provider service usage, coding practices and ratesetting methodology, and the agency identified aberrant data (defined as data so abnormal that they skew the resulting geometric mean per diem costs) from CMHCs and hospital-based providers which it excluded from the calculation of the PHP geometric mean per diem costs. CMS finalizes its proposal to continue its policy to exclude data from any CMHC when the CMHC’s costs are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs and to exclude hospital-based PHP services days when a CCR greater than 5 (CCR>5) is used to calculate costs for at least one of the component services.

CMS reminds PHP providers that services of physicians, clinical psychologists, clinical nurse specialists, nurse practitioners, and physician assistants will continue to be billed separately as professional services; costs for these services are not PHP service costs. Instead, payment for PHP services represents the provider’s overhead, support staff and services of clinical social workers and occupational therapists.

CMS also provides a detailed description of the PHP ratesetting process to improve transparency and understanding of the steps it takes to calculate the geometric mean per diem costs and rates by provider type. CMS encourages CMHCs and hospital-based PHPs to review their accounting and billing processes to ensure greater accuracy in the procedures for calculating costs and rates for PHPs.

**B. Outlier Policy for CMHCs**

CMS did not receive any comments on its proposals for its CMHC outlier policy and outlier cap, and it finalizes them without modification.

1. **Estimated Outlier Threshold**
For 2017, CMS designates less than 0.01 percent of the estimated 1.0 outlier target amount specifically for CMHCs for PHP outliers. This is consistent with the percentage of projected payments to CMHCs under the OPPS in 2017. CMS will set the outlier threshold for CMHCs for 2017 at 3.4 times the highest CMHC PHP APC payment rate (new CMHC PHP APC 5853), and to pay 50 percent of CMHC per diem costs over the threshold. Specifically, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC’s cost for the services and the product of 3.4 times the APC 5853 payment rate. CMS does not set a dollar threshold for CHMC outlier payments as it applies to other OPPS outlier payments.

2. **CMHC Outlier Cap**

CMS reiterates its concern that outlier payments are largely benefiting a small number of CMHCs. This suggests that outlier payments are not being used as intended for exceptionally high cost patients, but instead as a routine supplement to the per diem payment. CMS’ analysis of 2015 claims data showed that Medicare paid CMHCs $3.2 million in outlier payments, with over 99 percent of those payments made to 4 CMHCs. CMS notes its belief that these excessive outlier payments to some CMHCs are the result of inflated costs, which result from artificially inflated charges. While CMS has efforts geared towards limiting very high outlier payments, such as the outlier reconciliation process, these efforts are typically made after the outlier payments are made.\(^8\)

Given these program integrity concerns, CMS finalizes its proposal to implement a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments. The CMHC outlier payment cap will be set at 8 percent of the CMHC’s total per diem payments for that same calendar year. CMS simulated the effect of varying outlier cap percentage options (see Table 42 in final rule) and found that 8 percent would have the intended effect of reducing outlier payments to those CMHCs with excessive outlier payments, while not harming those CMHCs with more reasonable outlier payment amounts. CMS notes that its existing outlier reconciliation policy continues to remain in effect with the CMHC outlier payment cap serving as a complement. This policy is included in §419.43(d)(7) of the regulations.

CMS will provide detailed information on its implementation strategy for the outlier payment cap through sub-regulatory channels. However, CMS provides a summary of how this will work with its claims processing system. Specifically, for each CMHC, the claims processing system will maintain a running tally of the year-to-date total CMHC per diem payments. The claims processing system will ensure that each time an outlier claim for a CMHC is processed, actual outlier payments would never exceed 8 percent of the CMHC’s year-to-date total payments.

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\(^8\) The outlier reconciliation policy is applied at the time of cost report settlement if the CMHC’s CCR changed by 0.10 or more.
C. Regulatory Impact

CMS estimates that payments to CMHCs will decrease by 13.7 percent in 2017. Almost all of the decrease is attributable to the CMS policy to combine APCs 5851 and 5852 into new APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). CMS’ estimates also include the trimming.

IX. Procedures That Would Be Paid Only as Inpatient Procedures

A. Changes to the Inpatient Only (IPO) List

CMS is continuing to use the same methodology to review the inpatient-only list. Under that methodology, CMS proposed to remove the six procedures (four spine procedures and two laryngoplasty codes) from the inpatient-only list for 2017. CMS received comments both in support of and opposed to removing these procedures from inpatient-only list. In response to comment, CMS is removing one additional code from the inpatient-only list:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Code Descriptor</th>
<th>CY 2017 APC Assignment</th>
<th>CY 2017 Status Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>22585*</td>
<td>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)</td>
<td>N/A</td>
<td>N</td>
</tr>
<tr>
<td>22840</td>
<td>Posterior non-segmental instrumentation (eg, 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.</td>
<td>N/A</td>
<td>N</td>
</tr>
<tr>
<td>22842</td>
<td>Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments. List separately in addition to code for primary procedure.</td>
<td>N/A</td>
<td>N</td>
</tr>
<tr>
<td>22845</td>
<td>Anterior instrumentation; 2 to 3 vertebral segments. List separately in addition to code for primary procedure.</td>
<td>N/A</td>
<td>N</td>
</tr>
<tr>
<td>22858</td>
<td>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.</td>
<td>N/A</td>
<td>N</td>
</tr>
<tr>
<td>31584</td>
<td>Laryngoplasty; with open reduction of fracture</td>
<td>5165</td>
<td>J1</td>
</tr>
</tbody>
</table>
[31587] Laryngoplasty, cricoid split  5165  J1

*Not included in the proposed rule. Added to list of codes removed from the inpatient only list in the final rule.

Other than the last two codes, each of the codes being removed from the inpatient only list are add-ons that are not paid separately. Addendum E of the final rule contains the complete list of codes that will be paid only as inpatient procedures for 2017.

B. Solicitation of Public Comments on the Possible Removal of Total Knee Arthroplasty Procedure from the IPO List

In the proposed rule, CMS sought public comments on whether it should remove total knee arthroplasty (TKA) or total knee replacement procedure, CPT code 27447, from the IPO list. In 2013, CMS had made a similar proposal, but did not finalize it. Most commenters had disagreed with the 2013 proposal and believed that it would be unsafe to perform outpatient TKA for Medicare beneficiaries (see 77 FR 68419). The proposed rule reminded readers of two principles of the IPO list that may be misunderstood by the public. First, just because the procedure is not on the IPO list does not mean that the procedure cannot be performed on an inpatient basis. Second, the IPO status of a procedure has no effect on the MPFS payment for the procedure.

CMS specifically ask for public comment on the following questions:

1. Are most outpatient departments equipped to provide TKA to some Medicare beneficiaries?

2. Can the simplest procedure described by CPT code 27447 be performed in most outpatient departments?

3. Is the procedure described by CPT code 27447 sufficiently related to or similar to the procedure described by CPT code 27446 (i.e., is it related to codes that CMS has already removed from the IPO list)?

4. How often is the procedure described by CPT code 27447 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?

5. Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of a TKA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

6. How could CMS modify the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment for Care Improvements (BPCI) models if the TKA procedure were to be moved off the IPO list? In particular, CMS is seeking comment on how to reflect the shift of some Medicare beneficiaries from an inpatient to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation process. For example, CMS would need to ensure target prices account for potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings.
CMS received comments both in support of and opposed to removing TKA from the IPO list and will consider those comments in developing future policy. The overwhelming majority of the commenters supported removing TKA from the IPO 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 representing professional organizations, health systems, and hospital associations, opposed the removal of a TKA procedure from the IPO 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 IPO 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 IPO list.

X. Nonrecurring Policy Changes

A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

Section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74) excludes from the definition of covered OPD services “applicable items and services” furnished on or after January 1, 2017 by certain off-campus outpatient departments of a provider (generally those that did not furnish covered OPD services before November 2, 2015) and provides for payment for those services furnished by what CMS refers to in the rule as off-campus provider-based departments (PBDs) under a Part B payment system other than the OPPS (“applicable payment system” under Part B).

CMS proposed a set of implementation policies which included provisions that raised major concerns with stakeholders, including a proposal to not make any payment to facilities during 2017 for the costs they incurred in providing applicable items and services to Medicare beneficiaries. In reaction to this and other concerns, stakeholders urged CMS to delay implementation so the agency could develop policies that would be less burdensome to providers and CMS. CMS rejects arguments calling for a delay, and it finalizes a set of policies to implement section 603 in 2017. Some of the finalized policies have been significantly modified from CMS’ proposals, including a substantially revised payment policy that will be implemented.
through an interim final rule with comment period (IFC), to apply to items and services furnished during 2017. CMS does clarify that section 603 applies to any entity that is paid under section 1833(t) (which includes a provider-based FQHC but excludes a hospital operated by the Indian Health Service, or by a tribe or tribal organization since the latter are paid pursuant to section 1880 of the Act).

Generally, CMS implements section 603 as follows:

1. It creates and defines the term “excepted items and services” to determine whether items and services are excepted from the section 603 applicable payment system policy and paid under the OPPS.
2. It defines off-campus PBDs and establishes requirements for those off-campus PBDs to maintain excepted status (both for the facility and for the items and services it furnishes).
3. It establishes payment policies for nonexcepted items and services (that are substantially revised from those policies in the proposed rule) through an IFC.

Under the finalized proposal, all excepted off-campus PBDs may continue to bill for excepted items and services under the OPPS, including those furnished in an emergency department (ED), in an on-campus PBD, or within the distance (250 yards) from a remote location of a hospital facility.

CMS reiterates that while there is no legislative history to guide its implementation of section 603, the Congressional Budget Office scored the provision as saving $9.3 billion over a 10-year budget period. Please note, however, that CMS estimates a net reduction in Part B spending of roughly $50 million in 2017 in the final rule which is a significant reduction from its proposed estimated savings of $330 million for 2017. This figure is explained in more detail below.

CMS adds a new §419.48 to the regulations that (1) defines the term excepted items and services, (2) defines the term excepted off-campus PBD, and (3) codifies the MPFS, generally, as the applicable payment system.

Definition of Excepted Items and Services (§419.48(a))

CMS finalizes the definition of excepted items and services to mean those items and services furnished on or after January 1, 2017 that are furnished by:

(a) A dedicated emergency department (as defined in §489.24(b) of the regulations⁹), or

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⁹ §489.24(b) defines an emergency department as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that 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 emergency department; (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.
(b) An excepted off-campus provider-based department (as defined in §419.48(b) of the regulations) that has not impermissibly relocated or changed ownership.

CMS clarifies that all items and services (emergency and nonemergency) that are furnished in a dedicated ED will continue to be paid under the OPPS.

CMS adds a new paragraph (v) to §419.22 that, beginning January 1, 2017, excludes payments for hospital services from the OPPS provided by an off-campus PBD that does not meet the definition of excepted items and services under §419.48(a).

Definition of Excepted Off-Campus PBD (§419.48(b))

CMS finalizes its definition of an excepted off-campus provider-based department with modifications. An excepted off-campus PBD means a “department of a provider” (as defined at §413.65(a)(2) of the regulations) that as of November 2, 2015 was located on the campus (as defined in §413.65(a)(2)) or within the distance described in such definition from a “remote location of a hospital” (as defined in §413.65(a)(2)) that meets the requirements for provider-based status under §413.65. The definition also includes a department of a provider that was billing under the OPPS with respect to covered OPD services furnished prior to November 2, 2015.

On-Campus Locations. Under this definition, on-campus PBDs and the items and services furnished by them will continue to be paid under the OPPS. CMS notes that the definition of the term department of a provider (as in effect on November 2, 2015) includes both the specific physical facility that is the site of service and the personnel and equipment required to furnish services at the facility. CMS did not propose to modify existing provider-based regulations or to change the definition of campus under §413.65(a)(2) and believes hospitals may adequately determine whether departments are on campus, including through the voluntary provider-based attestation process. CMS believes the current definition of campus and the flexibility afforded to CMS Regional Offices to exercise discretion on a case-by-case basis is appropriate. However, CMS notes that as it gains experience with section 603 implementation, it may make revisions through future rulemaking.

Distance from Remote Locations. Section 603 also provides for an exception for off-campus PBDs that are within the distance described in the definition of campus under §413.65(a)(2). CMS finalizes its proposal to except those off-campus PBDs located at or within 250 yards from a remote location of a hospital facility. CMS notes that because neither section 603 nor the regulations specify the point from which to measure, CMS interprets 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. In the proposed rule, CMS noted that hospitals should use surveyor reports or other documentation to ensure off-campus PBDs are within 250 yards (straight-line) from any point of a remote location.

Exception at Section 1833(t)(21)(B)(ii) of the Act.

Section 603 provides that an off-campus PBD that was billing for a covered OPD service
furnished before November 2, 2015 will continue to be paid under the OPPS. CMS states that its major concern with implementing the scope of the exception was with respect to relocation of, or expansion of services lines of, an excepted off-campus PBD. Commenters argued that section 603 exempts these facilities and that the exemption applies regardless of whether the facility relocates, expands services, or both. CMS is concerned about a set of policies that could be used by providers to circumvent the intent of section 603.

(i) Relocation

The statute does not address the issue of relocation. CMS had proposed a strict general rule that an excepted off-campus PBD would lose its excepted status if it is moved or relocated from the physical address (including a change in the unit number of the address) listed on the provider’s hospital enrollment form as of November 1, 2015. CMS acknowledges that some circumstances may require a facility move, such as natural disasters or federal or state requirements. Commenters raised many other situations under which a facility would have to move, including lease expiration, building safety code compliance, building deterioration, population shifts, natural disaster, seismic requirements, and other situations beyond a hospital’s control. Commenters also suggested alternatives under which (1) relocation would be permitted if the total number of off-campus PBDs for a hospital did not increase relative to the number before November 2, 2015 or (2) relocation would be determined under a "substantially similar test" (which could be similar to the CAH relocation requirements) to determine if the relocated location is actually new.

CMS rejects the argument that an excepted off-campus PBD should be able to relocate under any circumstances and retain its excepted status. CMS also rejects the alternative suggestions because it fears loopholes might undermine the intent behind section 603. CMS is sympathetic to the argument that relocation should be permitted without loss of excepted status for extraordinary circumstances outside the control of the facility, such as natural disasters, significant seismic building codes, or significant public health and public safety issues, that necessitate moving to a new building (either temporarily or permanently).

CMS finalizes its relocation policy (i.e., relocation of an excepted off-campus PBD will generally result in loss of excepted status), but it will establish an extraordinary exceptions process through subregulatory guidance under which exceptions to the relocation policy will be evaluated on a case-by-case basis by the appropriate CMS Regional Office. CMS intends that exceptions will be both limited and rare. Some commenters asked whether the relocation of an on-campus PBD to an off-campus location would result in the loss of the excepted status of that PBD; CMS confirms that the facility would lose its excepted status.

(ii) Expansion of Clinical Family of Services

Stakeholders also expressed a desire to expand the number or type of services that an excepted off-campus PBD could furnish and still maintain excepted status. Again, CMS believes the statute requires a reading that to maintain excepted status an off-campus PBD is limited to offering services only within the clinical family of services it furnished before November 2, 2015. CMS had proposed a clarification that services furnished that are not part of the clinical family of services (established by CMS) furnished and billed before November 2, 2015, would not be payable under the OPPS. CMS had proposed to define service types by 19 clinical
families of hospital outpatient service types described in Table 21 of the proposed rule. Under the proposal, if an excepted off-campus PBD billed for any specific service within a clinical family of services before November 2, 2015, the clinical family of services would be eligible for OPPS reimbursement. CMS also considered, but did not propose, to require a specific timeframe during which service lines had to be billed under the OPPS; it did not propose to limit the volume of services furnished within a clinical family of services that the hospital billed before November 2, 2015.

CMS does not finalize this proposal at this time. It will monitor service line growth and may propose limitations on expansions of services or service lines in the future. Thus, an excepted off-campus PBD may be paid under the OPPS for items and services furnished regardless of whether the facility furnished those items and services before November 2, 2015.

Opposition to the proposed rule policy on this issue was widespread among commenters who presented a number of arguments: (1) the statute did not address service mix by excepted off-campus PBDs; (2) limits on service lines fails to take into account the value of evolving and new therapies; (3) the entire clinical family of services was a new and undeveloped concept; and (4) the proposal would create significant operational challenges and administrative burdens on providers and the agency. While CMS disagrees with the legal arguments presented by commenters, it does acknowledge that its proposal could be complex and burdensome to identify, track, and monitor billing for clinical services. CMS is interested in stakeholder feedback on how a limitation on volume of services or on lines of service would work in practice. It is specifically interested in what data are currently available or could be collected to implement such a limitation. CMS also seeks feedback for changes to the clinical families of services it set forth in table 21 of the proposed rule (81 FR 45685 through 45686).

(iii) Facilities Under Development
In response to comments, CMS notes it did not propose a policy that would exempt mid-build off-campus PBDs or those under development at the time of the enactment of section 603 under section 1833(t)(21)(B)(ii) of the Act. Those facilities will be considered nonexempt off-campus PBDs that will be reimbursed under the applicable payment system described below for nonexcepted items and services.

