Overview
On July 6, 2016, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2017 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Payment System proposed rule.

Page numbers in the summary refer to the public display version of the proposed rule which can be viewed here. Comments will be accepted through September 6, 2016. The final rule will be released in early November 2016.

OPPS General Provisions
CMS proposes to increase the CY 2017 OPPS conversion factor to $73.725 (p. 121). This is the result of several factors. CMS proposes to increase CY 2017 OPPS payments by 1.55 percent (p. 43). This is based on the proposed inpatient market basket increase of 2.8 percent minus a productivity adjustment of 0.5 percent, as well as a 0.75 percent reduction required by the Patient Protection and Affordable Care Act (ACA). Per usual, CMS proposes that if more recent data becomes available, it will use the updated data to alter the conversion factor in the OPPS final rule with comment period (p. 119).

In total, CMS estimates that CY 2017 OPPS payments will increase by approximately $5.1 billion over CY 2016 estimated payments to a total of approximately $63 billion. In addition, CMS proposes to continue to reduce payments by 2.0 percent for hospitals that fail to meet the outpatient quality reporting requirements (p. 43). When accounting for changes in enrollment, utilization and case-mix, CMS states that the overall impact of the policies in the rule would result in a 1.6 percent or $671 million overall increase in OPPS payments to providers (p. 53).

Recalibration of APC Relative Payment Weights (p. 64)
CMS uses the same annual process to update the APC relative weights and payments for CY 2017. CMS makes the payment rates (including the relative payment weights for each APC) available via the CMS Web site Addendum A and Addendum B updates. CY 2017 rates are based on data submitted from claims for services furnished after January 1, 2015 and before January 1, 2016. CMS proposes to continue its policy of using hospital cost-to-charge ratios to estimate costs for rate setting purposes (p. 66). CMS also proposes to continue its policy of establishing OPPS relative payment rates based on geometric mean costs as it has done since CY 2013 (p. 69).

Comprehensive APCs (p. 77). In CY 2015, CMS implemented several new Comprehensive APCs, which included the final transition of all Device-Dependent APCs to Comprehensive APCs. For Comprehensive APCs, there is a single payment for the stay regardless of how many days the beneficiary is a hospital outpatient. The packaging formula goes beyond what is typically packaged in an OPPS APC payment and includes payment for all services that are ancillary, supportive, dependent, and adjunctive to the
primary service (to which CMS collectively refers as “adjunctive services”). CMS finalized 10 additional Comprehensive APCs in CY 2016.

Payment for Comprehensive APCs does not include payment non-OPPS charges or services that, because of statute, must be paid separately. These services include mammography and ambulance services; brachytherapy seeds; pass-through drugs and devices; and self-administered (non-Part B) drugs. CMS also excludes certain preventive services from the packaged payment. Addendum J lists the services excluded from Comprehensive APC payment packaging.

CMS made several other statements regarding its Comprehensive APC payment policy:

- **Complexity Adjustments.** CMS proposes to continue its methodology for assessing Comprehensive APCs to qualify for a complexity adjustment. CMS will allow for certain add-on codes (those that had previously been assigned to Device-dependent APCs) to qualify for a “complexity adjustment.” For those primary service and add-on code combinations that are determined to be sufficiently frequent and sufficiently costly, CMS believes that a payment adjustment is warranted. CMS proposes, however, to discontinue the requirement that a code combination that qualifies for a complexity adjustment (via the frequency and cost criteria) also not create a 2 times rule violation in the higher level APC. The add-on code and complexity adjustment methodology are discussed beginning on p. 83. The list of add-on codes eligible for the complexity adjustment can be found in Addendum J available on the CMS Web site.

- **Proposed CY 2016 Comprehensive APCs.** CMS proposes to continue the Comprehensive APC payment methodology implemented in CY 2015, to continue the use of the CY 2016 Comprehensive APCs, and to add 25 additional Comprehensive APCs for CY 2017 (p. 87). Table 2 (p. 88) lists all proposed CY 2017 Comprehensive APCs. Below is a table of the newly proposed Comprehensive APCs for CY 2017.
### New Comprehensive APCs Proposed for CY 2017

<table>
<thead>
<tr>
<th>Medical Procedure</th>
<th>APC Level</th>
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<tbody>
<tr>
<td><strong>Excision/Biopsy/Incision and Drainage</strong></td>
<td></td>
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<tr>
<td>Comprehensive APC 5072</td>
<td>Level 2</td>
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<tr>
<td>Comprehensive APC 5073</td>
<td>Level 3</td>
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<tr>
<td><strong>Breast Surgery</strong></td>
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<tr>
<td>Comprehensive APC 5091</td>
<td>Level 1</td>
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<tr>
<td>Comprehensive APC 5092</td>
<td>Level 2</td>
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<tr>
<td><strong>Orthopaedic Surgery</strong></td>
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<tr>
<td>Comprehensive APC 5112</td>
<td>Level 2</td>
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<tr>
<td>Comprehensive APC 5113</td>
<td>Level 3</td>
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<tr>
<td><strong>Airway Endoscopy</strong></td>
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<tr>
<td>Comprehensive APC 5153</td>
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<tr>
<td>Comprehensive APC 5154</td>
<td>Level 4</td>
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<tr>
<td>Comprehensive APC 5155</td>
<td>Level 5</td>
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<tr>
<td><strong>ENT Procedures</strong></td>
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<td>Comprehensive APC 5164</td>
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<tr>
<td><strong>Vascular Procedures</strong></td>
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<tr>
<td>Comprehensive APC 5191</td>
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<tr>
<td><strong>Wireless PA Pressure Monitor</strong></td>
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<td>Comprehensive APC 5200</td>
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<tr>
<td><strong>Stem Cell Transplant</strong></td>
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<tr>
<td>Comprehensive APC 5244</td>
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<tr>
<td><strong>Gastrointestinal Procedures</strong></td>
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<td>Comprehensive APC 5302</td>
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<tr>
<td>Comprehensive APC 5303</td>
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<tr>
<td>Comprehensive APC 5313</td>
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<tr>
<td>Comprehensive APC 5341</td>
<td>Abdominal/Peritoneal/Biliary and Related Procedures</td>
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<td><strong>Urologic Procedures</strong></td>
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<tr>
<td>Comprehensive APC 5373</td>
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<tr>
<td>Comprehensive APC 5374</td>
<td>Level 4</td>
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<tr>
<td><strong>Gynecologic Procedures</strong></td>
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<tr>
<td>Comprehensive APC 5414</td>
<td>Level 4</td>
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<tr>
<td><strong>Nerve Procedures</strong></td>
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<td>Comprehensive APC 5431</td>
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<tr>
<td>Comprehensive APC 5432</td>
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<td><strong>Intraocular Surgery</strong></td>
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<td><strong>Extraocular Ophthalmic Surgery</strong></td>
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<td>Comprehensive APC 5503</td>
<td>Level 3</td>
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<tr>
<td>Comprehensive APC 5504</td>
<td>Level 4</td>
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- **Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Comprehensive APC (p. 90).**
  Allogeneic hematopoietic stem cell collection procedures are performed on the donor (not the beneficiary). This service cannot be paid separately under the OPPS “because hospitals may bill and receive payment only for services provided to a Medicare beneficiary who is the recipient of the HSCT and whose illness is being treated with the transplant.” Therefore, under current OPPS policy, payment for the acquisition services are packaged into the APC payment for the allogeneic HSCT when the transplant occurs in the hospital setting. CMS previously assigned...
allogeneic HSCT to APC 5281 (Apheresis and Stem Cell Procedures) with a CY 2016 OPPS payment rate of $3,015. CMS states that the charges can include (but are not limited to):
- National Marrow Donor Program fees
- Tissue typing of donor and recipient
- Donor evaluation
- Physician pre-procedure donor evaluation services
- Costs associated with the collection procedure (e.g., general routine and special care services, procedure/operating room and other ancillary services, apheresis services)
- Post-operative/post-procedure evaluation of the donor
- Preparation and processing of stem cells.