(iv) Bill submission before November 2, 2015
For purposes of qualifying for the exception, in the proposed rule, CMS had interpreted the statute to require that an off-campus PBD must have actually submitted a bill before the enactment date of section 603. Some commenters believed that CMS misinterpreted the law, and others requested a more flexible interpretation that would provide exceptions for those facilities that were operational on the date of enactment but either had not treated patients before November 2, 2015 or had treated patients before that date but had not billed for the services until after November 2, 2015. CMS finalizes its proposed interpretation with a modification; an off-campus PBD that furnished a covered OPD service before November 2, 2015 and billed for the service under the OPPS after that date under the timely filing limits will qualify for an exception.

Change in Ownership. CMS reiterates that current policy provides that if a participating hospital,
in its entirety, is sold or merged with another hospital, a PBD’s provider-based status generally transfers to the new ownership if the transfer does not result in material change of the provider-based status. Consistent with that policy, CMS finalizes its proposal that the excepted status of an off-campus PBD will transfer to new ownership only if (1) the main provider is also transferred and (2) the Medicare provider agreement is accepted by the new owner. If the provider agreement is terminated, all excepted off-campus PBDs and the excepted items and services furnished by them would lose their excepted status. Additionally, an individual excepted off-campus PBD that is transferred from one hospital to another will lose its excepted status.

CMS disagrees with those commenters who asserted that it did not have the authority under the statute to address change of ownership under section 603.

**Data Collection.** CMS notes that while hospitals identify names and addresses of off-campus PBDs under the Medicare enrollment process, PBDs bill under the CMS Certification Number (CCN) of the hospitals. CMS notes that currently it is unable to automate a process to link hospital enrollment information to claims processing information to identify items and services specific to off-campus PBDs. CMS sought comment on whether it should require hospitals to separately identify (1) all individual excepted off-campus PBD locations, (2) the date each such PBD began billing, and (3) the clinical families of services provided by each such PBD before November 2, 2015.

Commenters did not think that CMS could distinguish between individual off-campus PBDs of a hospital nor that it could determine if an individual off-campus PBD billed for certain services before enactment based on data currently available. This raised issues of the burden on providers to comply with additional data collection, especially in the context of the proposed relocation and service expansion policies. CMS notes that it will follow traditional monitoring and enforcement (including prepayment and postpayment reviews) to ensure hospitals are correctly identifying nonexcepted items and services, and that hospitals must maintain sufficient documentation to prove that it is an excepted off-campus PBD, including that it was an off-campus PBD billing for covered OPD services furnished before November 2, 2015. CMS plans to instruct Medicare contractors to update their systems using enrollment data that identifies each off-campus PBD by physical address and by the date it was added to the hospital’s enrollment.

CMS notes it is, and will continue, monitoring claims data that include the "PO" modifier; it is also establishing a new "PN" modifier to be used to bill for nonexcepted items and services (described further below). In response to a MedPAC comment that CMS should create a modifier to indicate when a service is provided in a dedicated ED and whether the ED is on-campus or off-campus, CMS states that it has not created such a modifier and notes that dedicated EDs are exempt under section 603 whether they are on-campus or off-campus.

**Payment for Nonexcepted Off-Campus PBDs**

While the statute calls for applicable items and services to be paid for under the “applicable payment system” under Part B, the law does not describe or define what applicable payment system means (other than it is not the OPPS). CMS observes that rules regarding provider and supplier enrollment, conditions of participation, coverage, payment, billing, cost reporting, and
coding vary across the institutional payment systems. It solicited comment on changes that might be needed to enrollment forms, claim forms, the hospital cost report and other operational changes in order for nonexcepted items and services to be billed by off-campus PBDs. In the proposed rule, CMS noted that it intended to develop a mechanism for an off-campus PBD to bill and be paid for furnishing nonexcepted items and services under the “applicable payment system,” but that there was no straightforward way to do that before January 1, 2017. The Multi-Carrier System (used to process physician and other supplier claims) does not accept or process institutional OPPS claims; CMS stated that it needs additional time to make significant changes to complex systems. Under the Provider Enrollment, Chain and Ownership System (PECOS), hospitals may only submit institutional claims for payment of covered OPD services under the OPPS using the hospital CCN; hospitals do not meet requirements to bill under other payment systems. CMS believed it would have to create a new provider/supplier type for nonexcepted off-campus PBDs to bill and be paid under an alternative payment system, such as the MPFS; MedPAC discouraged CMS from doing so.

CMS repeats its policy concerns that many freestanding physician practices initially enrolled in Medicare were converted to off-campus PBDs raising beneficiary cost-sharing as well as Medicare spending concerns. Recent physician employment trends show hospital ownership of physician practices has increased 86 percent and hospital employment of physicians has increased by almost 50 percent between July 2012 to July 2015.

**Applicable Payment System**

CMS had proposed to use the MPFS as the applicable payment system for 2017. Commenters had suggested using the ASC payment system, a combination of the ASC and the MPFS, or an entirely new part B payment system. CMS finalizes its proposal to use the MPFS under the rationale described above as well as findings from preliminary data billed by off-campus PBDs with the "PO" modifier that showed most of the furnished items and services are the same as those furnished in physician offices (e.g., E&M visits, diagnostic and imaging services, drugs or biologicals and drug administration).

However, the final policy is substantially revised from the proposed policy which provided that for 2017, physicians furnishing services in off-campus PBDs would be paid based on the professional claim and at the nonfacility rate to the physician (unless the hospital separately enrolls as a non-hospital provider type) for services for which they are permitted to bill and no separate facility payment would be made to the hospital. Commenters strongly objected to the proposed policy for a number of reasons, including the absence of payment for the costs facilities would incur (e.g., nursing, lab, imaging, chemotherapy, surgical services etc.), the impact of fraud and abuse laws on financial arrangements that would be required of hospitals and referring physicians, the impact on State corporate practice of medicine and fee-splitting laws, and the impact on rural providers. CMS agrees its proposals raised many of these concerns, and it does not finalize its 2017 physician and facility payment as proposed.

Instead, CMS issued an IFC to establish rates under the MPFS for nonexcepted items and services furnished by off-campus PBDs on or after January 1, 2017 (described in more detail below). Under the final policy, payment will be made to physicians at the MPFS facility rate and to the
off-campus PBD under new MPFS rates that are based on the OPPS rates for most nonexcepted items and services. CMS considers these rates to be site-of-service specific for the technical component of MPFS. Several OPPS payment policies (e.g., C-APCs and OPPS packaging logic) are adopted under the new site-of-service MPFS rates; CMS sets the rates at 50 percent of the OPPS rates for each nonexcepted item or service (with some exceptions) as the interim technical component payment rate. Providers will use an institutional claim to bill for these services using a new claim line modifier "PN" to indicate that the item or service was nonexcepted. **CMS seeks comment on the new payment rates and mechanisms, and will make adjustments as necessary based on that input as early as 2017.**

CMS notes that payments under the IFC policy may not equal payments under the technical component of the MPFS for any specific item or service. CMS will continue to pay for therapy services, preventive services, and separately payable drugs at the MPFS rate. CMS believes its IFC policies address commenters' concerns about nonpayment generally (including nonpayment under the incident to rules), nonpayment or confusion over payment for certain types of items and services, and concerns about the implication of the physician self-referral law, the anti-kickback law and other fraud and abuse laws and regulations to the proposed payment policies.

Additionally, commenters were concerned that the proposed payment policy might impact a off-campus PBD’s eligibility as a covered entity under the 340B program because nonexcepted items and services would not be billed on the institutional claim and thus would not be automatically recorded as a reimbursable cost center on the cost report. Under the IFC payment policies, off-campus PBDs will continue to bill using the institutional claim, and services will continue to be reported on the hospital cost report. CMS directs interested parties to HRSA for questions relating to 340B eligibility, and it notes that if the final CMS payment policies require a change for hospital cost reporting, it will issue subregulatory guidance.

CMS notes that a hospital may enroll a nonexcepted off-campus PBD as another provider or supplier type (such as an ASC or group practice) to meet the requirements of the non-OPPS Part B payment system involved, provided it meets all Medicare and other requirements.

**B. Interim Final Rule with Comment Period (IFC): Establishment of Payment Rates under the MPFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus PBDs of a Hospital**

CMS issues an IFC to establish initial section 603 payment policies under the MPFS for nonexcepted items and services furnished on or after January 1, 2017. As noted above, CMS finalizes its proposal that the MPFS will be the applicable payment system. CMS had also proposed a temporary 1-year payment policy for 2017 (described above) while it explored operational changes to permit nonexcepted items and services to be billed by off-campus PBDs under the MPFS; a policy which CMS does not finalize. Instead, the IFC establishes payment policies under the MPFS for off-campus PBDs to bill and be paid for nonexcepted items and services. **CMS seeks comment on the new payment mechanisms and rates and will make adjustments through rulemaking that could be effective for 2017.**
Payment Mechanisms

CMS discusses the MPFS, its facility and nonfacility payments as well as payments for the professional and technical components, and certain facilities currently paid under the MPFS (e.g., IDTFs). CMS concludes that the MPFS is appropriate to use as the applicable payment system to carry out section 603, but it recognizes that using the MPFS without implementing simultaneous billing mechanisms for nonexcepted items and services furnished by hospitals under the MPFS might have significant negative consequences, such as fraud and abuse law implications as well as existing “incident to” regulations, which would preclude the physician or the hospital from billing for certain nonexcepted items and services. This in turn could lead to reduced access to care for Medicare beneficiaries. Thus, for 2017 CMS establishes MPFS rates for the technical component of nonexcepted items and services furnished by nonexcepted off-campus PBDs to provide the facilities a mechanism to bill for these services.

CMS believes it is currently operationally infeasible for nonexcepted off-campus PBDs to bill under the MPFS for the subset of MPFS services for which there is a separately valued technical component (either through a "TC" value or through unique HCPCS codes). CMS also acknowledges that hospitals are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued MPFS technical component. Thus, CMS establishes a new set of payment rates under the MPFS that reflects the relative resource costs of furnishing the technical component of a broad range of services to be paid to off-campus PBDs of a hospital with packaging rules that are significantly different from the current MPFS rules. The new payment rates will establish a means to report the technical aspect of all applicable items and services under the MPFS.

CMS states that the payment rates under this mechanism must reflect the estimated relative resource costs in furnishing these services as compared to other MPFS services based on the information available at this time. However, CMS does not make any changes to the current payment rules used by other practitioners or suppliers that bill under the MPFS. Instead, for nonexcepted off-campus PBDs, CMS establishes a mechanism to permit them to bill for nonexcepted items and services through the institutional claims processing systems to be paid in 2017. Thus, for 2017 these facilities will continue to bill on the institutional claim which will pass through the Outpatient Code Editor and into the OPPS PRICER for calculation of payment under the MPFS because CMS cannot make the necessary revisions to the Multi-Carrier System to accept and process institutional claims before January 1, 2017. Other than the additional requirement to report modifier "PN" on each UB-04 claim line to indicate a nonexcepted item or service, nonexcepted off-campus PBDs should continue to bill as they currently do except, as noted below, for radiation treatment delivery services.

Establishment of Payment Rates

CMS finalizes new MPFS payment amounts for a new site of service—nonexcepted off-campus PBDs—for 2017. CMS establishes a payment mechanism for 2017 under the MPFS for nonexcepted items and services that, at the code level, is based on relative payment rates and packaging and billing rules for those services furnished under the OPPS. While the agency believes it is appropriate to use OPPS data to establish code-level relativity, it will only use...
OPPS payment rates to the extent they establish appropriate payment under the MPFS based on the relative resources involved, pursuant to the packaging rules.

After analysis of hospital outpatient claims data from January 1, 2016 through August 26, 2016 that contained the "PO" modifier for a limited number of services, CMS adopts (with some exceptions) a set of payment rates for 2017 that are based on a 50-percent reduction to the OPPS payment rates (inclusive of packaging) for nonexcepted items and services furnished by nonexcepted off-campus PBDs. CMS describes the manner in which it arrived at this 50-percent reduction (referred to as the MPFS relativity adjuster for 2017) in the final rule, and the agency believes that it does not underestimate the overall relativity between the OPPS and the MPFS based on the limited data currently available. CMS emphasizes that it views this 50-percent reduction for 2017 as a transitional policy until it gathers more precise data.

CMS establishes several exceptions to the percentage reduction. CMS will not adjust the payment rates for the following:

- Services currently paid under the OPPS based on payment rates from other Medicare fee schedules (including the MPFS) on an institutional claim (i.e., items and services assigned status indicator “A” in Addendum B to the 2017 OPPS/ASC final rule) that will continue to be reported on an institutional claim and paid under the MPFS, the CLFS, or the Ambulance Fee Schedule without a payment reduction.
- Drugs and biologicals that are separately payable under the OPPS (identified by status indicator “G” or “K” in Addendum B to the 2017 OPPS/ASC final rule) will be paid under section 1847A of the Act (i.e., typically ASP + 6 percent), consistent with payment rules in the physician office setting.
- Drugs and biologicals that are unconditionally packaged under the OPPS and are not separately payable (i.e., those drugs and biologicals assigned status indicator of “N” in Addendum B to the 2017 OPPS/ASC final rule) will be bundled into the MPFS payment and will not be separately paid to hospitals billing for nonexcepted items and services.

CMS will likely make available a table showing the full range of exceptions and adjustments to the otherwise applicable OPPS payment rates; table X.B.2 identified in the preamble was not included in the display copy of the final rule.

**MPFS Relativity Adjuster.** CMS notes that if it uses the IFC payment mechanisms for years after 2017, it would use Medicare claims data to develop a MPFS relativity adjuster that incorporates the specific mix of services furnished in nonexcepted off-campus PBDs. CMS notes it arrived at the 50-percent reduction by comparing (i) the payment differential between the OPPS and the ASC payment rates (where covered surgical procedures in ASCs are paid at 55 percent of the rate under the OPPS) and (ii) the weighted average payment differential for overall payment under the OPPS and the MPFS for clinic visits from a list of most frequently billed HCPCS codes reported with the “PO” modifier (45 percent). 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 nonexcepted off-campus PBDs furnishing nonexcepted items and services to adjust the technical component rates in lieu of the MPFS geographic practice cost.
indices.

Coding Consistency. CMS notes that the same HCPCS codes are used to describe services paid under both the MPFS and the OPPS for most services. However, E&M services are reported under the OPPS using the single HCPCS code G0463 while 10 CPT codes are used to describe these services under the MPFS. The MPFS payment rate for nonexcepted off-campus PBDs furnishing nonexcepted E&M services in 2017 will be based on the rate for HCPCS code G0463 reduced by the 50-percent MPFS relativity adjuster.

CMS established HCPCS Level II "G" codes for radiation treatment delivery services furnished in a physician's office; under the OPPS, CPT codes are used to describe these services furnished in the hospital outpatient department. CMS will require off-campus PBDs to bill for nonexcepted items and services using the HCPCS "G" codes under the MPFS to describe radiation treatment delivery services; the off-campus PBD must append modifier "PN" to each applicable claim line for nonexcepted 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 MPFS payment rates for nonexcepted off-campus PBDs furnishing nonexcepted items and services that are billed by hospitals. The claims processing logic that is used for OPPS payment for comprehensive APCs, conditionally and unconditionally packaged items and services, and major procedures will all be incorporated into the newly established MPFS 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 outpatient quality reporting 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 CMHC for payment under the OPPS and it met all Medicare requirements and conditions of participation for CMHCs. Commenters clarified that this was not a viable option and noted that access to PHP services could be limited under the policy; they requested that CMS develop a policy for payment for PHP services furnished by nonexcepted off-campus PBDs. Under the IFC, PHP services will be paid at the CMHC rate for APC 5853 for providing 3 or more PHP services per day. 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. CMS reiterates that an off-campus PBD may still enroll as a CMHC if it chooses to do so.

Supervision Rules. CMS notes that the amendments made by section 603 did not change the status of off-campus PBDs as provider-based departments; the amendments only changed the manner in which these provider-based departments are reimbursed for their nonexcepted items and services. Thus, the supervision rules under 42 CFR 410.27 continue to apply to off-campus PBDs that furnish nonexcepted items and services.
Beneficiary Cost-Sharing. CMS specifies that all beneficiary cost-sharing rules that apply under the MPFS pursuant to sections 1848(g) and 1866(a)(2)(A) of the Act will continue to apply for all nonexcepted items and services furnished by off-campus OPDs, 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; thus, CMS intends that its payment policies should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible.

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

- For most services, the MPFS-based rate would equal the nonfacility payment rate under the MPFS minus the facility payment rate under the MPFS for the service in question.
- For other services for which separate payment is not made under the MPFS, if payment is made under OPPS, the MPFS-based rate would equal the MPFS nonfacility rate. [Note: HPA restates the policy here as it is stated in the final rule even though it is unclear how Medicare can make payment at the MPFS nonfacility rate for a service that does not receive separate payment under the MPFS.]
- For other services, the technical component rate under the MPFS would serve as the MPFS-based rate.
- For services billable under OPPS but not under MPFS, CMS would consider the relative resources involved in furnishing the service. It envisions a rate similar to the ASC rate for similar services.

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

CMS also seeks comment on continuing to use the IFC payment methodology, or one similar to it, for future years. Under this approach, the MPFS relativity adjuster could fluctuate based on available data; however, CMS’ goal would be to equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible. It acknowledges that the rates would not be equal on a procedure-by-procedure basis which 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 packaging rules, and cost-report relative payment rate determinations under the OPPS would
Audits. CMS notes that audits of hospital billing will examine whether off-campus PBDs are billing correctly for nonexcepted items and services. CMS expects hospitals to maintain proper documentation showing which off-campus PBDs were billing Medicare prior to November 2, 2015, and to make this documentation available to the agency and its contractors upon request.

Regulatory Impact

CMS states that the IFC does not impose any new information collection, recordkeeping, or third-party disclosure requirements for 2017. Thus, there is no need for OMB review under the Paperwork Reduction Act.

CMS estimates a net reduction in Part B spending of roughly $50 million in 2017; this represents a significant reduction from its proposed estimated savings of $330 million for 2017. CMS states that the lower impact is primarily attributable to changes in technical assumptions about the services affected by this provision. Based on its analysis of 2016 claims data with the "PO" modifier, it substantially reduced the volume of services it expected to be impacted by the provision. CMS also excludes the associated Medicare Advantage (MA) impact for 2017 since the MA rates will be set before the IFC is implemented. CMS notes that if it had finalized the proposed rule policy using the revised assumptions, it would have estimated aggregate Part B reductions in spending at $70 million.

C. Changes in Payment for Film X-Ray

Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Public Law 114–113) reduces payment under the OPPS 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 finalizes its proposal to establish a new modifier "FX" to be used on claims for these imaging services. Beginning in 2017, hospitals must use the "FX" modifier for these claims. The applicable HCPCS codes describing these imaging services are found in Addendum B to the final rule (available on the CMS website).

In response to comments, CMS clarifies that use of the "FX" modifier is only required for claims for payment under the OPPS; if a provider does not bill for the service under the OPPS (e.g., a CAH or a Maryland hospital), the use of the modifier is not required and there will be no associated payment reduction. CMS also declines to provide exemptions to the policy for certain types of X-ray services; thus radiographic-fluoroscopic (R&F) services that combine both radioscopy and radiography in a single examination, vascular imaging services which use radioscopy and do not use CR or film technologies, and mammography imaging services which largely involve the use of digital technology still require use of the modifier and associated payment reduction. However, 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, and the associated payment reduction would be 0 percent (or 20% of $0) in this circumstance.
Section 502(b) also reduces payment for imaging services that are X-rays using computed radiography (including the X-ray component of a packaged service) as follows:

- For such imaging services furnished during 2018 through 2022, by 7 percent.
- For such imaging services furnished during 2023 or a subsequent year, by 10 percent.

CMS will propose a modifier to be used for these claims in future rulemaking.

The payment reductions for these imaging services are applied before any other adjustment and are not implemented in a budget neutral manner.

D. Changes to Certain Scope-of-Service Elements for Chronic Care Management (CCM) Services

CMS finalized the required CCM scope of service elements for hospitals to bill and receive OPPS payment for furnishing CCM services in the 2016 OPPS/ASC final rule. CMS is finalizing what it describes as minor changes to certain CCM scope of service elements in the 2017 MPFS final rule that will also apply to CCM services furnished to hospital outpatients under the OPPS. For example, electronic sharing of care plan information must be timely but not necessarily on a 24 hour a day/7 day per week basis. Please see the 2017 MPFS final rule, or the HPA summary of that rule, for further details.

E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of PAMA directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. 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 MPFS final rule. (See 42 CFR 414.94.) The program’s criteria and requirements are established and updated through MPFS 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 MPFS, the OPPS, and the ASC payment system. The 2017 MPFS 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 MPFS final rule also includes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. Please see the 2017 MPFS final rule, or the HPA summary of that rule, for further details.

XI. CY 2017 OPPS Payment Status and Comment Indicators

2017 OPPS Payment Status Indicator Definitions. For 2017, CMS revises the current definition of status indicator “E” by creating two new status indicators as follows:
• “E1” Specific to items and services not covered by Medicare; and
• “E2” Exclusive to items and services for which pricing information or claims data are not available.

Commenters supported the proposed revisions to the definition of status indicator “E;” they also recommended that CMS not assign the noncovered I/OCE edit to status indicator “E2” services since noncoverage is not a reason for nonpayment of these services. In response, CMS will assign edit 13 to status indicator “E2” items and services which will result in a line item rejection. CMS explains that a line item rejection is when a line has reached a final disposition with no payment for a reason other than medical necessity under section 1862(a)(1) of the Act.

The 2017 status indicator assignments for APCs and HCPCS codes (displayed in Addendum A and Addendum B, respectively, to the final rule) and the complete list of 2017 status indicators and their definitions (displayed in Addendum D1) are available from the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Comment Indicator Definitions. CMS finalizes its proposal to use four comment indicators for 2017. It will continue to use the same three comment indicators that are in effect for the 2016 OPPS (“CH”, “NI”, and “NP”), and creates a new comment indicator “NC.” Comment indicator “NC” is used in the final rule to indicate the HCPCS codes that were assigned to comment indicator “NP” in the proposed rule. Codes assigned the comment indicator “NC” in the final rule will not be subject to comment in the final rule. The four comment indicators and their descriptions are as follows:

• “CH” – Active HCPCS code in current and next calendar year; status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
• “NI” – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
• “NP” – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.
• “NC” – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year for which CMS requested in the proposed rule, final APC assignment; comments will be not be accepted on the final APC assignment for the new code.

CMS did not receive any comments on its proposals. The definitions of the OPPS comment indicators for 2017 are listed in Addendum D2 to the final rule and are available at the CMS website hyperlink immediately above.
XII. Updates to the Ambulatory Surgical Center (ASC) Payment System

Summary of selected key elements of proposed and final ASC payment rates for 2017

<table>
<thead>
<tr>
<th></th>
<th>Proposed Rule</th>
<th>Final Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASCs reporting quality data</td>
<td>$44.190</td>
<td></td>
</tr>
<tr>
<td>ASCs not reporting quality data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016 ASC Conversion Factor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017 Update</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPI-U update</td>
<td>1.7%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Multi-factor productivity adjustment (MFP)</td>
<td>-0.5%</td>
<td>-0.3%</td>
</tr>
<tr>
<td>Net MFP adjusted update</td>
<td>1.2%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Penalty for not reporting quality data</td>
<td>0.0%</td>
<td>-2.0%</td>
</tr>
<tr>
<td>Net MFP and quality adjusted update</td>
<td>1.2%</td>
<td>-0.8%</td>
</tr>
<tr>
<td>Wage index budget neutrality adjustment</td>
<td>0.9992</td>
<td>0.9996</td>
</tr>
<tr>
<td>2017 ASC Conversion Factor</td>
<td>$44.684</td>
<td>$45.030*</td>
</tr>
<tr>
<td></td>
<td>$43.801</td>
<td>$44.330*</td>
</tr>
</tbody>
</table>

*These are the published numbers in the final rule, but the 2017 ASC conversion factors listed are not the product of the CY 2016 conversion factor multiplied by the wage index budget neutrality adjustments and the MFP-adjusted CPI-U payment update. Using the numbers CMS provided in the final rule, the 2017 conversion factor for ASCs reporting quality data would be $45.012; for ASCs not reporting quality data would be $44.128.

CMS estimates that under the final rule, total ambulatory surgical center (ASC) payments for 2017 will increase by $177 million over 2016 levels.

As with the rest of the OPPS final rule and other CMS rules, addenda related to the ASC section (and referenced in this summary) are available only on the CMS website, at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-FC.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-FC.html).

A. Background

CMS reviews the legislative history and regulatory policies regarding changes to the lists of codes and payment rates for ASC covered surgical procedures and covered ancillary services.

- Covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS and that would not be expected to:
  - Pose a significant risk to beneficiary safety when performed in an ASC; or
  - Require an “overnight stay”: active medical monitoring and care at midnight following the procedure.
- Separate ASC payments are made for selected ancillary items and services when they are provided integral to ASC covered procedures. Payment for ancillary items and services that are not paid separately are packaged into the ASC payment.
- ASC payments are based on the OPPS payment policies.
- CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and
finalize decisions.

B. Treatment of New and Revised Codes

CMS continues to recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CMS continues its policy to evaluate all new Category I and III CPT codes and Level II HCPCS codes that describe surgical procedures in order to make preliminary determinations during the annual rulemaking process about whether they meet the criteria for payment in an ASC setting, and if so, whether they are office-based procedures. CMS also identifies new and revised codes as ASC covered ancillary services based on the final payment policies in the revised ASC payment system.

CMS finalizes proposals for new codes in two categories:

- treatment of codes previously identified during the year in the quarterly update process and on which it sought comments in the proposed rule; and
- new codes for which it will be seeking comments in this final rule with comment period.

CMS clarifies that it considers revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator.

CMS sets out in Table 43 its process and timeline for updating codes through the quarterly update CRs, seeking public comment, and finalizing treatment of the new codes.

<table>
<thead>
<tr>
<th>ASC Quarterly Update CR</th>
<th>Type of Code</th>
<th>Effective Date</th>
<th>Comments Sought</th>
<th>When Finalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1, 2016</td>
<td>Level II HCPCS Codes</td>
<td>April 1, 2016</td>
<td>2017 OPPS/ASC proposed rule</td>
<td>2017 OPPS/ASC final rule with comment</td>
</tr>
<tr>
<td>July 1, 2016</td>
<td>Level II HCPCS codes Category I (certain vaccine codes) and III CPT codes</td>
<td>July 1, 2016</td>
<td>2017 OPPS/ASC proposed rule</td>
<td>2017 OPPS/ASC final rule with comment</td>
</tr>
<tr>
<td>October 1, 2016</td>
<td>Level II HCPCS Codes</td>
<td>October 1, 2016</td>
<td>2017 OPPS/ASC final rule with</td>
<td>2018 OPPS/ASC final rule with</td>
</tr>
</tbody>
</table>


January 1, 2017 | Level II HCPCS Codes | January 1, 2017 | comment | comment

Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April and July of 2016 for Which CMS Solicited Public Comments in the Proposed Rule

CMS did not receive any public comments regarding the proposed ASC payment indicators and payments rates. CMS adopts as final the new Level II HCPCS codes. Tables 44, 45, and 46 in the final rule, reproduced below, identify the codes.

The final 2017 payments rates for these codes can be found in Addendum AA and BB of the final rule at the CMS website referenced above.

### New Level II HCPCS Codes for Covered Surgical Procedures for Covered Ancillary Services Implemented in April 2016 (Table 44)

<table>
<thead>
<tr>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>C9137</td>
<td>J7207</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.</td>
<td>K2</td>
</tr>
<tr>
<td>C9138</td>
<td>J7209</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.</td>
<td>K2</td>
</tr>
<tr>
<td>C9461</td>
<td>A9515</td>
<td>Choline C 11, diagnostic, per study dose</td>
<td>K2</td>
</tr>
<tr>
<td>C9470</td>
<td>J1942</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9471</td>
<td>J7322</td>
<td>Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9472</td>
<td>J9325</td>
<td>Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)</td>
<td>K2</td>
</tr>
<tr>
<td>C9473</td>
<td>J2182</td>
<td>Injection, mepolizumab, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9474</td>
<td>J9205</td>
<td>Injection, irinotecan liposome, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9475</td>
<td>J9295</td>
<td>Injection, necitumumab, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J7503</td>
<td>J7503</td>
<td>Tacrolimus, extended release, (Envarsus XR), oral, 0.25 mg</td>
<td>K2</td>
</tr>
</tbody>
</table>

### New Level II HCPCS Codes for Covered Ancillary Services Implemented in July 2016 (Table 45)

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C9476</td>
<td>J9145</td>
<td>Injection, daratumumab, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9477</td>
<td>J9176</td>
<td>Injection, elotuzumab, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9478</td>
<td>J2840</td>
<td>Injection, sebelipase alfa, 1 mg</td>
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<tr>
<td>C9479</td>
<td>C9479</td>
<td>Instillation, ciprofloxacin otic suspension, 6 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9480</td>
<td>J9352</td>
<td>Injection, trabectedin, 0.1 mg</td>
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<tr>
<td>Q9981</td>
<td>J8670</td>
<td>Rolapitant, oral, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q5102</td>
<td>Q5102</td>
<td>Injection, infliximab, biosimilar, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q9982*</td>
<td>Q9982</td>
<td>Flutemetamol F 18, diagnostic, per study dose, up to 5 millicuries</td>
<td>K2</td>
</tr>
</tbody>
</table>
**HCPCS Code C9459 was deleted on June 30, 2016 and replaced with HCPCS Code Q9982 effective July 1, 2016.**

**HCPCS Code C9458 was deleted on June 30, 2016 and replaced with HCPCS Code Q9983 effective July 1, 2016.**

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Q9983**</td>
<td>Q9983</td>
<td>Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries</td>
<td>K2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*HCPCS Code C9459 was deleted on June 30, 2016 and replaced with HCPCS Code Q9982</td>
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<tr>
<td></td>
<td></td>
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<td>**HCPCS Code C9458 was deleted on June 30, 2016 and replaced with HCPCS Code Q9983</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>effective July 1, 2016</td>
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</tr>
<tr>
<td>0437T</td>
<td>0437T</td>
<td>Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial</td>
<td>N1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>reinforcement of the abdominal wall (List separately in addition to primary procedure)</td>
<td></td>
</tr>
<tr>
<td>0438T*</td>
<td>0438T</td>
<td>Transperineal placement of biodegradable material, periprostatic (via needle),</td>
<td>G2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>single or multiple, includes image guidance</td>
<td></td>
</tr>
<tr>
<td>0439T</td>
<td>0439T</td>
<td>Myocardial contrast perfusion echocardiography; at rest or with stress, for</td>
<td>N1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>assessment of myocardial ischemia or viability (List separately in addition to</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>primary procedure</td>
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<tr>
<td>0440T</td>
<td>0440T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity</td>
<td>G2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>distal/peripheral nerve</td>
<td></td>
</tr>
<tr>
<td>0441T</td>
<td>0441T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity</td>
<td>G2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>distal/peripheral nerve</td>
<td></td>
</tr>
<tr>
<td>0442T</td>
<td>0442T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or</td>
<td>G2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>other truncal nerve (eg, brachial plexus, pudendal nerve)</td>
<td></td>
</tr>
<tr>
<td>0443T</td>
<td>0443T</td>
<td>Real time spectral analysis of prostate tissue by fluorescence spectroscopy</td>
<td>G2</td>
</tr>
<tr>
<td>0444T</td>
<td>0444T</td>
<td>Initial placement of a drug-eluting ocular insert under one or more eyelids,</td>
<td>N1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>including fitting, training, and insertion, unilateral or bilateral</td>
<td></td>
</tr>
<tr>
<td>0445T</td>
<td>0445T</td>
<td>Subsequent placement of a drug-eluting ocular insert under one or more eyelids,</td>
<td>N1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>including re-training, and removal of existing insert, unilateral or bilateral</td>
<td></td>
</tr>
</tbody>
</table>

*HCPCS Code C9743 was deleted on June 30, 2016 and replaced with CPT code 0438T effective July 1, 2016.
Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2017 for Which CMS Responds to Comments in the 2017 Final Rule

For the 115 new and revised Category I and III CPT codes effective January 1, 2017 that were received in time to be included in the proposed rule, CMS responds and finalizes Ambulatory Payment Classification (APC) and status indicator assignments, as well as payment rates. Those new and revised codes are listed in Addendums AA and BB, and the long descriptors are in Addendum O at the ACS website.

CMS finalizes with one modification, the proposed 2017 ASC payments indicators for new and revised CPT codes, effective January 1, 2017. CMS modifies its proposal and assigns CPT code 0465T to payment indicator “P3”. CMS agrees with commenters that the procedure described by HCPCS code 05X1T (finalized as CPT code 0465T) is similar to the procedure described by CPT code 67028, which has a payment indicator of “P3”.

Process for New and Revised Level II HCPCS Codes That Will be Effective October 1, 2016 and January 1, 2017 for Which CMS is Soliciting Public Comments in this 2017 OPPS/ASC Final Rule with Comment Period

CMS continues its policy to assign comment indicator “NI” in Addendum B to the 2017 OPPS/ASC final rule with comment for those new and revised Level II HCPCS codes that are effective October 1, 2016 and January 1, 2017. Theses codes are included in Addendum B to that final rule and flagged with the “NI” comment indicator to indicate that CMS has assigned the codes an interim OPPS payment status for 2017.

CMS invites public comments on the interim status indicators and APC assignments, and payment rates that will be finalized in the 2018 OPPS/ASC final rule with comment period. There are 268 HCPCS codes identified as having a “NI” comment indicator in the Addendum B file.

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

Covered Surgical Procedures Designated as Office-Based

CMS annually reviews volume and utilization data to identify “office-based” procedures that are added to the ASC list of covered surgical procedures and are performed more than 50 percent of the time in physicians’ offices and that CMS’ medical advisors believe are of a level of complexity consistent with other procedures performed routinely in physicians’ offices.