CMS has received comments stating concerns related to the amounts included to compensate hospitals for these services. In order to address these concerns (and general stem cell transplant ratesetting concerns), CMS proposes the creation of Comprehensive APC 5244 (Level 4 Blood Product Exchange and Related Services). CMS believes this would allow for the costs of covered outpatient services (including donor acquisition services) to be included on a claim and packaged into the Comprehensive APC payment rate and to be used for establishing the future payment rate. CMS proposes a CY 2017 payment rate for Comprehensive APC 5244 of $15,267. CMS also proposes to add a new cost center (“Allogeneic Stem Cell Acquisition”) and revenue code (“Allogeneic Stem Cell Acquisition Services”) for hospital cost reporting to better capture the costs associated with these services.

**Comprehensive APCs (p. 95).** CMS has had a policy since 2008 for Composite APCs which provide 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 proposing to continue its policy for the following existing Composite APCs:
- Low dose rate (LDR) prostate brachytherapy (Composite APC 8001);
- Mental health services (Composite APC 8010); and
- Multiple imaging services (Composite APCs 8004, 8005, 8006, 8007, and 8008) (Table 3, p. 103).

**Packaged Items and Services (p. 107).** CMS has relied on packaging policies in the OPPS to ensure that incentives exist for hospitals to “furnish services most efficiently and to manage their resources with maximum flexibility.” CMS is proposing several modifications to its packaging policies.
- **Clinical Diagnostic Lab Test Packaging Policy (p. 109).** CMS’ current policy states that “certain clinical 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 hospital outpatient setting.” CMS will only pay separately for lab tests only when:
  - They are the only services provided to a beneficiary on a claim;
  - They are unrelated laboratory tests (i.e., they are on the same claim as other hospital outpatient services but are ordered for a different diagnosis and are ordered by a different practitioner);
  - They are molecular pathology test; or
  - They are considered preventive services.
CMS addresses several of the exceptions:

- **“Unrelated” Lab Tests**. The current CMS is directed at the exception that allows for separately payable lab tests when the test is “unrelated” to the other services on the claim. Unrelated claims are currently designated on claims with the L1 modifier. **CMS proposes to eliminate the “unrelated” test exception and the use of the L1 modifier.** CMS states that hospitals have commented that the exception is not helpful, and CMS believes that the requirements for the exception “do not necessarily correlate with the relatedness of a laboratory test to the other HOPD services that a patient receives during the same hospital stay.” CMS also believes that just because a test was ordered by a different physician does not mean that the lab test is not related to other services provided. Therefore, **CMS proposes to package any and all laboratory tests if they appear on a claim with other hospital outpatient services (p. 111-112).**

- **Molecular Pathology Test Exception (p. 112).** For CY 2016, CMS expanded its exception for molecular pathology testing to include all new molecular pathology tests. CMS agreed with commenters that “the exception that currently applies to molecular pathology tests may be appropriately applied to other laboratory tests that, like molecular pathology tests, are relatively new and may have a different pattern of clinical use than more conventional laboratory tests, which make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.” **CMS proposes to expand the exception for molecular pathology tests to “all advanced diagnostic laboratory tests” (ADLTs) that meet the criteria set out in the Social Security Act.**

- **Conditional Packaging Status Indicators Q1 and Q2 (p. 113).** Conditional packaging means that under certain circumstances items and services are packaged and in others they are separately payable. The CMS proposal focuses on two of the conditional packaging status indicators:
  
  o **Q1**: Packages items and services on the **same date of service** with services assigned a status indicator of:
    
    - “S” (procedure or service, not discounted when multiple);
    - “T” (procedure or service, multiple procedure reduction applies); or
    - “V” (clinic or emergency department visit)
  
  o **Q2**: Packages items and services on the **same date of service** with services assigned a status indicator of “T”

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1 The CMS proposals limits the expansion of the exception to the Social Security Act section 1834A(d)(5)(A). The section generally defines ADLTs as “a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria...” Subsection A (to which the proposal is limited) states: “The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.” ([https://www.ssa.gov/OP_Home/ssact/title18/1834A.htm](https://www.ssa.gov/OP_Home/ssact/title18/1834A.htm); accessed July 7, 2016).
CMS also uses Q4 (which conditional packages lab tests) and J1 and J2 (which packages hospital Part B services paid through a Comprehensive APC) regardless of the date of service as long as they are on the same claim. To align the reporting logic of the conditional packaging status indicators, CMS proposes to alter Q1 and Q2 so that packaging occurs at the claim level rather than by date of service.

OPPS Payments to Certain Cancer Hospitals (p. 139)
The 11 PPS-exempt cancer hospitals, while exempted from the Inpatient Prospective Payment System, are paid under the OPPS for covered outpatient services. The Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) required that designated cancer (as well as children’s) hospitals receive OPPS payments based on their pre-Balanced Budget Act of 1997 (BBA) payment amounts so as to be “held harmless” from otherwise mandated cuts. This means that these cancer hospitals are paid for covered outpatient services at rates that they would have received prior to the implementation of the OPPS.

- The ACA required the Secretary to conduct a study to determine whether the 11 cancer hospitals did, in fact, have outpatient costs that exceeded other hospitals’ costs. The ACA required that the Secretary take into consideration of drugs and biologicals. If the Secretary determined that the costs were indeed greater, then the Secretary should provide an appropriate adjustment to reflect those higher costs.
- The Secretary conducted the requisite study in 2011 and found that the 11 cancer hospitals did have greater outpatient costs than other OPPS hospitals. Based on this information, in CY 2012, CMS finalized a policy to provide additional payments to these cancer hospitals.
- CMS proposes to continue its policy to provide these additional payments to these cancer hospitals (p. 142).
- For CY 2017, CMS estimates that other OPPS hospitals are approximately 92 percent of those of the 11 cancer hospitals (defined as the “percent of reasonable cost.”). However, each hospital receives a separate adjustment factor based on a cost report settlement and the hospital’s actual CY 2016 payments and costs.
- The payments to ensure the cancer hospitals are reimbursed at pre-BBA levels are applied separately.
- CMS is proposing that cancer hospital payment adjustments “to be determined at cost report settlement would be the additional payment needed to result in a proposed target [payment-to-cost ratio] PCR equal to 0.92 for each cancer hospital.” (p. 143)

Hospital Outpatient Outlier Payments (p. 144)
CMS provides outlier payments “to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss.”