Based on its review of 2015 data, CMS finalizes its proposal to permanently designate one additional procedure as office-based: CPT Code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), with payment indicator of “R2” in 2017. CMS did not receive any public comments on this proposal.

CMS also reviews 2015 volume and utilization data for the eight procedures finalized for
temporary office-based status in last year’s final rule. CMS found that there were very few or no claims data for these procedures, and finalizes its proposal to maintain the temporary office-based designations for these eight codes for 2017. Table 48 in the final rule (reproduced below) lists the procedures and CMS’ payment indicators for 2017.

<table>
<thead>
<tr>
<th>2017 CPT Code</th>
<th>2017 Long Descriptor</th>
<th>2016 ASC Payment Indicator*</th>
<th>Final 2017 ASC Payment Indicator**</th>
</tr>
</thead>
<tbody>
<tr>
<td>0299T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including</td>
<td>R2*</td>
<td>R2**</td>
</tr>
<tr>
<td></td>
<td>topical application and dressing care;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0402T</td>
<td>Collagen cross-linking of cornea (including removal of the corneal epithelium and</td>
<td>R2*</td>
<td>R2**</td>
</tr>
<tr>
<td></td>
<td>intraoperative pachymetry when</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10030</td>
<td>Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma,</td>
<td>P2*</td>
<td>P2**</td>
</tr>
<tr>
<td></td>
<td>seroma, lymphocele, cyst), soft tissue (e.g., extremity abdominal wall, neck),</td>
<td></td>
<td></td>
</tr>
<tr>
<td>64461</td>
<td>Paravertebral block (PVB) (paraspinous block), thoracic; single injection site</td>
<td>P3*</td>
<td>P3**</td>
</tr>
<tr>
<td></td>
<td>(includes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>64463</td>
<td>Continuous infusion by catheter (includes imaging guidance, when performed)</td>
<td>P3*</td>
<td>P3**</td>
</tr>
<tr>
<td>65785</td>
<td>Implantation of intrastromal corneal ring segments</td>
<td>R2*</td>
<td>P2**</td>
</tr>
<tr>
<td>67229</td>
<td>Treatment of extensive or progressive retinopathy, one or more sessions; preterm</td>
<td>R2*</td>
<td>R2**</td>
</tr>
<tr>
<td></td>
<td>infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>age (e.g., retinopathy of prematurity), photoagulation or cryotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G0429***</td>
<td>Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and</td>
<td>R2*</td>
<td>R2**</td>
</tr>
<tr>
<td></td>
<td>provision of Radiesse or Sculptra dermal filler, including all items and supplies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* If designation is temporary.
** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates.
***HCPCS code G0429 replaces HCPCS code C9800, effective January 1, 2017.

CMS finalizes its proposal to designate two new 2017 codes (CPT codes 36901 and 36473) for ASC covered surgical procedures as temporarily office-based. Because CMS has no utilization
data, CMS makes the office-based designations temporary. Table 49 lists the procedures and CMS’ payment indicators for 2019.

ASC Covered Surgical Procedures Designated as Device-Intensive – Finalized Policy for 2016 and Final Policy for 2017

CMS previously implemented its 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 the ASC payment system. CMS continued its policy that all separately paid ancillary services provided integral to surgical procedures that map to a comprehensive APC would continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS.

CMS continues 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 in the 2016 rulemaking cycle also solicited and received comments about calculating device intensity at the HCPCS level rather than at the APC level, but finalized no changes. CMS now 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.

CMS finalizes its proposal for 2017, without modification, that 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 ratesetting methodology would be designated as an ASC device-intensive procedure, and modifies 42 CFR 416.171(b)(2) to reflect that change. The majority of commenters supported CMS’ proposal and a few requesting that CMS lower the threshold to 30 percent to qualify a larger number of ASC procedures as device-intensive. CMS disagreed with this logic and stated that lowering the threshold to 30 percent would create a disparity in the number of procedures designated as device-intensive in the ASC setting, when compared to the HOPD setting.

In addition, CMS finalizes its proposal, without modification, that for new HCPCS codes requiring the implantation of medical devices that do not yet have associated claims data, it would apply device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. The purpose of applying this offset would be to ensure ASC access for new procedures until claims become available. CMS notes that in certain rare instances, such as for a very expensive implantable device, it may apply a higher offset percentage if warranted by additional information provided by a manufacturer.

Commenters were generally supportive and asked CMS to specify how additional information can be submitted to CMS, including the deadline and type of information, so that CMS can consider a higher device offset percentage for a new implant procedure. In response, CMS states
that additional information for CMS consideration of a medical device that does not yet have associated claims data, such as pricing data or invoices, may be directed to CMS staff in the Division of Outpatient Care. This information can be submitted prior to the issuance of an OPPS/ASC proposed rule or as a public comment in response to a proposed rule.

For 2017, CMS finalizes its proposal to update 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. Addendum AA at the CMS ACS website lists the procedures, including the CPT code and short-descriptor, the 2017 payment indicator, device offset percentage, and an indication of the full credit/partial credit device adjustment policy that would apply.

**Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices**

CMS finalized a modification in payment for devices furnished with full or partial credit under the OPPS in the 2014 final rule, but there is no mechanism in the ASC claims processing system for ASCs to submit the actual amount received when furnishing a device without cost or with full or partial credit. CMS finalizes its proposal to continue its policy for ASCs, for 2017:

- When the device is furnished at no cost or with full credit from the manufacturer, the contractor will reduce payment to the ASC by 100 percent of the device offset amount, which is the amount that CMS estimates as the cost of the device. The ASC will append the HCPCS “FB” modifier on the claim line with the procedure to implant the device.

- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, the contractor will reduce payments to the ASC by 50 percent of the device offset amount. In order to report a partial credit, the ASC will have the option of either submitting the claim after the procedure, but prior to manufacturer acknowledgement of credit for the device, and having the contractor make a claim adjustment, or holding the claim for payment until a determination is made by the manufacturer. The ASC will then submit the claim with a “FC” modifier if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device.

**Additions to the List of ASC Covered Surgical Procedures**

CMS conducted its annual review of procedures paid under the OPPS but not included on the list of covered ASC procedures. After consideration of public comments, CMS finalizes its proposal with respect to seven of the eight procedures it proposed to add to the list of covered surgical procedures that could meet the standards for inclusion – that is, they could be safely performed in the ASC setting and would not require an overnight stay.

CMS notes that, as in prior years, this update includes review of procedures proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. CMS finalizes its proposal to add the procedures described by CPT codes 22585,
22840, 22842, and 22845, which are being removed from the OPPS inpatient list for 2017, to the list of ASC covered surgical procedures for 2017. CMS also includes the procedure described by CPT code 22585 on this list. Based on its review, three other codes proposed for removal from the OPPS inpatient list (CPT codes 22858, 31584 and 31587) were not included on the ASC list because the procedures would generally be expected to require at least an overnight stay.

Table 51 in the final rule (reproduced below) displays the 11 procedures that CMS is adding to the ASC list of covered surgical procedures.

<table>
<thead>
<tr>
<th>2017 CPT Code</th>
<th>2017 Long Descriptor</th>
<th>2017 ASC Payment Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>20936</td>
<td>Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision (List separately in addition to code for primary procedure)</td>
<td>N1</td>
</tr>
<tr>
<td>20937</td>
<td>Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)</td>
<td>N1</td>
</tr>
<tr>
<td>20938</td>
<td>Autograft for spine surgery only (includes harvesting the graft); structural, biocortical or tricortical (through separate skin fascial incision)</td>
<td>N1</td>
</tr>
<tr>
<td>22552</td>
<td>Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophysectomy and decompression of spinal cord and/or nerve roots; cervical C2, each additional interspace (List separately in addition to code for separate procedure)</td>
<td>N1</td>
</tr>
<tr>
<td>22840</td>
<td>Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)</td>
<td>N1</td>
</tr>
<tr>
<td>22842</td>
<td>Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)</td>
<td>N1</td>
</tr>
<tr>
<td>22845</td>
<td>Anterior instrumentation; 2 to 3 vertebral segments</td>
<td>N1</td>
</tr>
</tbody>
</table>
Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure) N1

22854*

Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure) N1

22859*

Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure) N1

* Effective January 1, 2017, CPT codes 22853, 22854, and 22859 replaced CPT code 22851, which was deleted April 13, 2016 by the AMA Editorial Panel.

Covered Ancillary Services:

CMS finalizes its proposal, without modification, to update theASC list of covered ancillary services to reflect the payment status for the services under the OPPS. ASC covered ancillary services and their payment indicators for 2017 are included in Addendum BB at the ASC website.

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

Payment for Covered Surgical Procedures; Update to ASC Covered Surgical Procedure Payment Rates for 2017

CMS finalizes its proposal, without modification, to update payments for office-based procedures and device-intensive procedures using its established methodology, and using its modified definition for device-intensive procedures. CMS notes that because the OPPS relative payment weights are based on geometric mean costs for 2017 and subsequent years, the ASC system will use geometric means to determine the relative payment weights under the ASC standard methodology. CMS will update the payment amount for the service portion of device-intensive procedures using the ASC standard ratesetting methodology, and the payment amount for the device portion based on the 2017 OPPS device offset percentages. CMS will make payment for office-based procedures at the lesser of the 2017 MPFS nonfacility PE RVU-based amount, or the 2017 ASC payment amount calculated according to the standard methodology.

CMS finalizes its proposal to continue its policy (same as in 2014, 2015, and 2016) for device
removal procedures – such procedures that are conditionally packaged in the OPPS would be assigned the current ASC payment indicators and continue to be paid separately under the ASC payment system.

Several commenters disagreed with the proposed 2017 rates for certain surgical procedures described by the following CPT codes: 29883, 28293, 43239, 45378, 66982, and 66984. CMS did not make any additional adjustments, and finalizes its proposed polices, without modification.

**Payment for Covered Ancillary Services**

CMS finalizes its policies, as proposed, regarding payment for covered ancillary services:

- CMS continues its policy to update payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services.
- CMS also continues its policy to set payment methodologies for brachytherapy services and separately payable drugs and biologicals equal to the 2017 OPPS rates.
- CMS continues its policy to base payment for separately payable covered radiology services based on the lower of the 2017 MPFS nonfacility PE RVU-based amounts and the 2017 ASC rate calculated under standard ratesetting methodology (except in the case of nuclear medicine procedures and services that use contrast agents). If the radiology service is packaged or conditionally packaged under the OPPS, payment for the radiology service will be packaged into the payment for the ASC. Addendum BB indicates the payment status for each radiology service.
- In the case of nuclear medicine procedures designated as radiology services paid separately when provided integral to a surgical procedure on the ASC list, CMS will continue to set payments based on the OPPS relative payment weights, and therefore will include the cost of the diagnostic radiopharmaceutical. In the case of radiology services that use contrast agents, CMS will continue to set payment based on the OPPS relative payment rate, and will, therefore, include the cost of the contrast agent.
- CMS will continue to not make separate payment for procurement of corneal tissue when used in any noncorneal transplant procedure.
- With regards to contractor-priced codes, CMS will continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant. In addition, consistent with its established ASC payment policy, CMS will continue its policy that the 2017 payment for devices that are eligible for pass-through payment under the OPPS would be separately paid under the ASC payment system and contractor-priced. The four devices eligible for pass-through payment in the OPPS are HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system); HCPCS code C2613 (Lung biopsy plug with delivery system); C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); C2613 (Lung biopsy plug with delivery system); and C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components).
• Consistent with its current policy, CMS will continue its policy that certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. CMS will pay for the tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard rate-setting methodology. CMS identifies no new codes that meet this criterion for 2017.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2017 by the March 1, 2016 deadline. CMS did not change its payment adjustment of $50 per lens for a 5-year period from the implementation date of a new NTIOL class.

F. ASC Payment and Comment Indicators

CMS finalizes its proposal to continue using the current comment indicators “NP” and “CH.” CMS also finalizes its proposal that Category I and III CPT codes that are new and revised for 2017 and any new and existing Level II HCPCS codes with substantial revisions will be labeled with the new comment indicator ‘NP” to indicate that these codes were open for comment as part of the 2017 proposed rule.

Addenda DD1 and DD2 provide a complete list of the ASC payment and comment indicators for 2017. CMS did not receive any public comments on the ASC payment and comment indicators.

G. Calculation of the ASC Conversion Factor and the ASC Payment Rates

Updating the ASC Relative Payment Rates for 2017 and Future Years

CMS finalizes its proposal to continue to update relative weights using the national OPPS relative weights and the MPFS nonfacility PE RVU-based amounts when applicable. CMS scales the relative weights as under prior policy. Holding ASC use and mix of services constant from 2015, CMS computes the ratio of:

- Total payments using the 2016 relative payment rates, to
- Total payments using the 2017 relative payment rates.

The resulting ratio, 0.9000 (compared with 0.9992 in the proposed rule), is the weight scaler for 2017. The scaler would apply to the payment for covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes for which the ASC payments are based on OPPS relative weights. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights. That includes drugs and biologicals that are separately paid, and services that are contractor-priced or paid at reasonable cost in ASCs.
Updating the ASC Conversion Factor

CMS finalizes its proposal to compute the budget neutrality adjustment factor for changes in wage index values as under prior policy. Holding constant ASC use and mix of services in 2015 and the 2017 national payment rates after application of the weight scalar, CMS proposes to compute the ratio of:

- ASC payments using the 2016 ASC wage indices, to
- ASC payments using the 2017 ASC wage indices.

The resulting ratio, 0.9996 (compared with 0.9992 in the proposed rule) is the wage index budget neutrality adjustment for 2017.

CMS finalizes its proposal to continue its policy of updating the conversion factor by the CPI-U estimated for the 12-month period ending with the mid-point of 2017. CMS uses the IHS Global Insight (IGI) 2016 third quarter forecast, which yields a projected CPI-U update of 2.2 percent and a multifactor productivity adjustment of -0.3 percent. That yields an update of 1.9 percent for ASCs meeting quality reporting requirements.

CMS continues its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of -0.1 percent (a 0.9999 update factor) for such ASCs.

The resulting 2017 ASC conversion factor published by CMS is $45.030 for ASCs reporting quality data, and $44.330 for those that do not, computed as follows:

<table>
<thead>
<tr>
<th>ASC reporting quality data</th>
<th>ASC not reporting quality data</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 ASC conversion factor:</td>
<td>$44.190</td>
</tr>
<tr>
<td>Wage adjustment for budget neutrality</td>
<td>x 0.9996</td>
</tr>
<tr>
<td>Net MFP-adjusted update</td>
<td>x 1.019</td>
</tr>
<tr>
<td>2017 ASC conversion factor</td>
<td>$45.030*</td>
</tr>
<tr>
<td></td>
<td>$44.330*</td>
</tr>
</tbody>
</table>

*These are the published numbers in the final rule, but the 2017 ASC conversion factors listed are not the product of the CY 2016 conversion factor multiplied by the wage index budget neutrality adjustments and the MFP-adjusted CPI-U payment update. Using the numbers CMS provided in the final rule, the 2017 conversion factor for ASCs reporting quality data would be $45.012; for ACSs not reporting quality data would be $44.128.

Impact

CMS sets out estimated aggregate increases by surgical specialty group for the six groups that account for the most ASC utilization and spending in Table 53 of the final rule, replicated below, which assumes the same mix of services as reflected in 2015 claims data.

The eye and ocular adnexa group remains the largest source of payments, with a 2 percent increase attributable to the payment changes in 2017. The second largest group, digestive
system, is estimated to see a 1 increase. The Musculoskeletal group is estimated to receive the largest increase of 8 percent.

Summary of Table 53: Aggregate 2017 Medicare Program Payments by Surgical Specialty, for the six largest groups

<table>
<thead>
<tr>
<th>Surgical Specialty Group</th>
<th>Estimated 2016 ASC Payments (in Millions)</th>
<th>Estimated 2017 Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$3,993</td>
<td>2%</td>
</tr>
<tr>
<td>Eye and ocular adnexa</td>
<td>$1,556</td>
<td>2%</td>
</tr>
<tr>
<td>Digestive system</td>
<td>$813</td>
<td>1%</td>
</tr>
<tr>
<td>Nervous system</td>
<td>$687</td>
<td>0%</td>
</tr>
<tr>
<td>Musculoskeletal system</td>
<td>$466</td>
<td>8%</td>
</tr>
<tr>
<td>Genitourinary system</td>
<td>$178</td>
<td>-1%</td>
</tr>
<tr>
<td>Integumentary system</td>
<td>$132</td>
<td>-3%</td>
</tr>
</tbody>
</table>

Notes: The six items total $3,832 million, $161 million less than the total provided. The difference is presumed to be spending for specialty groups with lower volume and spending that were included in the table in previous years but not included this year: respiratory system, cardiovascular system, ancillary items and services, auditory system and hematologic & lymphatic systems. CMS states in the text that the costs of separately payable covered ancillary items and services is estimated to be $31 million for 2017.

CMS sets out estimated increases for 30 selected procedures in Table 54 in the final rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far, and is estimated to see a 1 percent increase.