- CMS stated that CY 2016 outlier payments are provided when the cost of furnishing the service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount by at least $3,250. If the costs exceed both of those thresholds, the hospital receives an outlier payment at 50 percent of the amount that passed the thresholds.
CMS attempts to maintain a target of no more than 1 percent of OPPS spending in outlier payments. CMS estimates that CY 2016 aggregate outlier payments will be approximately 1.0 percent of total OPPS payments. **CMS proposes to continue its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPPS (p. 146).**

In order to maintain outlier payments at 1 percent of OPPS spending, **CMS is proposing to maintain the percentage threshold for outlier payments at 1.75 times the APC payment amount; CMS is proposing to increase the dollar amount threshold to $3,825 (p. 147).**

**APC Group Policies (p. 162)**

**New CPT and Level II HCPCS Codes**

Upon creation of new CPT codes (Category I and III) as well as Level II HCPCS codes, CMS will assign the new codes to an interim status indicator and APC assignment through the quarterly update process and will finalize the policies in the OPPS/ASC final rule. **Table 6 (p. 164)** outlines the CMS timeframe for taking comments on new codes.

CMS is currently seeking comment on the APC assignments and status indicators for the following categories of codes:

- New Level II HCPCS Codes Implemented in April 2016 (**Table 7** on p.166)
- New Category III CPT and Level II HCPCS Codes Implemented in July 2016 (**Table 8** on p.168)
- New and Revised CY 2016 Category I and III CPT Codes that will be effective January 1, 2017 (p. 171). The codes are available for review in **Addendum B** with an “NP” comment indicator to indicate that the code is new for the next calendar year or it is an existing code that underwent a substantial revision to its code descriptor in the next calendar year (compared to the current calendar year).

**Two Times Rule (p. 175)**

According to statute, the services within an APC cannot be considered “comparable” if the highest cost service in the APC is more than 2 times greater than the lowest costs for an item or service within the same APC.

- CMS lists the reassignments to avoid violation of this rule on its Web site in **Addendum B** with the “CH” comment indicator.
- When reassignments are necessary, in some cases, CMS proposes to change the status indicators for some procedure codes, rename existing APCs, or create new clinical APCs to reflect the new APCs due to the reassignments.
- CMS often makes exceptions when the 2 Times Rule has been violated, typically in cases of low-volume items or services. CMS is proposing to apply the exception in 4 cases for CY 2017. **Table 9 (p. 179)** lists the 4 APCs where the exception is being made:
  - APC 5521: Level 1 Diagnostic Radiology without Contrast
  - APC 5735: Level 5 Minor Procedures
  - APC 5771: Cardiac Rehabilitation
  - APC 5841: Psychotherapy
New Technology APCs (p. 179)

CMS currently has 48 new technology APCs. **CMS is proposing to add 3 more levels of New Technology APCs by adding Levels 49 through 51.** Because of the need to create APCs by status indicator (both “S” and “T”), this proposal results in the creation of 6 new APCs (Table 10 on p. 182):

- New Technology- Level 49 ($100,001 - $120,000): APCs 1901 and 1902
- New Technology- Level 50 ($120,001 - $140,000): APCs 1903 and 1904
- New Technology- Level 51 ($140,001 - $160,000): APCs 1905 and 1906

The proposed payment rates for the proposed New Technology APCs can be found in Addendum A.

Proposed OPPS APC-Specific Policies (p. 185)

CMS is proposing to make changes to APC clinical families to achieve better clinical and resource homogeneity. The specific APC assignments for each service grouping is listed in Addendum B.

- **Imaging Services** (Tables 11 and 12, p. 186): CMS includes 2 tables in the proposed rule for the proposed changes: the CY 2016 APCs and the proposed CY 2017 APCs. The proposal consolidates the imaging APCs from 17 to 8. CMS notes that some of imaging procedures are assigned to APCs that are not listed in the tables (e.g. vascular procedure APCs) and that nuclear medicine services are not included in the proposal.

- **Strapping and Cast Application** (p. 188): Level 1 and 2 Strapping and Cast Application APCs are assigned to status code “S” (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment). **CMS proposed to revise the status indicator to “T” to indicate that the services are paid separately but a multiple procedure payment reduction applies when two or more services assigned to “T” are billed on the same date of service.**

- **Transprostatic Urethral Implant Procedure** (p. 188). The procedure uses HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants). This is one of two procedure codes that uses the UroLift System to treat patients diagnosed with benign prostatic hyperplasia (BPH). The code is currently assigned to New Technology APC 1565 (New Technology- Level 28 ($5,000 - $5,500)) with a payment rate of $5,250. Based on a review of claims data, **CMS proposes to reassign C9740 to APC 5376 (Level 6 Urology and Related Services) which has a geometric mean cost of approximately $7,723.**

OPPS Payment for Devices (p. 190)

Expiration of Transitional Pass-Through Payments for Certain Devices (p. 190)

Devices eligible for a transitional pass-through payment are eligible for at least 2, but not more than 3 years. One current device eligible for pass through payments will lose its pass-through status on December 31, 2016:

- HCPCS C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) (effective January 1, 2015)

CMS has proposed packaging the device into an appropriate APC.
The following devices with pass-through status that will retain their payment status in CY 2017:

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

**CY 2017 Device Pass-Through Payment Applications (p. 195)**

CMS received three applications by the March 1, 2016 quarterly deadline. Applications received after March 31, 2016 will be addressed in the CY 2018 OPPS proposed rule. CMS states that none of the applications received by March 31, 2016 was approved for pass-through payment during the quarterly review process:

- **BioBag® (Larval Debridement Therapy in a Contained Dressing) (p. 197).** CMS believes that the technology could be considered to be a surgical supply “similar to a surgical dressing that facilitates either mechanical or autolytic debridement” and is therefore ineligible for pass-through payments. CMS also did not believe the literature submitted with the application helped support that the technology met the substantial clinical improvement criterion.

- **Encore™ Suspension System (p. 201).** While CMS believes the application meets the newness criterion, CMS states that several components of the system appear to instruments or supplies which are not eligible for pass-through, and the only implantable devices in the kit are bone screws, which are already described by an existing pass-through code (HCPCS code C1713). CMS also believed that “specific data addressing substantial clinical improvement . . . was lacking.”

- **Endophys Pressure Sensing System (Endophys PSS) or Endophys Pressure Sensing King (p. 205).** CMS believes the technology meets the newness criterion as it received FDA 510(k) clearance on January 7, 2015. However, CMS believes that the technology is already described by HCPCS code C1894 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser). The applicant stated that it met the substantial clinical improvement criterion because the technology’s use eliminates the need for a second arterial line to monitor blood pressure, reduces the time to treatment for the patient, and reduces potential complications from the second arterial line. CMS states that “there were minimal direct clinical data provided . . . to support substantial clinical improvement.”

**General Pass-Through Payment Proposals**

- **CMS proposes to amend current regulation to provide that the pass-through eligibility period begins on the first date on which pass-through payment is made (p. 209).**
- **CMS proposes to allow for a quarterly expiration of pass-through status** “to afford a pass-through period that is as close to a full 3 years as possible for all pass-through payment devices.” (p. 211).
Proposed Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups (p. 214)

CMS has a policy and methodology to estimate the portion of an APC payment amount attributable to the cost of associated devices eligible for pass-through payments (the “device APC offset amount”). CMS proposes to begin calculating the portion for each device-intensive procedure payment rate that can be reasonable attributed to the cost of an associated device at the HCPCS code level rather than at the APC level. The device APC offset amounts are made available on the CMS Web site for use in developing device pass-through payment applications.

Device-Intensive Procedures (p. 215)

CMS defines Device-Intensive Procedures as those with a device offset amount greater than 40 percent and assigns the status at the APC level. For CY 2017, CMS proposes 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 (p. 216). CMS believes that creating the offset at the HCPCS code level would “be a better representation of a procedure’s device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. In addition, for new HCPCS codes (requiring the implantation of a device) that do not yet have associated claims data, CMS is proposing to establish a default device offset amount of 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedure. CMS notes that in rare circumstances of a very expensive implantable device that it might establish a temporary higher offset percentage if additional information is presented (e.g. pricing data from the device manufacturer).

Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices (p. 220)

In CY 2007, CMS established a payment policy to account for situations where a hospital receives a device at no or reduced cost or provides a device without cost. CMS is proposing to modify its previous policies for reporting and paying for devices in these situations to account for its proposal to recognize device intensive procedures at the HCPCS level rather than the APC level.

Specifically, CMS is proposing to continue use the three criteria implemented in 2007 for use at the APC level now at the HCPCS level:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- 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
- 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.

2 CMS proposes requisite changes in its device edit policy to account for the proposal to move from APC-level to HCPCS level device intensive status (p. 219).
Low-Volume Device-Intensive Procedures (p. 224)

CMS proposes 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 be calculated using the median cost instead of the geometric cost.” CMS states that it is making this proposal to mitigate year-to-year payment fluctuations while preserving claims-based payment rates for low-volume device procedures.

OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals (p. 225)

OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices (p. 225)

CMS currently makes transitional pass through payments for certain drugs and biologicals. As in the case of devices, pass-through eligibility is for at least 2 but not longer than 3 years.

- In addition, the BBRA requires that the Secretary make additional payments to hospitals for orphan drugs (as defined under law) as well as drugs and biological and brachytherapy sources used in cancer therapy and radiopharmaceutical drugs and biologicals for which payment was made as of the date the OPPS was implemented.
- Transitional pass-through payments are also provided for new drugs and biologicals where the cost is “not insignificant” relative to the OPPS payment for the procedure or services associated with the drug or biological.
- Beginning with pass-through drugs and biologicals newly approved in CY 2017, CMS proposes to allow for a quarterly expiration of pass through status to afford a pass through period as close to the 3 year maximum as possible (p. 229). CMS proposes this change because it believes that the timing of the pass-through application should not determine the duration of pass-through payment status.

Proposed Drugs and Biologicals with Expiring Pass-Through Status in CY 2016 (p. 229).

CMS is proposing that 15 drugs and biologicals’ pass-through status would expire on December 31, 2016. The list of these drugs and biologicals is available in Table 13 (p. 231).

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2017 (p. 232).

- CMS is proposing to continue pass through status for 38 drugs and biologicals. They can be viewed on the CMS Web site in Addenda A and B (and will be listed with the status indicator of “G”). They are also available in Table 14 (p. 234).
- CMS is proposing to continue to pay for pass-through drugs and biologicals at the Average Sales Price plus 6 (ASP+6) percent level.
- CMS is proposing that “a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2017 OPPS because the different between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the

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3 CMS again states that a “biological” as used in this rule “includes (but is not necessarily limited to) ‘biological product’ or ‘biologic’ as defined by the Public Health Service Act.” (p. 255)
portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is ASP+6% is $0.” (p.232).

- CMS proposes to continue to update pass-through payment rates on a quarterly basis during CY 2017 if later quarter ASP submissions indicate that adjustments are necessary (p. 233).
- CMS also proposes to continue its policy to pay for pass-through diagnostic and therapeutic radiopharmaceuticals based on the ASP methodology; if the ASP is not available, CMS proposes to provide a payment at the Wholesale Acquisition Cost plus 6 (WAC+6) percent rate. If WAC information is not available, CMS will pay for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP) (p.234).

**Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups (p. 237).** CMS proposes to continue its policies and methodologies for reducing the amount of the pass-through payment by the amount of the APC payment attributable to the cost of the drug, biological, or radiopharmaceutical predecessor product. This policy applies equally to pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. CMS is proposing to continue to annually post a file with the APC offset amounts on the CMS OPPS Web site.

**OPPS Payment for Drugs, Biologics, and Radiopharmaceuticals without Pass-Through Payment Status (p. 239)**
CMS pays for drugs, biologics, and radiopharmaceuticals either as a packaged item within an APC or separately (in which the item has its own APC). CMS sets a cost threshold for packaging based on cost and proposes for CY 2017 to set the threshold at $110 (the CY 2016 threshold is $100). Therefore, using its standard methodology to set the threshold, CMS proposes to package items with a per day cost less than or equal to $110 and separately pay for these items if they have a per day cost greater than $110 (p. 241).

**Proposed High/Low Cost Threshold for Packaged Skin Substitutes (p. 243).** In CY 2014, CMS unconditionally packaged skin substitute products into their associated procedures. CMS also finalized a methodology to divide skin substitutes into high and low cost groups with the goal of ensuring adequate resource homogeneity among APC assignments for the skin substitute application procedures. In response to stakeholder concerns about the CMS methodology for assigning skin substitutes to high and low cost categories, in CY 2015 CMS finalized basing the high/low cost assignments on the weighted average mean unit cost (MUC) rather than ASP as it had done previously. In CY 2015, CMS also finalized a policy that skin substitutes with pass-through payment status would be assigned to the high cost category. CMS also stated in the CY 2015 Final Rule that it would also calculate the per day cost (PDC) and compare it to the MUC methodology in CY 2016.
- For CY 2017, CMS proposes to continue its policy of determining the high/low cost status for each skin substitute product “based on either a product’s geometric MUC exceeding the geometric MUC threshold or the PDC (the total units of a skin substitute multiplied by the mean unit cost and dividing by the total number of days (exceeding the PDC threshold).” (p. 244)
• Based on the methodology, **CMS is proposing the weighted average MUC threshold for CY 2017 is $25 per cm² and a PDC of $729**: Skin substitutes that exceed the MUC threshold of $25 per cm² or the PDC of $729 will be classified as high cost (p. 245).

• CMS will continue its policy that skin substitutes without claims data to calculate the MUC will be assigned to the high or low cost category based on the product’s ASP+6 percent payment rate (if not ASP, then WAC+6, if not WAC, then 95 percent of AWP).

• Any new skin substitute without pricing information will continue to be assigned to the low cost category until pricing information is available.

• **CMS also proposes that a skin substitute assigned to the high cost group in CY 2016 and exceeds either the MUC or PDC threshold in this proposed rule would be assigned to the high cost group for CY 2017** “even if it no longer exceeds the MUC or PDC CY 2017 thresholds based on updated claims data and pricing information used in the CY 2017 final rule with comment period.” (p. 245)

• **Table 15** (p. 246) lists skin substitutes and their proposed CY 2017 classifications.

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages (p. 247). CMS is proposing to continue its policy to make packaging determinations on a drug-specific basis (rather than a HCPCS code-specific basis) for those HCPCS codes that describe the same drug or biological but different dosages.⁴ **Table 16** (p. 249) lists the proposed HCPCS codes to which the CY 2017 drug specific packaging methodology would apply.

Proposed Payment for Items without Pass-Through Status That Are Not Packaged (p. 250).

• **CMS proposes to continue to apply the same payment policy to all separately payable drugs and biologicals and the statutorily defined “specific covered outpatient drugs” or SCODs.** CMS notes that the Social Security Act requires payment for SCODs to “be equal to the average acquisition cost for the drug for the year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account hospital acquisition cost survey data collected by [the GAO].” (p. 251).