Excerpt from Table 54: Estimated Impact of the 2017 Update to the ASC Payment System on Aggregate Payments for the Top 10 Procedures

<table>
<thead>
<tr>
<th>CPT/ HCPS Code</th>
<th>Short Descriptor</th>
<th>Estimated 2016 ASC Payments (in Millions)</th>
<th>Estimated 2017 Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>66984</td>
<td>Cataract surg w/iol, 1 stage</td>
<td>$1,108</td>
<td>1%</td>
</tr>
<tr>
<td>43239</td>
<td>Egd biopsy single/multiple</td>
<td>$185</td>
<td>-9%</td>
</tr>
<tr>
<td>45380</td>
<td>Colonoscopy and biopsy</td>
<td>$180</td>
<td>13%</td>
</tr>
<tr>
<td>45385</td>
<td>Colonoscopy w/lesion removal</td>
<td>$118</td>
<td>13%</td>
</tr>
<tr>
<td>66982</td>
<td>Cataract surgery, complex</td>
<td>$96</td>
<td>1%</td>
</tr>
<tr>
<td>64483</td>
<td>Inj foramen epidural l/s</td>
<td>$87</td>
<td>6%</td>
</tr>
<tr>
<td>63685</td>
<td>Insert redo spine n generator</td>
<td>$82</td>
<td>10%</td>
</tr>
<tr>
<td>64493</td>
<td>Inj paravert f jnt 1/s 1 lev</td>
<td>$71</td>
<td>-24%</td>
</tr>
<tr>
<td>63650</td>
<td>Implant neuroelectrodes</td>
<td>$66</td>
<td>12%</td>
</tr>
<tr>
<td>66821</td>
<td>After cataract laser surgery</td>
<td>$65</td>
<td>4%</td>
</tr>
</tbody>
</table>

See Table 54 for full list of 30 procedures.

As noted at the beginning of this ASC section, Addenda tables available only on the website provide additional details. They are at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-FC.html.
XIII. Hospital Outpatient Quality Reporting Program Updates

CMS adopts changes to the Hospital Outpatient Quality Reporting (OQR) Program including the addition of seven new measures beginning with the 2020 payment determination. In addition, a change is made to the deadline for extraordinary circumstances exemptions. A summary table at the end of this section shows all adopted OQR Program measures for the 2014 through 2020 payment determinations.

A. Background

CMS reviews the history of the various quality reporting programs currently in place and discusses its goal of aligning clinical quality measures across these programs, including the OQR Program.

No changes were proposed to existing policies regarding the retention and removal of OQR Program measures, measure selection, or criteria for “topped out” measures. As established under the 2013 OPPS final rule, once a measure is adopted for the Hospital OQR Program for a payment determination year it is automatically adopted for subsequent years until CMS removes, suspends, or replaces it. No measures are removed under this rule. Previously, CMS adopted 23 measures for the 2017 payment determination, and 25 mandatory (plus 1 voluntary) measures for the 2018 and 2019 payment determinations.

B. New Measures Beginning with the 2020 Payment Determination

CMS adopts all seven of the proposed new OQR Program measures to begin with the 2020 payment determination. Two are claims-based measures and five are measures from the Outpatient and Ambulatory Surgery Center Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey, which hospitals must collect and report via a CMS-approved vendor. For each of the new measures the final rule discusses the rationale, data sources, the measure calculation, cohort, and risk adjustment. Specifications for the two claim-based measures are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInitis/Measure-Methodology.html and for the OAS CAHPS Survey at https://oascahps.org/.

Responding to commenters concerned that only one of the measures has been endorsed by the National Quality Forum (NQF), CMS states that it sought and received extensive input on the

- AA -- List of ASC Covered Surgical Procedures for 2017 (Including surgical procedures for which payment is packaged)
- BB -- ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2017 (Including Ancillary Services for Which Payment is Packaged)
- DD1 -- ASC Payment Indicators for 2017
- DD2 -- ASC Comment Indicators for 2017
- EE -- Surgical Procedures Excluded from Payment in ASCs for 2017
measures from stakeholders and clinical experts and reiterates that it believes consensus on a measure can be achieved through the measure development process, use of Technical Expert Panel and public comments. Further, it says the non-endorsed measures were reviewed by the Measure Applications Partnership (MAP) which conditionally supported or encouraged further development of the now finalized measures.

1. Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Treatment

This claims-based measure aims to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in the OPD. It includes calculation of two mutually exclusive outcomes within 30 days of chemotherapy in the OPD:

(1) one or more inpatient admissions, and
(2) one or more ED visits for any of ten diagnoses (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia or sepsis).

An individual patient will only be counted toward one outcome, and a patient experiencing both counts only in the inpatient admission score. CMS says that both adverse events are signals of quality and important patient outcomes, but they should be treated separately because the severity and cost of an inpatient admission is greater than an ED visit.

The two components of the measure will each be risk standardized rates calculated as the ratio of predicted to expected outcomes multiplied by the national observed rate. In proposing the measure, CMS noted that the MAP conditionally supported the measure pending NQF endorsement with special consideration for sociodemographic status (SDS) adjustments and the selection of exclusions. Responding to commenter concerns about the lack of risk adjustment for SDS, CMS repeats its past concern that risk adjustment for SDS could minimize incentives to improve outcomes of disadvantaged populations, and notes again that it is monitoring the work of the Assistant Secretary for Planning and Evaluation on the impact of SDS on quality measures.

Further, CMS reports that during measure development it undertook assessment of the relationship between SDS factors and the measure outcomes in accordance with the NQF SDS trial period. It looked specifically at patient race, Medicaid dual eligible status and the Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) Index for the patient’s neighborhood and found no significant associations between these factors and the measure outcomes. Further, CMS says that at the hospital level there was “no clear relationship” between median risk-standardized rates under this measure and hospital case mix by the three SDS factors and that hospitals with a higher percentage of low SDS patients have similar rates of inpatient stays and ED visits within 30 days of hospital outpatient chemotherapy.

Responding to comments regarding the lack of NQF endorsement for this measure, CMS cites clinical literature regarding the gap in care for patients receiving chemotherapy in the hospital outpatient setting and says that the analyses it conducted during measure development demonstrate that the measure is accurate, valid, and actionable. In particular, because the
measure is limited to diagnoses that are commonly cited reasons for unplanned hospitalizations and ED stays it believes the performance rate will be more meaningful and actionable to hospitals. CMS believes that adopting this measure will make visible to clinicians, meaningful quality differences that will encourage improvement and reduce adverse patient outcomes after outpatient chemotherapy.

Some commenters noted that the NQF Cancer Project 2015-2017 failed to endorse the measure citing reliability concerns, but CMS disagrees with that conclusion and argues that the measure is reliable. A discussion of its reliability methodology and findings is provided; it says the reliability rate (interclass correlation coefficient or ICC) for risk-standardized admissions was 0.41 with a 95 percent confidence interval of 0.37 to 0.45 for a half-year data sample but increased to 0.63 with a 95 percent confidence interval of 0.58 to 0.68 when statistically adjusted to account for a full-year data sample. For risk-standardized ED visits the full-year estimated ICC was 0.47 with a 95 percent confidence interval of 0.40 to 0.53. Using NQF standards CMS says these results represent strong and moderate reliability, respectively. CMS also believes this measure to be valid and provides a link to the NQF website where it submitted materials on the measure. http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80703. Readers must find the measure on the list and click through a series of web pages to access the materials.

CMS responds to a number of other comments including those regarding the appropriateness of the measure and clinical basis of the particular 10 conditions chosen to assess unplanned admissions and ED visits, the 30-day window, potential exclusions of planned admissions and certain diagnoses, and other measure specifications.

The performance period for this measure is one year; claims data for patients receiving OPD chemotherapy during calendar year 2018 will be used for the 2020 payment determination.

2. Hospital Visits after Hospital Outpatient Surgery (NQF #2687)

The second new claims-based measure addresses hospital visits after same-day surgery in the OPD. The specific outcomes measured are inpatient admissions directly after the surgery and unplanned hospital visits defined as an ED visit, observation stay, or unplanned hospital admission within 7 days of the surgery. If more than one unplanned hospital visit occurs, only the first visit is counted in the measure.

Same day surgeries are substantive surgeries and procedures on Medicare’s covered list of ASC procedures, excluding eye surgeries. Eye surgeries are excluded because the risk profile is more representative of minor surgery. The ASC list for 2017 is included in ASC 2017 Addendum AA available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

The performance period for this measure is one year; claims data for patients receiving same-day surgeries in the OPD during calendar year 2018 will be used for the 2020 payment determination.
This measure was endorsed by the NQF in September 2015; the MAP supported the inclusion of this measure in the OQR but noted that the NQF endorsement occurred prior to the start of the SDS trial period and should be re-examined during measure maintenance to determine whether SDS adjustments are needed. In proposing the measure, CMS repeated its long-standing position regarding risk adjustment for SDS, as summarized above.

In addition, in responding to comments regarding the lack of SDS adjustment, CMS reports that it evaluated the potential effects of adjusting for Medicaid dual eligibility and race and found that these factors had little effect on measure scores; the adjusted and unadjusted ratios were highly correlated (0.99 for dual eligibility and 0.998 for race). CMS says it further considered the distribution of measure scores by quartiles for the race and dual eligible factors and found that many OPDs with high proportions of dual eligibles or African American patients perform well on the measure.

Some comments suggested adding outpatient surgeries performed in ASCs to OP-36, and in response CMS states that the comparison would not be appropriate because ASCs tend to specialize in a few procedures whereas OPDs perform a wide range of procedures. CMS agrees that it is appropriate to hold both ASCs and OPDs accountable and notes that to avoid favoring ASCs it is developing two new outcome measures that assess hospital visits within 7 days following orthopedic and urology procedures performed at ASCs. These measures are expected to undergo MAP review in December 2016. CMS refers readers to results of public comment on these measures available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html.

CMS responds to a number of other comments on the post-surgery hospital visits measure involving the value of procedure-specific outcome measures, treatment of planned readmissions, the specification of surgical procedure complexity in risk adjustment, and clarifications regarding place of service coding and identification of qualifying stays. CMS disagrees with commenters concerned that this measure creates disincentives for appropriately seeking care in the ED, and notes that the goal of the measure is not to reach zero ED visits and that the measure is risk adjusted to protect hospitals with higher-risk patients from being disadvantaged. CMS notes that it plans a dry run of this measure in 2017 and will assess some implementation issues at that time.

3. Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems

The OAS CAHPS Survey contains 37 questions that cover access to care, communications, experience at the facility, and interactions with facility staff. Global ratings and demographic information are also collected. Voluntary implementation of the OAS CAHPS Survey began in January 2016. More information can be found on the OAS CAHPS Survey website at https://oascahps.org/. The survey questions along with the Protocols and Guidelines Manual can be found under the “Survey Materials” tab.

Five OAS CAHPS-based measures are finalized for addition to the OQR Program for 2020 payment. (The same measures are added to the ASC Quality Reporting Program, as discussed in
section XIV below.) The measures are listed here and include three composite measures, each of which consist of at least 6 OAS CAHPS Survey questions, and two global rating measures, involving one survey question each. More information about the OAS CAHPS Survey and these measures, including the survey cohort and risk adjustment, can be found at the OAS CAHPS Survey website noted above.

- OP-37a: OAS CAHPS – About Facilities and Staff (composite)
- OP-37b: OAS CAHPS – Communication About Procedure (composite)
- OP-37c: OAS CAHPS – Preparation for Discharge and Recovery (composite)
- OP-37d: OAS CAHPS – Overall Rating of Facility

Included in the patient cohort for this measure are those who are age 18 or older who had at least one outpatient surgery or procedure during the month. The OAS CAHPS Survey Protocols and Guidelines Manual details the cohort inclusions and exclusions, such as eligible CPT and G-codes. Exclusions include patients residing in a nursing home, those discharged to hospice following the surgery as well as those who are deceased.

The OAS CAHPS Survey is not NQF-endorsed, but CMS says it will be submitted under an applicable call for measures “in the near future.” Responding to concerns of commenters, CMS reiterates that the MAP encouraged continued development of the measures and that subsequent to the MAP submission the five measures were “fully developed.” CMS discusses how it collected stakeholder input on the survey through a January 2013 request for information (78 FR 5460) and convened two Technical Advisory Panels. Testing of the survey in 36 facilities (half hospitals and half ASCs) occurred in 2014 and 2015 and CMS says it was found reliable. Readers are referred to the Collection of Information request for more information on testing. This is available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201510-0938-003. Readers need to click through to earlier ICR reference numbers to find supporting statements discussing survey testing. CMS further discusses how the field test data were used to identify item-level refinements to the survey instrument.

Regarding commenter concerns about the resources needed to collect the survey information, CMS says that it believes the benefits of assessing patient experience of care outweigh the burdens. Some commenters expressed concern about the possibility of patient confusion if they receive multiple patient experience surveys around the same episode of care (e.g., inpatient, outpatient hospital, clinician), and CMS responds by saying that the surveys focus on different aspects of care and the introduction letter (and telephone survey) includes the date and location of the procedure which it believes will avoid confusion.

In proposing this measure, CMS specifically noted that the OAS CAHPS Survey includes two questions regarding pain management that would be part of the communications composite measure. Section XIX of this summary describes the removal of the pain management dimension (involving three survey questions) from the inpatient hospital patient survey (HCAHPS) for purposes of performance scoring in the hospital VBP Program. CMS noted that the OAS CAHPS Survey pain management questions are very different from the HCAHPS, but welcomed feedback on the questions. In particular, CMS said the OAS CAHPS Survey
questions do not address the adequacy of the hospital’s pain management efforts and the OAS CAHPS Survey is used only for public reporting so that hospital payment would not be affected by performance on these measures.

The current specific pain management questions on the OAS CAHPS Survey are as follows:

Q15: Some ways to control pain include prescription medicine, over-the-counter pain relievers or ice packs. Did your doctor or anyone from the facility give you information about what to do if you had pain as a result of your procedure?
   A1: Yes, definitely.
   A2: Yes, somewhat.
   A3: No.

Q16: At any time after leaving the facility, did you have pain as a result of your procedure?
   A1: Yes.
   A2: No.

CMS identifies the second question as a control question used to determine whether the hospital should have given the patient additional guidance on how to handle pain after leaving the facility. The facility is not scored on this question and the results will not be publicly reported.

Responding to comments on the pain management questions, CMS elaborates that the question regarding whether the patient has pain (Q16) is used only to determine whether to count in the score the answer to the question about whether information was given to the patient on what to do if they experienced pain (Q15). That is, a patient answering yes they experienced pain would indicate that the answer to whether or not they were given the information about what to do with pain is to be included in the score. CMS says that for a procedure such as a colonoscopy where pain is not expected a doctor or the facility may not have given the patient information about pain and in that case the response to Q15 would not be counted unless the patient response is top-box (“yes, definitely). CMS further notes that questions 17 and 18 regarding whether information was provided on nausea and vomiting and whether nausea/vomiting was experienced are similarly constructed, with the latter being used only to determine whether the former answer is counted in the score. CMS says it will review data from the voluntary national implementation and evaluate the appropriateness of these control questions and whether there are unintended consequences.

Regarding concerns from commenters about the length of the 37-question survey, CMS say that the OAS CAHPS Survey is similar in length to other patient experience of care surveys. For example, it reports that the 32-question HCAHPS survey has a response rate of about 32 or 33 percent, while OAS CAHPS Survey had a 39 percent response rate in the 2015 test of three modes of survey administration. CMS also believes most of the survey questions are directly actionable; it is however contemplating removing the gender and age demographic questions in its net update because that information can be retrieved from facility records.
In response to comments, CMS discusses the Emergency Department Patient Experiences with Care (EDPEC) survey, which it has under development and notes that the OAS CAHPS Survey, which involves patients receiving select outpatient procedures, should not be administered to ED patients. More information on the EDPEC is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/ed.html.

CMS responds to a number of other comments on this measure including those involving the use of the HCAHPS four-point scale for OAS CAHPS Survey, overlap with the clinician and surgical CAHPS tools, the role of facilities versus clinicians in patient education, and CPT codes for identifying eligible surgeries and procedures.

Administrating and Scoring the OAS CAHPS Survey

Hospitals will be required to contract with a CMS-approved vendor to collect survey data on a monthly basis for quarterly reporting to CMS. Hospitals may elect to also collect data on up to 15 supplemental questions. As noted above, for the 2020 payment determination, data will be collected during calendar year 2018; in general, the performance period is the calendar year 2 years prior to the affected payment year. Nondiscrimination requirements for effective communication with persons with disability and language access for persons with limited English proficiency apply.

Hospital eligibility to perform the OAS CAHPS Survey will be determined at the individual Medicare participating hospital level. All data collection and submission, and also public reporting, for these measures will be at the Medicare participating hospital level as identified by the hospital’s CCN. Therefore, the reporting for a CCN would include all eligible patients from all eligible hospital locations of the Medicare participating hospital that is identified by the CCN.

Hospitals will be required to survey eligible patients each month. In general, over each 12-month reporting period, hospitals must collect at least 300 completed surveys (an average of 25 per month). As discussed below, certain low-volume hospitals may apply for an exemption but absent an exemption, smaller hospitals that cannot collect 300 completed surveys over a 12-month reporting period are required to survey all eligible patients.