• **CMS is proposing to continue its payment policy to pay for separately payable drugs and biologicals at ASP +6% (p. 253).** CMS continues to list separately payable drugs and biologics in Addenda A and B.⁵

• **CMS proposes to continue the same payment policy for biosimilar biological products as finalized for CY 2016 (p. 254).**

• **CMS proposes to continue the same payment policy for therapeutic pharmaceuticals as used since 2010 (p. 255).**

• **CMS proposes to continue to pay for blood clotting factors at ASP+6% (p. 258).**

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⁴ CMS did not have pricing information for the ASP methodology and therefore use the mean unit cost available from CY 2015 claims data to make the packaging determinations for the following drugs: HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg), J1850 (Injection, kanamycin sulfate, up to 75 mg), and HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units) (p. 248).

⁵ CMS reminds stakeholders that the current rates listed in the addenda do not reflect the actual 2017 payment rates since data is updated quarterly and the 2016 Q3 data submitted by manufacturers will inform January 2017 payments (p. 254).
Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices (p. 259). Statute limits pass-through payment spending at 2.0 percent of total OPPS payments. CMS estimates that pass-through spending in CY 2016 would equal approximately $148.3 (112.7 million for devices and $35.6 million for drugs and biologicals) or 0.24 percent of total projected CY 2017 OPPS spending and would therefore not cross the 2.0 percent program spending limit.

OPPS Payment for Hospital Outpatient Visits (p. 267)

CMS proposes to continue its current payment policy for clinic, emergency department hospital outpatient visits, and critical care services without change.

Inpatient Only Procedures (p. 311)

CMS conducts an annual assessment to identify procedures that would be paid only as inpatient procedures and therefore are not payable under the OPPS. CMS also reviews whether there are procedures on the list that should be removed (and thus payable under the OPPS). The criteria utilized by CMS for the analysis include:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes that we have already removed from the inpatient list.
- A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

For CY 2017, CMS has identified six (6) procedures that it proposes for removal from the Inpatient Only list (p. 312):

- **CPT 22840** Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
- **CPT 22842** 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)
- **CPT 22845** Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
CPT 22858  Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)

CPT 31584  Laryngoplasty; with open reduction of fracture

CPT 31587  Laryngoplasty, cricoid split

**CMS also solicits comments on whether to remove total knee arthroplasty** (CPT 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) *from the Inpatient Only list (p. 314).* 6 CMS previously proposed removal of CPT 27447 from the Inpatient Only list in the CY 2013 OPPS/ASC proposed rule, but did not finalize the proposal based on stakeholder feedback.

### Collecting Data on Services Furnished in Off-Campus Provider Based Departments (*p. 322*)

CMS has continued to monitor concerns that the trends in hospital acquisition of physician practices and increased delivery of physician services in a hospital setting have led to total higher Medicare payments. When care is delivered in a hospital Provider Based Department (PBD), Medicare makes two payments: one for the facility fees (under the OPPS) and the other for the physician’s professional services (under the Physician Fee Schedule). Medicare and other stakeholders have been concerned that the total of those two payments are higher for many services when billed out of a PBD than they were when they were previously provided in the physician office setting.

The Bipartisan Budget Act of 2015 included a provision that “applicable items and services” furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered OPD service . . . for purposes of payment under the OPPS and will instead be paid ‘under the applicable payment system; under Medicare Part B.” The statute defines “off-campus outpatient department of a provider” as “a department of a provider . . . that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility.” The statute also excepts from that definition “an off-campus PBD that was billing . . . with respect to covered OPD services furnished prior to” November 2, 2015. **CMS is proposing that “excepted” off campus PBDs would continue to be paid under the OPPS.**

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6 CMS also solicits input on how the Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Improvements (BPCI) models might need to be altered if CPT 27447 is removed from the Inpatient Only list given that CJR and several BPCI tracks are triggered by hospital inpatient admissions (*p. 320*).

7 The statutory definition of “applicable items and services” specifically excludes items and services furnished by a dedicated emergency department (*p. 325*). Therefore, these items and services will continue to be paid under the OPPS.

8 Current regulation defines “remote location of a hospital” as “a facility or an organization that is either created by, or acquired by a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider . . .” (*p. 328*).
Under current regulation, a hospital may treat “provider-based departments” as an off-campus outpatient department if it meets certain requirements (p. 327), including:

- It generally must be located within a 35-mile radius of the campus of the main hospital;
- Its financial operations must be fully integrated within those of the main provider;
- Its clinical services must be integrated with those of the main hospital and patients treated at the off-campus outpatient department who require further care must have full access to all services of the main hospital;
- It is held out to the public as part of the main hospital.

The statutory provisions make distinctions between whether a department of a hospital is “on” or “off” campus.⁹

CMS also notes that in CY 2016 CMS required off-campus PBDs to use the “PO” claim modifier to identify services furnished in off-campus PBDs (other than emergency departments, remote locations, and satellite locations of the hospital). CMS states that the modifier does not identify the type of PBD or between multiple PBDs of the same hospital (p. 330).

**Defining “Applicable Items and Services” (p. 331).**

While CMS acknowledges that an ED may furnish both emergency and non-emergency services, CMS proposes that all services furnished in an ED (regardless of whether they are emergency services) would be exempt from the provisions and will continue to be paid under the OPPS. To implement this, CMS proposes to define “applicable items and services” to include “all items and services not furnished by a dedicated ED.” (p. 332).

**Defining “Off-Campus PBD” (p. 332)**

- CMS is not proposing to change its current regulatory definition of “campus” (p. 333).
- CMS proposes that on-campus PBDs (and the items and services provided by such a department) would be excepted and would continue to be paid under the OPPS.
- The statute also defines off-campus PBDs that are “not located within the distance from a remote location” of a hospital facility. In determining whether a PBD is excepted from the policy, CMS proposes that the off-campus PBD must be located at or within the distance of 250 years from a remote location of a hospital facility.
- The statute also excepts off-campus PBDs that were billing under the OPPS for services furnished prior to November 2, 2015. CMS proposes that if an off-campus PBD meets the exception, the provisions of the Act do not apply to that department or to the types of items and services furnished by that department. While CMS received input that these locations should be allowed to relocate or expand, CMS stated that it believes that the provisions apply to off-campus PBDs “as they existed at the time of enactment and only excepts those items and services that were being furnished and billed by off-campus PBDs prior to November 2, 2015” (p. 337).

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⁹ Current regulation defines a campus as the “physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS Regional Office, to be part of the provider’s campus.” (p. 328)
CMS proposes that excepted off-campus PBDs (and the items and services that are furnished by such departments) would no longer be excepted if the excepted off-campus PBD moves or relocates from the physical address that was listed on the provider’s hospital enrollment form as of November 1, 2015 (p. 337).

CMS is seeking input on whether it should issue a clearly defined, limited relocation exception process (similar to the disaster/extraordinary circumstance exception under the Hospital Value Based Purchasing Program).

CMS proposes that the excepted off-campus PBD would be limited to seeking payment under the OPPS for the provision of items and services it was furnishing prior to the date of the enactment of the statute (p. 339). In addition, CMS proposes that items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 are not payable under the OPPS.¹⁰

CMS proposes to define the “clinical families” as those hospital outpatient services types identified in Table 21 on p. 342.

- CMS received questions related to whether excepted off-campus PBDs could maintain their excepted status if the hospital were purchased, merged with another hospital, or if the excepted PBD itself were sold to another hospital.
  - CMS proposes that excepted status for an off-campus PBD would transfer to a new owner “if ownership of the main provider is also transferred and the Medicare provider agreement is accepted by the new owner.” (p. 343).
  - CMS proposes that individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain excepted status (p. 344).