Responding to comments expressing concern about the proposed target minimum number of surveys that hospitals must collect, CMS clarifies that hospitals will fall into one of three categories:

- Hospitals receiving more than 300 completed surveys during the reporting period must either randomly sample their eligible patient population or survey the entire population. That is, random sampling of 300 surveys is optional. The OAS CAHPS Survey Protocols and Guidelines Manual lists acceptable sampling methods (https://oascahps.org/Survey-Materials).
- Hospitals that anticipate not receiving 300 completed surveys during the 12-month reporting period must survey all patients. There is no option for random sampling.
- Hospitals with relatively few survey-eligible patients may request an exemption from the OAS CAHPS survey administration. The exemption is available to hospitals that treat fewer than 60 survey-eligible patients during an “eligibility period,” which is the calendar...
year before the data collection period (e.g., calendar year 2017 for the 2020 payment
determination). Hospitals may submit a participation exemption request form, on the
https://oascahps.org website by May 15 of the data collection calendar year (e.g., May 15,
2018 for the 2020 payment determination).

Other requirements for administration of the OAS CAHPS survey are discussed in item XIII.C.2
below.

Scores for public reporting purposes will be based on “top box” responses (“Yes” or “Yes
Definitely”). For each composite measure, the percentage of top box responses for each survey
question will be calculated. These will be summed across all the survey questions for that
composite and then divided by the number of survey questions in that composite to obtain the
raw measure score. The raw score will be risk adjusted for patient characteristics such as age,
education, overall health status, mental status, type of surgical procedure and English
proficiency.

CMS intends to propose a format and timing for public reporting of OAS CAHPS Survey data in
future rulemaking prior to implementation of the measures. It intends to use data from this
voluntary national implementation which began in January 2016 to inform the displays for public
reporting of OAS CAHPS Survey data.

Responding to a comment suggesting that the OAS CAHPS survey use the same administration
method as the HCAHPS survey, CMS says that procedures used by vendors are aligned for the
two surveys, and that the only difference between the two is that for the HCAHPS hospitals may
either self-administer or contract with a vendor, and for the OAS CAHPS self-administration is
not an option. Further, CMS says that the administration of the OAS CAHPS follows recent
protocols for other CAHPS surveys regarding the release of patient-level data. Under that
protocol, patient-level data may not be released to the hospital unless the patient has consented.
Because hospitals can self-administer the HCAHPS CMS does not state that responses will not
be shared with the hospital. However, when administered by a vendor, surveys are not linked to a
patient name unless the patient gives consent. Facilities may choose to add a “content to share”
question to the OAS CAHPS survey. CMS encourages facilities to consult with counsel to ensure
compliance with applicable privacy and security laws.

4. Possible Hospital OQR Program Measure Topics for Future Consideration

CMS discusses comments it received regarding possible future measure topics for the OQR
Program. Some commenters suggested adding a series of adult immunization measures.
Responding to comments sought by CMS regarding the potential addition of electronic
clinical quality measures (eCQMs) to the OQR Program, CMS states that it gives high priority
to alignment with the Hospital Inpatient Quality Reporting (IQR) Program requirements and
those of the Joint Commission’s ORYX program
(https://www.jointcommission.org/facts_about_oryx_for_hospitals/).

In the proposed rule CMS indicated that it is in the early development of a new eCQM that
would measure the proportion of adults who have an active prescription for an opioid and have
additional opioids or benzodiazepine prescribed to them during a care encounter. CMS discusses the numerous comments it received on this measure concept, which it will take into account in ongoing measure development and testing, and commits to working with stakeholders in developing the measure. It notes that public comment opportunities will be available prior to rulemaking, such as during MAP review and the NQF process.

C. Administrative and Data Submission Requirements and Public Reporting

1. Continuation of Policies

CMS describes ongoing OQR Program policies for which it proposed no changes, which are related to the following: maintenance of technical specifications for measures; the QualityNet account and security administrator; requirements regarding participation in the OQR Program; data submission deadlines; requirements for reporting chart-abstracted measures; requirements for claims-based measures, which will also apply to the two new claims-based measures added to the OQR Program beginning with 2020 payment; requirements for measures submitted via a web-based tool; population and data sampling requirements; and data validation requirements.

2. Data Submission Requirements for the OAS CAHPS Measures

For the new OAS CAHPS measures, hospitals must meet the following requirements:

- Contract with a CMS-approved OAS CAHPS Survey vendor to administer the survey. A list of approved vendors is available at the OAS CAHPS website (https://oascahps.org). Hospitals would register on that website to authorize the CMS-approved vendor to administer the survey and submit data on their behalf.
- Administer (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the Protocols and Guidelines Manual and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.
- Through the vendor collect survey data via mail-only, telephone-only and mixed mail/telephone modes. Guidelines on these modes are available on the https://oascahps.org website under the Survey Materials tab.
- Initiate data collection no later than 21 days after the month in which a patient has a surgery or procedure at a hospital and complete it with 6 weeks (42 days) after initial contact of an eligible patient.
- Make multiple attempts to contact patients unless they refuse participation or are found to be ineligible.

The OAS CAHPS Survey administration requirements for hospitals and survey vendors under the Hospital OQR Program are codified in new regulatory text at 42 CFR 419.46(g).

Responding to commenters, CMS indicates that it is investigating email and web-based survey administration options for administering the OAS CAHPS in the future.

CMS encourages hospitals to participate in the voluntary implementation of OAS CAHPS that began in January 2016 and urges hospitals to be fully appraised of the methods and actions of
their survey vendor and to inspect all data warehouse reports in a timely manner. CMS notes that
the use of predictive or auto dialers in telephonic survey administration is governed by the
Telephone Consumer Protection Act (TCPA) (47 USC 227) and subsequent regulations
promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal
Trade Commission. To the extent that any existing CMS technical guidance conflicts with the
TCPA, its implementing regulations, or any other applicable law, CMS expects vendors to
comply with applicable law. Readers are referred to the FCC’s declaratory ruling released on
July 10, 2015 further clarifying the definition of an auto dialer, available at:

3. Extension for Extraordinary Circumstances Exemption Request Deadline

CMS extends the extraordinary circumstances exemption (ECE) request deadline for both chart-
abstracted and web-based measures from 45 days following an event causing hardship to 90 days
following an event causing hardship. This will be effective with ECEs requested on or after
January 1, 2017 for the 2019 payment determination. The 90-day deadline aligns with the ECE
request deadlines for the Hospital VBP Program, the Hospital-Acquired Condition Reduction
Program, the Hospital Readmissions Reduction Program, the Hospital IQR Program and the long
term care hospital quality reporting program. A parallel proposal is finalized below with respect
to the ASCQR Program.

4. Public Display of OQR Measures

CMS finalizes formal adoption of its current practices regarding the timing of public display and
the preview period. Specifically, CMS proposes to
- publicly display data on Hospital Compare Web or another CMS website, as soon as
  possible after measure data have been submitted to CMS;
- generally give hospitals approximately 30 days to preview their data; and
- announce the timeframes for the preview period starting with the CY 2018 payment
determination on a CMS website or applicable listservs.

5. Clarification Regarding OQR Program Reconsideration and Appeals

The process by which participating hospitals may submit requests for reconsideration was
previously codified at 42 CFR 419.46(f), and language at §419.46(f)(3) addresses appeals to the
Provider Reimbursement Review Board. In this rule, CMS clarifies that if a hospital fails to
submit a timely reconsideration request to CMS via the QualityNet website by the applicable
deadline, the hospital will not subsequently be eligible to file an appeal with the Provider
Reimbursement Review Board. This clarification is effective January 1, 2017 for the 2017
payment determination and subsequent years.

D. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program
   Requirements for the 2017 Payment Determination

CMS continues existing policies with respect to computing and applying the payment reduction
for hospitals that fail to meet the Hospital OQR Program requirements for the 2017 update
factor. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the
“reporting ratio”, is 0.98. It is calculated by dividing the reduced conversion factor of $75.001 by the full conversion factor of $73.501. Continuing previous policies, when applicable the reporting ratio is applied to all services calculated using the OPPS conversion factor and applied to all HCPCS codes to which CMS has assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, V, or U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T. CMS clarifies that the reporting ratio does not apply to codes with a status indicator of “Q4” because these services are either packaged or paid through the clinical laboratory fee schedule and are never paid under the OPPS.

The reporting ratio continues to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services. All other applicable standard adjustments to the OPPS national unadjusted payment rates apply, and OPPS outlier eligibility and outlier payment are based on the reduced payment rates. Beneficiaries and secondary payers share in the reduced payment to hospitals that are subject to the payment reduction.

CMS reports that for 2016 payment, 113 hospitals failed to meet the OQR Program requirements for a full update factor; 71 of these hospitals chose not to participate in the program.

E. Impact Analysis

In the Collection of Information Requirements and economic impact sections of the proposed rule, CMS discusses the potential effects of the OQR Program changes on hospitals. The burden on hospitals associated with fielding and reporting the OAS CAHPS Survey are acknowledged, but no estimates are provided.

F. Summary Table of OQR Program Measures

The table below shows the final measures for the 2020 payment determination along with OQR measures previously adopted for payment determinations from 2014 through 2019. (In some cases, measures were adopted but data collection suspended prior to the measure being removed. These measures are not listed here.) Specifications for OQR Program measures are available on the QualityNet website:


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<td>OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention</td>
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### XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

In the 2012 OPPS/ASC final rule, CMS finalized the implementation of the ASCQR Program beginning with the 2014 payment determination. That rule finalized measures for the 2014, 2015 and 2016 payment determinations. In several subsequent rules, additional program requirements were finalized and additional measures were adopted through 2019.

#### A. ASCQR Program Measures

In this rule, CMS adopts seven new measures for addition to the ASCQR Program beginning in 2020; no changes are made to the previously adopted measures, which continue unless proposed for removal. The new measures include two web-based measures and five OAS CAHPS measures that are also added to the OQR Program in this rule. For each of the new measures the final rule discusses the rationale for the measure, data sources, the measure calculation, measure cohort and exclusions, and risk adjustment. Specifications for the two proposed web-based measures are shown in the Specifications Manual available at [https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244](https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244).

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* CMS notes that NQF endorsement of these measures was removed.


1. Normothermia Outcome Measure

This measure assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. CMS believes this measure is relevant to the ASCQR program because impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia, which is associated with numerous adverse outcomes including cardiac complications; surgical site infections; impaired coagulation; and colligation of drug effects. The proposed rule included citations to a number of studies regarding these outcomes. The measure is not NQF endorsed, and the MAP conditionally supported its inclusion in the ASCQR Program pending completion of reliability testing and NQF endorsement. CMS notes that this measure is maintained by the ASC Quality Collaboration, which is recognized in the community as an expert in measure development for the ASC setting. CMS believes the measure is reliable and reports results of testing completed by the measure steward to support this view.

The data collection period for this measure will be the calendar year two years prior to the payment determination year (e.g., 2018 for the 2020 payment determination). Data will be submitted between January 1 and May 15 of the following year (e.g., 2019 for the 2020 payment determination).

Responding to comments, CMS acknowledges there is a lack of evidence regarding a performance gap on perioperative normothermia outcomes, but it believes the serious adverse associated outcomes and the volume of procedures performed with anesthesia in ASCs warrant monitoring using this measure. It believes that the addition of this measure will assist patient decision-making and promote ASC quality improvement activities. In addition, while CMS believes the measure’s temperature threshold of 36°C/98.6°F is appropriate, it recognizes that a measure recently endorsed by the NQF (#2681, Perioperative Temperature Management) and finalized for use in the MIPS uses a lower threshold of 35.5°C/95.9°F. CMS says it will engage the measure steward in harmonization efforts, and will discuss its continued evaluation of the measure in future rulemaking.

2. Unplanned Anterior Vitrectomy

This measure assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye). This procedure is performed when the vitreous inadvertently prolapses into the anterior segment of the eye during cataract surgery. CMS cites literature on the value of this measure and notes that rates of this procedure are between 2 to 4 percent of all cases. The measure is not NQF endorsed; the MAP supported its inclusion conditionally. In proposing this measure, CMS noted that the measure is also maintained by the ASC Quality Collaboration and has been found to be reliable.
Like the normothermia outcome measure, the data collection period for this measure will be the calendar year two years prior to the payment determination year (e.g., 2018 for the 2020 payment determination). Data will be submitted between January 1 and May 15 of the following year (e.g., 2019 for the 2020 payment determination).

3. Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems

CMS adopts for the ASCQR Program the same five OAS CAHPS measures adopted for the OQR Program as discussed above in item XIII.B.3. More information about the OAS CAHPS and the proposed measures, including the survey cohort and risk adjustment, can be found at the OAS CAHPS Survey website at https://oascahps.org/. The five new measures are:

- ASC-15a: OAS CAHPS – About Facilities and Staff (composite)
- ASC-15b: OAS CAHPS – Communication About Procedure (composite)
- ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery (composite)
- ASC-15d: OAS CAHPS – Overall Rating of Facility
- ASC-15e: OAS CAHPS – Recommendation of Facility

As is the case for hospitals, ASCs must contract with a CMS-approved OAS CAHPS vendor to collect survey data on eligible patients on a monthly basis and report to CMS by the quarterly deadlines. These requirements for ASCs are codified at 42 CFR 416.310(e). Parallel requirements to the OQR Program are made for the ASCQR Program with respect to the data collection period (e.g., 2018 for 2020 payment), target minimum number of surveys (300 surveys per 12-month reporting period, with random sampling an option for higher-volume ASCs and survey of all patients for those anticipating fewer patients) and an exemption process for ASCs with fewer than 60 survey-eligible patients in the prior year. Measure calculations and scoring (for purposes of public reporting) are also the same as those finalized for hospitals.

CMS notes that ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) in a year are not required to participate in the ASCQR Program (42 CFR 416.305(c)). For example, an ASC with fewer than 240 Medicare claims in 2017 (for the 2019 payment determination year) will not be required to participate in the ASCQR Program in 2018 (for the 2020 payment determination year). An ASC exempt from the ASCQR program does not have to also submit an exemption request form for the OAS CAHPS for the same time period. CMS is unclear on interaction of these thresholds, and because it may be possible for an ASC to treat enough patients to be eligible for the ASCQR yet not meet the 60 survey-eligible patient threshold for reporting the OAS CAHPS, it is adopting the separate exemption policy for this measure.

An individual ASC that meets the OAS CAHPS exemption criteria may submit a participation exemption request form regardless of whether it operates under an independent CCN or shares a CCN with other facilities. However, all data collection and submission, (and ultimately, also public reporting) for the OAS CAHPS Survey measures will be at the CCN level. Therefore, the reporting for a CCN will include all eligible patients from all eligible ASCs covered by the CCN. Responding to a comment, CMS indicates that it will consider for future rulemaking the
feasibility of requiring ASCs to collect and report OAS CAHPS Survey data at the National Provider Identifier level, which is done for other ASCQR Program measures.

Some commenters noted that many ASCs use a different patient experience survey, and CMS makes clear that in order to meet the ASCQR requirements, an ASC must administer the OAS CAHPS Survey in accordance with the Protocols and Guidelines Manual. It encourages ASCs to consider adding specific questions to the OAS CAHPS Survey rather than administering a second patient survey. The final rule provides that an ASC may add up to 15 supplemental questions.

An ASC that administers the OAS CAHPS Survey in accordance with the Survey Protocol and Guidelines Manual and submits data to CMS by the applicable deadline will not be penalized under the ASCQR, regardless of the number of completed surveys the facility receives. CMS notes that in the mode experiment for the OAS CAHPS Survey conducted in 2015, the response rate across all modes for ASCs was 39.6 percent.

See item XIII.B.3 above for CMS responses to other comments on this measure discussed regarding its application to hospitals, as many of these comments and responses are identical to those discussed with respect to ASCs in this section of the rule.

4. **ASCQR Program Measures for Future Consideration**

In the proposed rule, CMS invited public comments on a measure developed by the ASC Quality Collaboration for potential inclusion in the ASCQR Program in future rulemaking: the Toxic Anterior Segment Syndrome (TASS) measure. TASS, an acute, noninfectious inflammation of the anterior segment of the eye, is a complication of anterior segment eye surgery that typically develops within 24 hours after surgery. The TASS measure assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within 2 days of surgery. CMS believes this topic is of interest to the ASCQR Program because cataract surgery is an anterior segment surgery commonly performed at ASCs. The TASS measure was reviewed by the MAP, which conditionally supported its inclusion pending review and endorsement by the NQF. Specifications for this measure for the ASC setting can be found at: [http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf](http://ascquality.org/documents/ASC%20QC%20Implementation%20Guide%203.2%20October%202015.pdf).

Some comments were in support of measuring the incidence of TASS while others raised concerns about the attribution of TASS to an ASC. CMS will take the comments into consideration as it considers proposing this measure in the future.