### Establishing Policies for Payment for “Applicable Items and Services” furnished by an “Off Campus PBD” (p. 345)

CMS acknowledges that the Act requires the agency to develop a payment mechanism for non-excepted items and services furnished by an off-campus PBD. CMS states that it intends to provide a mechanism for this, but “there is no straightforward way to do that before January 1, 2017.” (p. 349). CMS continues that it is therefore not able to propose at this time a mechanism for an off-campus PBD to bill and receive payment for non-excepted items and services furnished on or after January 1, 2017 (“under the applicable payment system that is not the OPPS”) (p. 350). CMS proposes that the “applicable payment system” is the Medicare Physician Fee Schedule (p. 352). CMS is actively exploring mechanisms for off-campus PBDs to bill for these items and services under the Medicare Physician Fee Schedule. CMS is requesting input on changes that would be necessary to enable this (e.g. changes to enrollment forms, claims forms, the hospital cost report, etc).

For CY 2017, CMS is proposing to implement a temporary solution until it can develop an alternatively payment mechanism:

- CMS proposes that payment for non-excepted items and services provided in off-campus PBDs will no longer be made under the OPPS effective January 1, 2017 (p. 356).

¹⁰ CMS notes that it does not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish (p. 340).
• **CMS proposes that the physician or practitioner would bill and be paid for items and services in the off-campus PBD under the Medicare Physician Fee Schedule at the non-facility rate (instead of at the facility rate)** ([p. 353]; [p. 356]).

• CMS is not currently proposing new mechanisms that allow an off-campus PBD itself to bill and receive payment from Medicare for non-excepted items and services as a hospital-based department.

• CMS notes that many services include a professional component and a technical component. CMS states that “[w]hen the services is furnished in a setting where Medicare makes a separate payment to the facility under an institutional payment system, the technical component is not paid under the MPFS because the practitioner/supplier did not incur the cost of furnishing the technical component. Rather, it would be paid to the facility under the applicable institutional payment system.” ([p. 357]).

• Under the proposals, if a separately billable lab test is furnished by a non-excepted off-campus PBD (and is otherwise eligible for payment under the Clinical Lab Fee Schedule (CLFS)), the hospital may continue to bill and receive payment for it under the CLFS ([p. 359]).

• Provided it meets current requirements, hospitals retain the option of enrolling the non-excepted off-campus PBD as the type of provider/supplier it wishes to bill as (e.g. an ASC or group practice).

**CMS is soliciting comment on development of a new billing and payment policy proposal for CY 2018 ([p. 360]).** CMS is looking for input in the following areas:

• Whether an off-campus PBD should be allowed to bill non-excepted items and services on the professional (not institutional) claim and receive payment under the MPFS, provided the PBD meets all the applicable MPFS requirements.

• Whether there are administrative impediments for hospitals billing for such services.

• Whether making the necessary administrative changes that would allow the hospital to bill for these kinds of services under the MPFS would provide any practical benefit to the hospitals relative to the current requirements for billing under the MPFS.

• Other implications or considerations for allowing the hospital to do this, such as how the cost associated with furnishing such services might be reflected on the hospital cost report.

CMS expects that beneficiary cost-sharing for non-excepted items and services would “generally be equal to the beneficiary cost-sharing if the service was provided at a freestanding facility.” ([p. 361]).

**Changes for Payment for Film X-Ray ([p. 364])**

CMS states that the Consolidated Appropriations Act of 2016 requires that “effective for services furnished during 2017 or any subsequent year, the payment under the OPPS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPPS . . . shall be reduced by 20 percent.” In addition, “payments for imaging services that are X-rays taken used computed radiography (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be made under the OPPS . . . be reduced by 7 percent, and similarly if such X-ray services are furnished during CY 2023 or a subsequent year, by 10 percent.”
To implement the provision for services related to the CY 2017 payment year, CMS proposes to establish a new modifier to be used on claims with imaging services that are X-rays taken using film. The use of the modifier would result in a 20 percent payment reduction for an imaging service that is an X-ray taken using film. CMS notes that the HCPCS codes describing the imaging services that are “X-rays taken using film” can be found in Addendum B.

CMS will address the requirements regarding payment for X-rays taken using computed radiography technology in future rulemaking.

Changes to Certain Scope-of-Service Elements for Chronic Care Management (CCM) Services (p. 365)

CMS previously finalized the CCM scope of service elements (as described in the CY 2015 MPFS final rule with comment period) required in order for hospitals to bill and receive OPPS payment for furnishing CCM services. These scope-of-service elements are the same as those required for CCM under the MPFS. Given CMS is proposing minor changes to certain CCM scope of service elements in the CY 2017 MPFS proposed rule, it is proposing that these changes would apply to CCM services furnished to hospital outpatients under the OPPS. The CY 2017 MPFS proposed rule provides a detailed discussion of the proposed changes to the scope of service elements for CCM.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services (p. 366)

CMS highlights that the CY 2016 Medicare Physician Fee Schedule Final Rule with Comment Period addressed the initial components of the Medicare Appropriate Use Criteria (AUC) program mandated by the Protecting Access of Medicare Act of 2014 (PAMA). Specifically, the CY 2016 MPFS final rule specified the process for identifying applicable AUC and establishing CMS authority to identify clinical priority areas for making outlier determinations. CMS states that the appropriate mechanism for updating the provisions will continue to be the Medicare Physician Fee Schedule rulemaking process. However, CMS highlights the provisions here to remind stakeholders that ordering practitioners will be required “to consult AUC at the time of ordering advanced diagnostic imagine, 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.”

CMS notes that the CY 2017 MPFS proposed rule includes proposals related to the second component of the AUC program, the specification of qualified clinical decision support mechanisms (CDSMs). In addition, the CY 2017 MPFS proposed rule identifies clinical priority areas and exceptions to the AUC consultation and reporting requirements.
ASC Payment System Provisions (p. 369)

Treatment of New and Revised Codes (p. 373)

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

CMS invites public comment on proposed payment indicators and the proposed payment rates for the new Category III CPT codes and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2016 and July 2016 through the quarterly update CRs, as listed in Tables 23, 24, and 25 below. CMS proposes to finalize their payment indicators and their payment rates in the CY 2017 OPPS/ASC final rule with comment period.

**TABLE 23—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2016**

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

**TABLE 24—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2016**

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>C9476</td>
<td>Injection, daratumumab, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9477</td>
<td>Injection, elotuzumab, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9478</td>
<td>Injection, sebelipase alfa, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9479</td>
<td>Instillation, ciprofloxacin otic suspension, 6 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9480</td>
<td>Injection, trabectedin, 0.1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q9981</td>
<td>Rolapitant, oral, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q5102</td>
<td>Injection, infliximab, biosimilar, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q9982*</td>
<td>Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries</td>
<td>K2</td>
</tr>
<tr>
<td>Q9983**</td>
<td>Flurbetaben f18, diagnostics, per study dose, up to 8.1 millicuries</td>
<td>K2</td>
</tr>
</tbody>
</table>

*HCPCS code C9459 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries) was deleted on June 30, 2016, and replaced with HCPCS code Q9982 effective July 1, 2016.

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

*HCPCS code C9743 (Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies) 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**

CMS solicits public comment on proposed CY 2017 payment indicators for new and revised Category I and III CPT codes that will be effective January 1, 2017. The CPT codes are listed in Addendum AA and Addendum BB to this proposed rule with short descriptors only, and in Addendum O with long descriptors. CMS proposes to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2017 OPPS/ASC final rule with comment period. The proposed payment indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule.

**Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2016 and January 1, 2017 for Which We Will Be Soliciting Public Comments in the CY 2017 OPPS/ASC Final Rule with Comment Period**

Level II HCPCS codes that will be effective October 1, 2016 and January 1, 2017 will be flagged with comment indicator “NI” in Addendum B to the CY 2017 OPPS/ASC final rule with comment period to indicate that CMS assigned the codes an interim OPPS payment status for CY 2017. CMS will invite public comments in the CY 2017 OPPS/ASC final rule with comment period on the status indicator, APC.
assignments, and payment rates for codes that will be finalized in the CY 2018 OPPS/ASC final rule with comment period.

Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p. 383)

Covered Surgical Procedures: Proposed Covered Surgical Procedures Designated as Office-Based
CMS identified one covered surgical procedure, CPT code 0377T (Anoscopy with directed submucosal injection of bulking agent for fecal incontinence), that meets the criteria for designation as office-based. CMS’ data indicate that this procedure is performed more than 50 percent of the time in physicians’ offices. CMS further believes the services are of a level of complexity consistent with other procedures performed routinely in physicians’ offices. The CPT code that CMS proposes to permanently designate as office-based for CY 2017 is listed in Table 26 below.

TABLE 26—ASC COVERED SURGICAL PROCEDURE PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2017

<table>
<thead>
<tr>
<th>CY 2017 CPT Code</th>
<th>CY 2017 Long Descriptor</th>
<th>CY 2016 ASC Payment Indicator</th>
<th>Proposed CY 2017 ASC Payment Indicator*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0377T</td>
<td>Anoscopy with directed submucosal injection of bulking agent for fecal incontinence Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)</td>
<td>G2</td>
<td>R2</td>
</tr>
</tbody>
</table>

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, refer to the CY 2017 MPFS proposed rule.

CMS also proposes to maintain the temporary office-based designations in CY 2017 for the eight codes listed in Table 27 below, given there were very few claims in CMS’ data or no claims data for all those procedures. The procedures for which the proposed office-based designations for CY 2017 are temporary also are indicated by asterisks in Addendum AA to this proposed rule.

TABLE 27—PROPOSED CY 2017 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2016 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>0299T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound</td>
<td>R2*</td>
<td>R2**</td>
</tr>
<tr>
<td>0402T</td>
<td>Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)</td>
<td>R2*</td>
<td>R2**</td>
</tr>
<tr>
<td>10030</td>
<td>Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst), soft tissue (e.g., extremity abdominal wall, neck), percutaneous</td>
<td>P2*</td>
<td>P2**</td>
</tr>
<tr>
<td>64461</td>
<td>Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed)</td>
<td>P3*</td>
<td>P3**</td>
</tr>
</tbody>
</table>
Based on a review of the clinical characteristics, utilization, and volume of related codes, CMS also proposes to designate certain new CY 2017 codes for ASC covered surgical procedures as temporary office-based (see Table 28 below). However, because CMS did not have utilization data for the procedures specifically described by these new CPT codes, CMS proposes to make the office-based designations temporary rather than permanent. CMS will reevaluate the procedures when data become available. The procedures for which the proposed office-based designations for CY 2017 are temporary also are indicated by asterisks in Addendum AA to this proposed rule.

**TABLE 28—PROPOSED CY 2017 PAYMENT INDICATORS FOR NEW CY 2017 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED**

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>369X1***</td>
<td>Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report</td>
<td>P2*</td>
</tr>
<tr>
<td>36X41***</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated</td>
<td>P2*</td>
</tr>
</tbody>
</table>

* If designation is temporary.
** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2017. For a discussion of the MPFS rates, refer to the CY 2017 MPFS proposed rule.
*** New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2017. The proposed ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on the CMS Web site.


CMS proposes that, for 2017, a procedure with a HCPCS code-level device offset of greater than 40 percent of the APC costs when calculated according to the standard OPPS APC ratesetting methodology would be designated as ASC device-intensive and would be subject to all of the payment policies applicable to procedures designated as an ASC device-intensive procedure under CMS’ established methodology, including its policies on device credits and discontinued procedures.

For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, CMS proposes to 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 for the procedures. 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. The full listing of ASC device-intensive procedures can be found in Addendum AA to this proposed rule.

CMS also proposes to revise its methodology for designating ASC covered surgical procedures as device-intensive. Specifically, for CY 2017, CMS proposes to update the ASC list of covered surgical procedures that are eligible for payment according to its device-intensive procedure payment methodology, consistent with its proposed revised definition of device-intensive procedures, reflecting the proposed individual HCPCS code device offset percentages based on CY 2015 OPPS claims and cost report data available for this proposed rule. The ASC covered surgical procedures CMS proposes to designate as device-intensive and would be subject to the device-intensive procedure payment methodology for CY 2017 can be found in Addendum AA to this proposed.

Covered Surgical Procedures: Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

CMS proposes to update the list of ASC covered device-intensive procedures based on the proposed CY 2017 device-intensive definition, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2017. Specifically, when a device-intensive procedure is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS “FB” modifier on the line in the claim with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that CMS estimates represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC.

For partial credit, CMS proposes to reduce the payment for implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS “FC” modifier to the HCPCS code for a device-intensive surgical procedure that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.
Covered Surgical Procedures: Proposed Additions to the List of ASC Covered Surgical Procedures

CMS proposes to update the list of ASC covered surgical procedures by adding eight procedures to the list for CY 2017, as listed in Table 29 below. These eight procedures are not expected to pose a significant risk to beneficiary safety when performed in an ASC and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These codes are add-on codes to procedures that are currently performed in the ASC and describe variations of (including additional instrumentation used with) the base code procedure. Therefore, CMS proposes to include them on the list of ASC covered surgical procedures for CY 2017.

TABLE 29—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2017

<table>
<thead>
<tr>
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</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, osteophytectomy 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>
<tr>
<td>22851</td>
<td>Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methlmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)</td>
<td>N1</td>
</tr>
</tbody>
</table>

Covered Ancillary Services: Proposed List of Covered Ancillary Services

Consistent with the established ASC payment system policy, CMS proposes to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2017 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2017. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2015 may be proposed for packaged status under the CY 2017 OPPS and,
therefore, also under the ASC payment system for CY 2017. All ASC covered ancillary services and their proposed payment indicators for CY 2017 are included in Addendum BB to this proposed rule.

**ASC Payment for Covered Surgical Procedures and Covered Ancillary Services (p. 403)**

**Proposed ASC Payment for Covered Surgical Procedures: Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2017**

*CMS proposes to update ASC payment rates for CY 2017 and subsequent years using the established rate calculation methodologies under § 416.171 and using its proposed modified definition of device-intensive procedures.* Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2017 and subsequent years, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology.

**Proposed Payment for Covered Ancillary Services: Proposed Payment for Covered Ancillary Services for CY 2017**

For CY 2017, CMS proposes to continue the methodologies for paying for covered ancillary services established for CY 2016. Most covered ancillary services and their proposed payment indicators for CY 2017 are listed in Addendum BB to this proposed rule.

**Proposed ASC Conversion Factor and Proposed ASC Payment Rates (p. 419)**

For CY 2017, the proposed CY 2017 ASC wage indexes fully reflect the new OMB labor market area delineations (including the revisions to the OMB labor market delineations, as set forth in OMB Bulletin No. 15-01).