**B. Administrative and Data Submission Requirements**

Previously adopted ASCQR Program policies are continued regarding technical specifications; QualityNet account and administrator; participation status; data collection periods for claims-based measures; minimum threshold, case volume and data completeness requirements for claims based measures; requirements for data submitted via a non-CMS online tool; and program reconsideration procedures.
1. **Data Submission Deadline for CMS Online Tool**

The deadline for data submitted via a QualityNet website tool is changed from August 15 of the year prior to the payment determination year to May 15 of that year. This change is effective beginning with the 2019 payment determination. Five existing measures are affected and beginning with the 2020 payment determination, the two new web-based measures are also affected (ASC-6, ASC-7, ASC-9 ASC-10 ASC-11, ASC-13, ASC-14). As proposed, a change is made to the regulatory text to reflect this policy.

2. **Data Submission Requirements for the OAS CAHPS Survey-based Measures**

Data submission proposals for ASCs for the OAS CAHPS Survey measures parallel those for hospitals described in item XIII.C.2 above.

3. **Extension for Extraordinary Circumstances Exemption Request Deadline**

CMS extends the extraordinary circumstances exemption (ECE) request deadline from 45 days following an event causing hardship to 90 days following an event causing hardship, effective beginning with the 2019 payment determination. This change parallels the ECE request deadlines for other programs as well as the newly finalized change for the OQR Program discussed in section XIII.D.3 above.

4. **Public Reporting of ASCQR Program Data**

CMS finalizes its proposal to formalize current practices regarding the timing of public display and the preview period. Specifically, CMS will

- publicly display data on Hospital Compare or another CMS website, as soon as possible after measure data have been submitted to CMS;
- generally give ASCs approximately 30 days to preview their data; and
- announce the timeframes for the preview period starting with the CY 2018 payment determination on a CMS website or applicable listservs.

C. **Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements**

No changes are made to the policies for determining the payment reduction for ASCs that fail to meet the ASCQR Program requirements. Medicare law requires that a 2.0 percentage point reduction to the ASC annual update is applied to ASCs that fail to meet the requirements. The reduction applies to services calculated using the ASC conversion factor with the payment indicators of A2, G2, P2, R2, Z2, and the service portion of device-intensive procedures identified by J8. The reduction does not apply to services that are assigned other status indicators for which payments are not calculated using the conversion factor, including separately payable drugs and biologicals, pass through devices that are contractor-prices, brachytherapy sources that are paid based on OPPS payment rates, and others. When the 2.0 update reduction is applied to a facility’s update, beneficiary copayments are based on the reduced payment rate.
CMS reports that for the 2016 payment determination, 261 of the 5,260 ASCs that met eligibility requirements for the ASCQR Program failed to meet the requirements for a full payment update.

D. Impact Analysis

In the Collection of Information Requirements section of the proposed rule, CMS estimates that the reporting burden associated with each of the two proposed web-based measures would total $2.7 million across all ASCs. Estimates are not provided with respect to the OAS CAHPS Survey measures.

E. Summary Table of ASCQR Program Measures

A table of proposed ASCQR Program measures along with previously adopted measures follows. Specifications for ASCQR measures are available on the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagemenu=QnetPublic%2FPPage%2FQnetTier2&cid=1228772475754.

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### XV. Transplant Outcomes: Restoring the Tolerance Range for Patient and Graft Survival

As part of the Medicare Conditions of Participation (CoP) for solid organ transport programs, the regulations specify certain thresholds that a program cannot exceed and still be in compliance.\(^{11}\) Specifically, the regulations specify that a program is not in compliance with the CoPs for patient and graft survival if three thresholds are all crossed: (1) the observed to expected (O/E) ratio exceeds 1.5; (2) the results are statistically significant (\(p<.05\)); and (3) the results are numerically meaningful (that is, the number of observed events minus the expected number is greater than 3). If all three thresholds are exceeded, the program is not in compliance with the CMS standard. CMS finalizes without modification its proposals to change the O/E ratio related to patient deaths and graft failures programs from 1.5 to 1.85 in the CoPs for solid organ transport programs and to apply that same threshold to all organ types for both graft and patient survivals. The O/E ratio reports the aggregate number of patient deaths and graft failures that occurred within one year after each transplant patient’s receipt of an organ compared to the expected events. An O/E ratio of 1.5 means that the patient deaths or graft failures were 150 percent of the risk-adjusted expected number.\(^{12}\)

CMS re-states its rationale for the changes: as national outcomes have improved, it has become more difficult for an individual transplant program to meet the pre-existing outcomes standard. This is because the ratio is based on a transplant program’s outcomes in relation to the risk-adjusted national average. As the national average improves, individual transplant centers are more likely to fall over the threshold. The concern is that transplant programs may elect not to use certain available organs out of fear that such use will adversely affect their outcome statistics. CMS cites, for example, that the percentage of adult kidneys donated and recovered—but not used—increased from 16.6 percent in 2006 to 18.3 percent in 2007 to 18.7 percent in 2014 and 19.3 percent in 2015. During 2007 to 2015, the number of unused adult kidneys increased from 2,632 to 3,159. CMS believes that a change in the threshold from 1.5 to

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11 The CoPs for data submission, clinical experience, and outcome requirements are codified at 42 CFR 482.80 and 482.82. Solid organ transplantation includes kidney, heart, liver, lung, intestine, and pancreas.
1.85 would restore the approximate compliance levels for adult kidney transplants that were allowed in 2007 when national performance was not so high.

Some commenters supported the change to the O/E ratio while others thought the proposed ratio should have been increased to a number greater than 1.85. CMS agreed with other commenters noting that regulatory provisions should align with the Organ Procurement and Transplantation Network (OPTN) policies and that future data and analysis should be used to understand the impact of the O/E changes finalized in this rule. CMS reiterates that for future consideration, it may explore other approaches aimed at optimizing the effective use of available organs.

**XVI. Organ Procurement Organizations (OPOs): Changes to Definitions; Outcome Measures; and Documentation Requirements**

CMS finalizes its proposals with a few modifications, as described below, to ensure more consistent requirements with Organ Procurement Organizations (OPOs). OPOs are responsible for identifying eligible donors, recovering organs from deceased donors, reporting information to the United Network for Organ Sharing (UNOS) and OPTN, and complying with all CMS outcome and process performance measures.

1. **Definition of “Eligible Death”**

To ensure more consistent requirements, CMS proposed to replace the definition for “eligible death” at §486.302 with the upcoming revised OPTN definition of “eligible death.” CMS finalizes the proposed changes with one minor modification for clarity. As proposed, the finalized definition includes donors up to the age of 75 and replaces the automatic exclusion of potential donors with Multi-System Organ Failure with listed clinical criteria for suitable procurement. In response to comment, CMS adds a phrase indicating that changes regarding donors with HIV are consistent with the HIV Organ Policy Equity Act (the HOPE Act).

2. **Aggregate Donor Yield for OPO Outcome Performance Measures**

In the final rule, CMS revises its regulations at §486.318(a)(3) and §486.318(b)(3) to be consistent with the current aggregate donor yield metric in use by Scientific Registry of Transplant Recipients (SRTR), that was revised in 2012. CMS makes these changes because of concerns that its current donor yield measure may have created a hesitancy on the part of OPOs to pursue donors for only one organ due to the impact on the CMS yield measure. CMS states that the OPTN/SRTR yield metric is a more accurate measure for organ yield performance and accounts for differences between donor case-mixes across donation service areas. This metric is based on 29 donor medical characteristics and social complexities. In response to comment, CMS incorporates additional changes intended to clarify that the revised donor yield metric does not impact existing requirements that OPOs meet two out of three outcomes measures. CMS also restates its intent to revisit and revise other OPO measures at a future date.
3. Organ Preparation and Transport-Documentation with the Organ

CMS finalizes, without modification, its proposal to revise §486.346(b), which previously required that an OPO send complete documentation of donor information to the transplant center along with the organ. Specifically, CMS no longer requires that paper documentation, with the exception of blood typing and infectious disease information, be sent with the organ to the receiving transplant center. CMS also conforms the documentation requirement to be consistent with current OPTN policy, which requires that blood type source documentation and infectious disease testing results be physically sent in hard copy with the organ.

CMS notes that the pre-existing requirement resulted in a large volume of donor record materials being copied and sent to the transplant centers by the OPOs with the organ. However, all these data can now be accessed by the transplant center electronically. As a result, CMS estimates that the documentation changes will result in savings of a total of $259,000 per year for all 58 certified OPOs.

XVII. Transplant Enforcement Technical Corrections and Proposals

CMS finalizes as proposed a technical correction to the preamble and regulatory language it adopted in 2015 regarding enforcement provisions for organ transplant centers. CMS corrects a typographical error in the final citations in a response to a commenter: the response should have stated “In the final regulation, at §488.61(f)(1) and elsewhere, we [CMS] therefore limit the mitigating factors provision to deficiencies cited for noncompliance with the data submission, clinical experience, or outcomes requirements specified at §482.80 and §482.82.” CMS also amends §488.61(f)(1) to correct the same incorrect citations. CMS finalizes two additional proposals without modification in this section:

- CMS amends §488.61(f)(3) to extend the due date for programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days, and clarifies that the time period for submission of the mitigating factors information is calculated in calendar days (that is, 120 calendar days).

CMS revises §488.61(h)(2) to clarify that a signed Systems Improvement Agreement (SIA) with a transplant program remains in force even if a subsequent SRTR report indicates that the transplant program has restored compliance with the Medicare CoPs. CMS states, in its sole discretion, that it may shorten the timeframe or allow modification to any portion of the elements of the SIA.

XVIII. Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

CMS proposed to further modify the Modified Stage 2 and Stage 3 objectives and measures under the Medicare EHR Incentive Program for 2017 and 2018, and to change the 2016 reporting period for eligible professionals (EPs), eligible hospitals, and CAHs that have previously

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demonstrated meaningful use under the program. Other policies in the proposed rule related to EPs, eligible hospitals and CAHs that have not previously demonstrated meaningful use and are seeking to do so for the first time in 2017. Finally, changes were proposed with respect to measure calculations for actions occurring outside the EHR reporting period.

CMS adopts final policies based on its proposals, most without modification.

- It adopts the proposed changes to the objectives and measures for 2017 and 2018 for all eligible hospitals and CAHs that submit an attestation to CMS, including dual-eligible hospitals (described below).
- It provides for a 90-day EHR reporting period in both CYs 2016 and 2017 for all returning participants.
- It requires EPs, eligible hospitals and CAHs that have not successfully demonstrated meaningful use in a prior year and that are seeking to demonstrate meaningful use for the first time in 2017 to avoid the 2018 payment adjustment by attesting by October 1, 2017 to the Modified Stage 2 objectives and measures.
- It provides a one-time significant hardship exception from the 2018 payment adjustment for certain EPs who are new participants in the EHR Incentive Program in 2017 and are transitioning to MIPS in 2017.
- Beginning in CY 2017, it requires for measure calculations for actions outside the EHR reporting period, for all meaningful use measures, unless otherwise specified, that actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs.

CMS notes that it did not specifically address in the proposed rule the impact of these policies on eligible hospitals and on CAHs that are eligible to participate in both the Medicare and Medicaid EHR Incentives Programs; in this section of the final rule, CMS refers to these hospitals as "dual-eligible hospitals." Dual-eligible hospitals attesting to CMS (via systems such as the Hospital IQR Program reporting portal) will attest based on the revised objectives and measures for 2017 and 2018 (including the adopted revisions to eliminate the CPOE and CDS objectives and measures). Dual-eligible hospitals may submit one attestation for both the Medicare and Medicaid EHR Incentive Programs to CMS, and the attestation data will be shared with the appropriate State Medicaid agency to process the Medicaid incentive payment. State Medicaid agencies will be able to rely on these Medicare attestations to determine whether these hospitals qualify for incentive payments under the Medicaid EHR Incentive Program. Medicaid-only hospitals and dual-eligible hospitals that choose to attest directly to a State for the State’s Medicaid EHR Incentive Program will continue to attest to the measures and objectives as finalized in the 2015 EHR Incentive Programs.

A. Revisions to Objectives and Measures for Eligible Hospitals and CAHs

Responding to concerns about reporting burden, CMS adopts the set of changes it proposed to the objectives and measures of meaningful use for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2017 and later years. Further, the reporting thresholds
for a subset of the remaining Modified Stage 2 objectives and measures for 2017 and Stage 3 objectives and measures for 2017 and 2018 are reduced.

The changes relate only to the Medicare EHR Incentive Program; they do not affect requirements for an eligible hospital or CAH attesting under a State Medicaid EHR Incentive Program. CMS reiterates that it considered applying the changes to the Medicaid EHR Incentive Program as well, but it is concerned about the burden on states to update technology and reporting systems in a short period of time. Commenters stated that having two different sets of meaningful use requirements poses a reporting burden for health systems with providers that participate in both programs and encouraged CMS to align all programs to the same threshold requirements and measures (or as close as possible). CMS notes that under MACRA, eligible clinicians must report under MIPS; CMS believes the different statutory requirements limit the agency’s ability to align measures and thresholds between those programs.

Some commenters appreciated the additional flexibility under the revised objectives ad measures, but they noted the requirements are still burdensome and complicated. Others expressed concern about having to satisfy requirements through relatively untested technology and functionalities related to applicable programming interfaces (APIs) and about the practicability of Modified Stage 2 and Stage 3 objectives and measures; still others were concerned by the timing of the rule and its impact on their ability to successfully comply with requirements. CMS believes that its additional flexibility will address most concerns and that interoperability and EHR functionalities will advance for the 2015 Edition which will increase providers’ success.

1. Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs

CMS determined that, based on 2015 attestation data, performance on the CPOE objective and measures meets the criteria as “topped out,” and removes them from the Medicare EHR Incentive Program. The criteria involve statistically indistinguishable performance at the 5th and 99th percentiles and performance distribution curves at the 25th, 50th and 75th percentiles as compared to the required measure threshold.

While the CDS objective includes “yes/no” measures that cannot be analyzed as a performance distribution, CMS believes that the high level of successful attestation (99 percent for 2015) indicates widespread adoption of this objective and measures, and that they are no longer useful in comparing performance of eligible hospitals and CAHs.

CMS notes that, in the 2015 EHR Incentive Program final rule, it established a policy that where a measure is removed, the technology requirements will remain in the definition of Certified EHR Technology (CEHRT). Therefore, the two objectives and measures that are removed remain part of CEHRT requirements, but an eligible hospital/CAH attesting to meaningful use under Medicare is not required to report on them.

2. Reduction in Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018
CMS adopts its proposals without modification to reduce the required reporting thresholds for a subset of measures. CMS believes this will reduce reporting burden and allow eligible hospitals and CAHs to focus on quality patient care as well as on updating and optimizing CEHRT functionalities and preparing for Stage 3 of meaningful use. In general, the changes replace Stage 3 thresholds with Modified Stage 2 levels. CMS notes that it plans to work with providers toward adopting more stringent thresholds in the future, and welcomes comments on modifying the thresholds for the future or on adding new and more stringent measures. CMS also makes minor changes to the updated naming conventions.

The revised specific threshold changes follow. In discussing each of these changes CMS emphasizes the feedback it has heard from stakeholders regarding challenges in meeting the current thresholds. For example, providers have described the need to educate and communicate with patients who have limited knowledge of or proficiency with information technology and with patients declining to access portals made available to them on the importance of accessing their health information. Vendors have raised concerns that the fledgling state of development of API technology, the need for market testing, and the lack of compatibility functionalities will make it very difficult for hospitals to meet current patient access measure thresholds. Further, many hospital stakeholders have identified the lack of health IT adoption among other provider partners as a barrier to achieving wide scale, interoperable health information exchange.

Modified Stage 2 in 2017

**Objective: Patient Electronic Access**

- View Download Transmit (VDT) Measure: At least 1 patient (or patient authorized representative) [previously 5 percent of patients] who is discharged from the inpatient or emergency department (Place of service (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.

CMS notes that the reduced threshold does not apply to eligible hospitals and CAHs attesting to a state for the Medicaid EHR Incentive Program.

Stage 3 in 2017 and 2018

Some commenters requested that CMS keep the threshold for electronic prescribing at the Modified Stage 2 level (i.e., greater than 10 percent) because the measure is still quite new for hospitals. Others sought clarification on whether providers may include or exclude controlled substances based on a provider's situation. CMS retains the threshold for Stage 3 (i.e., greater than 25 percent), and clarifies that providers do have the flexibility to include or exclude controlled substances in the denominator for the Stage 3 electronic prescribing objective and measure.

**Objective: Patient Electronic Access to Health Information Objective**
• Patient Access Measure: For more than 50 percent [previously 80 percent] of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (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 programming interfaces (APIs) in the provider's CEHRT.

• Patient-Specific Education Measure: The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent [previously 35 percent] of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

In response to a comment, CMS clarifies that for a health care provider to implement an API under the patient access measure, it must fully enable the API functionality in such a way that any application chosen by patients 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.

Objective: Coordination of Care Through Patient Engagement

• VDT Measure (same as Modified Stage 2 above): At least 1 patient (or patient authorized representative) [previously 5 percent of patients] who is discharged from the inpatient or emergency department (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.

• Secure Messaging: For more than 5 percent [previously 25 percent] of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).

One commenter stated that it was premature to include measure 3 (Patient Generated Health Data) and recommended either that it be removed or that the threshold be lowered to one patient. CMS declines to take the commenter's suggestion and notes that providers only have to meet the thresholds for two of the three measures. Commenters believe the requirement to use APIs to connect to any app of a patient's choice in support of patient engagement and coordination of care through patient engagement objectives is premature. CMS declines to make any changes to the API functionality part of the measure.

Objective: Health Information Exchange

• Patient Care Record Exchange Measure: For more than 10 percent [previously 50 percent] of transitions of care and referrals, the eligible hospital 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 CEHRT; and (2) electronically exchanges the summary of care record.

- **Request/Accept Patient Care Record Measure**: For more than 10 percent [previously 40 percent] of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.
- **Clinical Information Reconciliation Measure**: For more than 50 percent [previously 80 percent] of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets: (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy. Review of the patient's known allergic medications; and (3) Current Problem list. Review of the patient's current and active diagnoses.

Commenters believe that the threshold reductions for each measure are not sufficient to address their core concerns about functionality, data blocking and interoperability issues that are outside the control of hospitals. CMS cites a May 2016 ONC report that shows an increase of hospital engagement in health information exchange from 50 percent in 2011 to more than 80 percent in 2015, with more than 85 percent of hospitals sending patient health information electronically in 2015. However, the report also shows that one major barrier is a lack of trading partners that have adopted and implemented certified health IT systems. CMS also refers stakeholders to a new EHR contracting guide on the ONC Web site to help providers address data blocking and other challenges with health IT.  

**Objective: Public Health and Clinical Data Registry Reporting**

- Eligible hospitals/CAHs must successfully attest to reporting any combination of three measures [previously six]. (The six measures from which providers may choose involve immunization registry reporting, syndromic surveillance reporting, electronic case reporting, public health registry reporting, clinical data registry reporting, and electronic reportable laboratory result reporting).

In response to a comment noting that there is a lack of entities ready to accept electronic reporting data, CMS believes the number of registries will increase over time. Additionally, CMS intends to make available in early 2017 a centralized repository for public health agency and clinical data registry reporting which will assist EPs, eligible hospitals and CAHs in finding entities that accept electronic public health data.

The final rule includes tables that summarize the Modified Stage 2 and Stage 3 objectives and measures. These tables are reproduced here.

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<table>
<thead>
<tr>
<th>Objective</th>
<th>Previous Measure Name/Reference</th>
<th>Measure Name</th>
<th>Threshold Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect Patient Health Information</td>
<td>Measure</td>
<td>Security Risk Analysis</td>
<td>Yes/No attestation</td>
</tr>
<tr>
<td>*CDS (Clinical Decision Support)</td>
<td>Measure 1</td>
<td>Clinical Decision Support Interventions</td>
<td>Five CDS</td>
</tr>
<tr>
<td></td>
<td>Measure 2</td>
<td>Drug Interaction and Drug-Allergy Checks</td>
<td>Yes/No</td>
</tr>
<tr>
<td>*CPOE (Computerized Provider Order Entry)</td>
<td>Measure 1</td>
<td>Medication Orders</td>
<td>&gt;60%</td>
</tr>
<tr>
<td></td>
<td>Measure 2</td>
<td>Laboratory Orders</td>
<td>&gt;30%</td>
</tr>
<tr>
<td></td>
<td>Measure 3</td>
<td>Radiology Orders</td>
<td>&gt;30%</td>
</tr>
<tr>
<td>Electronic Prescribing</td>
<td>Measure</td>
<td>e-Prescribing</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>Health Information Exchange</td>
<td>Measure</td>
<td>Health Information Exchange</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>Patient Specific Education</td>
<td>Eligible Hospital/CAH Measure</td>
<td>Patient-Specific Education</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>Medication Reconciliation</td>
<td>Measure</td>
<td>Medication Reconciliation</td>
<td>&gt;50%</td>
</tr>
<tr>
<td>Patient Electronic Access</td>
<td>Eligible Hospital/CAH Measure 1</td>
<td>Patient Access Measure</td>
<td>&gt;50%</td>
</tr>
<tr>
<td></td>
<td>Eligible Hospital/CAH Measure 2</td>
<td>View, Download or Transmit (VDT)</td>
<td>At least 1 patient</td>
</tr>
<tr>
<td>Public Health and Reporting</td>
<td>Immunization Reporting</td>
<td>Immunization Registry Reporting</td>
<td>Public Health Reporting to 3 Registries</td>
</tr>
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<td></td>
<td>Syndromic Surveillance Reporting</td>
<td>Syndromic Surveillance Reporting</td>
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<tr>
<td></td>
<td>Specialized Registry Reporting</td>
<td>Specialized Registry Reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Electronic Reportable Laboratory Result Reporting</td>
<td>Electronic Reportable Laboratory Result Measure</td>
<td></td>
</tr>
</tbody>
</table>

*Objective is removed.

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<table>
<thead>
<tr>
<th>Objective</th>
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<th>Measure Name</th>
<th>Threshold Requirement</th>
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<tr>
<td>Electronic Prescribing</td>
<td>Eligible Hospital/CAH Measure</td>
<td>e-Prescribing</td>
<td>&gt;25%</td>
</tr>
<tr>
<td>*CDS</td>
<td>Measure 1</td>
<td>Clinical Decision Support</td>
<td>Five CDS</td>
</tr>
</tbody>
</table>
CMS intends to reevaluate objectives, measures and other program requirements for Stage 3 in 2019 and subsequent years. One commenter disagreed with CMS making further changes since the 2015 EHR Incentive Programs final rule indicated that Stage 3 would remain unchanged and be the last stage of the program. CMS believes that continual advances, changes, and evolution in technology and in other aspects of the program (e.g., privacy, security, and practice standards) may necessitate additional rulemaking which may include additional stages to the EHR Incentive Programs.
B. Revisions to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs

CMS previously finalized the reporting period for 2016 under the Medicare and Medicaid EHR Incentive Programs as any continuous 90-day period in calendar year 2016 for EPs, eligible hospitals and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) and the full calendar year 2016 for EPs, eligible hospitals and CAHs that have successfully demonstrated meaningful use in a prior year (returning participants).

In this rule, CMS finalizes the reporting period for the 2016 and 2017 EHR reporting periods for returning participants as any continuous 90-day period within calendar year 2016 and 2017, respectively. CMS declines to make a 90-day reporting period a permanent feature of the programs citing its belief that a full year EHR reporting period is the most effective way to ensure that all actions related to patient safety that leverage CEHRT are fully enabled throughout the year. The applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2016 and 2017, as well as the deadlines for attestation and other related program requirements, remain the same.

CMS also finalizes a continuous 90-day reporting period for reporting clinical quality measures (CQMs) for all EPs, eligible hospitals and CAHs that choose to report CQMs by attestation in 2016. This does not affect previously adopted requirements for electronic reporting of CQM data. The 90-day reporting period used for CQM data submitted via attestation does not have to be the same 90-day reporting period that the provider uses for demonstrating meaningful use. CMS intends to permit states to determine the form and manner of reporting CQMs for their State Medicaid EHR Incentive Programs, subject to CMS approval.

C. Requirement for Modified Stage 2 for New Participants in 2017

The 2015 EHR Incentive Program final rule provides for the following in 2017:

- A provider that has technology certified to the 2015 Edition may attest to Stage 3 or to the Modified Stage 2 requirements.
- A provider that has technology certified to a combination of 2015 Edition and 2014 Edition may attest to: (1) the Modified Stage 2 requirements; or (2) potentially to the Stage 3 requirements if the mix of certified technologies would not prohibit them from meeting the Stage 3 measures.
- A provider that has technology certified to the 2014 Edition only may attest to the Modified Stage 2 requirements and may not attest to Stage 3.

CMS has subsequently determined that it is not technically feasible for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest to the Stage 3 objectives and measures in 2017 in the EHR Incentive Program Registration and Attestation System. Therefore, CMS proposed that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 or any CAH new participant seeking to avoid the FY 2017 payment adjustment by attesting for an EHR reporting period in 2017 would be required to attest to the Modified Stage 2 objectives and measures. CMS states that providers using 2014 Edition, 2015
Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 will have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures. CMS finalizes its proposal, emphasizing that it will not permit these providers to attest to Stage 3 objectives and measures. CMS also notes that this policy applies for all new providers, including those who participate in the Medicaid EHR Incentive Program. The attestation date for these providers is October 1, 2017; CMS declines to push that date back. CMS will post guidance materials on its Web site at: https://www.cms.gov/EHRIncentivePrograms/.

This policy does not apply to returning participants attesting for an EHR reporting period in 2017. CMS notes that in early 2018, returning eligible hospitals and CAHs will be transitioned to other reporting systems to attest for 2017, such as the Hospital IQR Program reporting portal. Eligible professionals who have successfully demonstrated meaningful use in a prior year will not be attesting under the Medicare EHR Incentive Program for 2017, because 2016 is the final year of the incentive payment under section 1848(o)(1)(A)(ii) of the Act.

D. Significant Hardship Exemption for New Participants Transitioning to MIPS in 2017

CMS discusses overlap between the new MIPS program performance period and previously adopted reporting for meaningful use. Specifically, in the MIPS and Alternative Payment Model (APM) Final Rule, 2017 is the initial MIPS performance year. Previously, 2017 was established as the last year in which new participants may attest to meaningful use (for a 90-day period) to avoid the 2018 EHR Incentive Program payment adjustment. Therefore, an EP could use a 90-day reporting period in 2017 to demonstrate meaningful use and report under the Advancing Care Information (ACI) performance category in MIPS.

Recognizing that new participants may find it difficult to manage separate requirements, CMS had proposed to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment; CMS finalizes this proposal. This application for a significant hardship exception is limited to EPs who have not previously demonstrated meaningful use in a prior year; who intend to make such an attestation by October 1, 2017 to avoid the payment adjustment; and who also intend to transition to MIPS and report on measures in the ACI category under the MIPS in 2017.

An EP must apply by October 1, 2017. The application must explain why demonstrating meaningful use for the first time in 2017 and reporting on the ACI performance category would result in a significant hardship. EPs must maintain documentation of the hardship application for six years. CMS rejects suggestions to make this hardship exception available to all new participants, rather than certain EPs. Some commenters observed that the application requirement is unnecessary and burdensome on physicians; CMS believes the application process is necessary to verify that an EP meets the criteria for the hardship exception.

E. Modifications to Measure Calculations for Actions Outside the EHR Reporting Period

CMS describes confusion that has arisen from its policy under which, for all meaningful use measures, unless otherwise specified, actions may fall outside the EHR reporting period timeframe but must take place no earlier than the start of the reporting year and no later than the
date of attestation (FAQ 8231). CMS notes that attestation dates, and therefore these timeframes, can vary by provider. For purposes of consistency, CMS finalizes a policy that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if that period is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. For example, if the EHR reporting period is any continuous 90-day period within 2017, the action must occur between January 1 and December 31, 2017, but it does not have to occur within the 90-day EHR reporting period timeframe. CMS says that a small number of actions may occur after December 31 of the year in which the EHR reporting period occurs. However, it notes that the reduced thresholds will significantly reduce the impact that these actions will have on performance. In addition, actions occurring after December 31 of the reporting year will count toward the next calendar year’s EHR reporting period; CMS also wishes to avoid counting the same action in two different years. CMS notes this policy applies to both Modified Stage 2 and Stage 3 objectives and measures. It will update FAQ 8231 to explain the new policy.

XIX. Additional Hospital Value-Based Purchasing Program Policies

CMS finalizes its proposal to remove the HCAHPS pain management dimension from the inpatient hospital VBP Program beginning with the 2018 payment determination year (calendar year 2016 performance period.) This dimension is based on three survey questions addressing whether during the hospital stay the patient needed pain medicine, how often pain was well controlled, and the frequency with which hospital staff did everything they could to help with pain. The change is made in light of ongoing stakeholder concerns that the link between these survey questions and VBP payment adjustment creates incentives for hospital staff to prescribe more opioids to achieve higher scores on this dimension. While it is unaware of any scientific studies that support an association between scores on the Pain Management dimension and opioid prescribing practices, CMS is concerned about possible confusion over the appropriate use of the Pain Management questions and the prescription opioid overdose epidemic.

In discussing these issues, CMS reiterates its belief that pain management is an important part of routine patient care, and notes that the current questions do not specify a particular type of pain control method. Further, it says many factors other than CMS quality program requirements may contribute to the perception of a link between the pain management dimension and opioid prescribing practices. As examples, it cites misuse of the survey such as using it for ED care rather than inpatient care, disaggregating hospital survey results to assess individual physician and staff performance, and failure to recognize that the HCAHPS survey sampling frame excludes individuals with a primary substance use disorder.15

Removing this dimension necessitates changes in VBP scoring. For purposes of scoring the HCAHPS measure beginning in 2018 CMS will continue to assign 10 points for each of the remaining eight dimensions and award up to 20 consistency points for performance across those

remaining eight dimensions. (As previously finalized beginning in 2018, nine HCAHPS dimensions would have been scored at 10 points each and then multiplied by 8/9 to total up to 80 HCAHPS base points with up to 20 consistency points additionally awarded based on performance across all nine dimensions.) The final rule includes tables setting forth the performance standards for the HCAHPS measure dimensions, excluding the pain management dimension, for the 2018 and 2019 payment years. The standards for the other dimensions are unchanged from those that were previously finalized.

Modified pain management questions are being developed, and when these become available for the HCAHPS Survey CMS intends to propose to adopt them for the VBP Program in future rulemaking. In particular, CMS intends to use its standard survey development process to “remove any potential ambiguity” in the HCAHPS Survey pain management questions. It says this involves drafting alternative questions, cognitive interviews and focus group evaluation, field testing, statistical analysis, stakeholder input, the Paperwork Reduction Act, and NQF endorsement. HHS is also conducting further research to understand stakeholder concerns and determine if there are any unintended consequences that link the Pain Management dimension questions to opioid prescribing practices. CMS also says it is in the early stages of developing several related measures. One is an electronically-specified process measure for the inpatient and outpatient hospital settings that would measure concurrent prescribing of an opioid and benzodiazepine. Another is a process measure that would assess whether inpatient psychiatric facilities are regularly monitoring for adverse drug events of opioid and psychotropic drugs. Specifications for these measures will be posted on the CMS website and public input will be invited before these measures are proposed for quality reporting purposes.

CMS disagrees with commenters who recommended that CMS also remove or exclude the pain management questions from the IQR Program and from public reporting on Hospital Compare, including the HCAHPS star ratings and overall ratings, until alternative questions are developed. Noting that public reporting is not tied to payment, CMS believes that continuing to collect and report on these questions will help ensure that hospitals continue to appropriately manage patients’ pain and engage in quality improvement related to pain management and communication. It does not believe there is empirical evidence that failing to prescribe opioids lowers a hospital’s HCAHPS rate.

At the suggestion of a commenter CMS notes that the CDC recently published “Guidelines for Prescribing Opioids for Chronic Pain,” which is available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

**XX. Files Available to the Public via the Internet**

Addenda for this 2017 OPPS/ASC final rule are available on the following CMS website:


Accept the licensing agreement related to CPT and a listing of the Addenda as zip files will appear.
For addenda related to 2017 ASC payments, please see:

Scroll to the “Related Links” sections to find ASC Addenda Addendum AA, BB, DD1, DD2, and EE.

**XXI. Collection of Information Requirements**

CMS discusses collection of information requirements. Costs associated with ASCQR Program requirements are discussed in section XIV above. No other data collection costs are identified.
## APPENDIX

### TABLE 52—ESTIMATED IMPACT OF THE CY 2017 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

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<thead>
<tr>
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<th>(3)</th>
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<td>(excludes hospitals permanently held harmless and CMHCs)</td>
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</tr>
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<td>Number of Hospitals</td>
<td>APC Recalibration (all changes)</td>
<td>New Wage Index and Provider Adjustments</td>
<td>All Budget Neutral Changes (combined cols 2,3) with Market Basket Update</td>
<td>All Changes</td>
</tr>
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<td><strong>DSH PATIENT PERCENT</strong></td>
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<td>574</td>
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</tr>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td>(5)</td>
</tr>
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<td>------</td>
</tr>
<tr>
<td></td>
<td>Number of Hospitals</td>
<td>APC Recalibration (all changes)</td>
<td>New Wage Index and Provider Adjustments</td>
<td>All Budget Neutral Changes (combined cols 2,3) with Market Basket Update</td>
<td>All Changes</td>
</tr>
<tr>
<td>DSH</td>
<td>548</td>
<td>-1.4</td>
<td>-0.3</td>
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<td>-13.7</td>
</tr>
</tbody>
</table>

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2017 OPPS policies and compares those to the CY 2016 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2017 hospital inpatient wage index, including all hold harmless policies and transitional wages. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0003 because the target payment-to-cost ratio target changes from 0.92 in CY 2016 to 0.91 in CY 2017 (80 FR 70362 through 70364).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 1.65 percent OPD fee schedule update factor. It also includes the impact of the additional adjustment of 1.0004 for laboratory services with “L1” modifiers packaged into the OPPS.

Column (5) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through payment estimate, and adding estimated outlier payments.

* These 3,906 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.