**Proposed Calculation of the ASC Payment Rates: Updating the ASC Relative Payment Weights for CY 2017 and Future Years**

*CMS proposes to scale the CY 2017 relative payment weights for ASCs consistent with previously established policy.* The proposed CY 2017 ASC scalar is 0.9030 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

For any given year’s ratesetting, CMS typically uses the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this proposed rule, CMS has available 98 percent of CY 2015 ASC claims data.

**Proposed Calculation of the ASC Payment Rates: Updating the ASC Conversion Factor**

Based on IHS Global Insight’s (IGI’s) 2016 first quarter forecast with historical data through the fourth quarter of 2015, for the 12-month period ending with the midpoint of CY 2017, the CPI-U update is projected to be 1.7 percent, and the MFP adjustment for the period ending with the midpoint of CY 2017 is projected to be 0.5 percent. Given these projections, for CY 2017, *CMS proposes to reduce the CPI-U update of 1.7 percent by the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted CPI-U update factor of 1.2 percent for ASCs meeting the quality reporting requirements.*

*CMS proposes to apply a 1.2 percent MFP-adjusted CPI-U update factor to the CY 2016 ASC conversion factor for ASCs meeting the quality reporting requirements.*
The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI-U for ASCs that fail to meet the ASCQR Program requirements. CMS proposes to reduce the CPI-U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.5 percentage point MFP reduction. Therefore, CMS proposes to apply a -0.8 percent quality reporting/MFP-adjusted CPI-U update factor to the CY 2016 ASC conversion factor for ASCs not meeting the quality reporting requirements.

If more recent data are subsequently available (for example, a more recent estimate of the CY 2017 CPI-U update and MFP adjustment), CMS would use such data, if appropriate, to determine the CY 2017 ASC update for the final rule with comment period.

For CY 2017, CMS proposes to adjust the CY 2016 ASC conversion factor ($44.190) by the proposed wage index budget neutrality factor of 0.9992 in addition to the MFP-adjusted CPI-U update factor of 1.2 percent discussed above, which results in a proposed CY 2017 ASC conversion factor of $44.684 for ASCs meeting the quality reporting requirements.

For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2016 ASC conversion factor ($44.190) by the proposed wage index budget neutrality factor of 0.9992 in addition to the quality reporting/MFP-adjusted CPI-U update factor of -0.8 percent discussed above, which results in a proposed CY 2017 ASC conversion factor of $43.801.
Hospital Outpatient Quality Reporting (OQR) Program Updates (p. 436)

The Hospital OQR Program is a pay for quality data reporting program for outpatient hospital services. The Hospital OQR Program requires hospital outpatient facilities to meet administrative, data collection, and submission, validation, and reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these requirements.

*CMS is not proposing any changes to the CY 2018 and CY 2019 Hospital OQR Program measure sets,* which include 26 measures—25 required and one voluntary. A table of previously adopted and newly proposed Hospital OQR Program quality measures is available [here](#).

Proposed New Hospital OQR Program Quality Measures for the CY 2020 Payment Determinations and Subsequent Years (p. 442)

CMS proposes to add a total of seven (7) measures to the Hospital OQR Program for the CY 2020 payment determination and subsequent years: Two claims-based measures, and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures. These measures are discussed below.

- **OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy:** This measure assesses the care provided to cancer patients and encourages quality improvement efforts to reduce the number of unplanned inpatient admissions and emergency department (ED) visits among cancer patients receiving chemotherapy in a hospital outpatient setting. CMS notes that there is an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department, yet a growing body of evidence demonstrating the unmet needs of this population despite treatment plans and guidelines that support the management of these conditions. CMS also notes that there are no publicly available quality of care reports for providers or hospitals that provide outpatient chemotherapy treatment so adoption of this measure would fill an important gap.

  CMS notes that this quality measure is well-defined, precisely specified, and allows for valid comparisons of quality among hospitals. The measure includes only outcome conditions demonstrated in the literature as being potentially preventable in this patient population, is important to patients, is specified to attribute an outcome to other hospital(s) that provided outpatient chemotherapy in the 30 days preceding the outcome, and is risk-adjusted for patient demographics, cancer type, clinical comorbidities, and treatment exposure. Validity testing demonstrated that the measure data elements produce measure scores that correctly reflect the quality of care provided and adequately identify differences in quality. CMS conducted additional assessments to determine the impact of including sociodemographic status (SDS) factors in the risk-adjustment model, and NQF will review its methodology and findings under its SDS trial period.

  The Measure Applications Partnership (MAP) conditionally supported the measure recommending that it be submitted for NQF endorsement with a special consideration for SDS adjustments and the selection of exclusions. CMS recognizes the important role that SDS plays in the care of patients, but continues to have concerns about holding hospitals to different
standards for the outcomes of their patients of diverse SDS because it does not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. However, CMS will continue to monitor the results of the NQF trial, as well as research being conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) on the impact of SDS on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act.

This measure relies on Medicare Part A and Part B administrative claims data from Medicare FFS beneficiaries receiving chemotherapy treatment in a hospital outpatient setting. The measure involves calculating two mutually exclusive outcomes: (1) one or more inpatient admissions; or (2) one or more ED visits for any of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment among cancer patients receiving treatment in a hospital outpatient setting. Although two scores will be reported for this measure, a patient can only be counted for any measured outcome once, and those who experience both an inpatient admission and an ED visit during the performance period are counted towards the inpatient admission outcome. CMS decided to calculate these rates separately because the severity and cost of an inpatient admission is different from that of an ED visit. The patient cohort includes Medicare FFS patients ages 18 years and older as of the start of the performance period with a diagnosis of any cancer (except leukemia) who received at least one hospital outpatient chemotherapy treatment at a reporting hospital during the performance period. Additional information about how these scores are calculated, CMS’ rationale for using a 30 day window, and more in-depth discussions about the cohort and CMS’ decision to use two distinct risk adjustment methodologies for inpatient admissions vs ED visits, is available here.

- **OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687), which assesses variations in patient outcomes following surgery at a hospital outpatient department.** CMS notes that nearly 70 percent of all surgeries in the U.S. are now performed in the outpatient setting, with most performed as same-day surgeries at hospitals. With the ongoing shift towards outpatient surgery, assessing the quality of surgical care provided by hospitals has become increasingly important. National estimates of hospital visit rates following same day surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and timeframe for measurement after surgery. CMS also notes that hospital visit rates vary among hospitals, suggesting variation in surgical and discharge care quality. Still, providers (hospitals and surgeons) are often unaware of their patients’ hospital visits after surgery because patients often present to the ED or to different hospitals. CMS believes that reporting this outcome will illuminate problems that may not currently be visible. There are currently no publicly available quality of care reports for providers or facilities that conduct same-day surgery in the hospital outpatient setting.

This measure relies on Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries with outpatient same-day surgery. The measure outcome is any of the following hospital visits: (1) an inpatient admission directly after the surgery; or (2) an unplanned hospital visit (ED visits, observation stays, or unplanned inpatient admissions) occurring after discharge and within 7 days of the surgery. If more than one unplanned hospital
visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome. The measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the hospital’s patients. The numerator of the ratio is the number of hospital visits predicted for the hospital’s patients accounting for its observed rate, the number of surgeries performed at the hospital, the case-mix, and the surgical procedure mix. The denominator of the ratio is the expected number of hospital visits given the hospital’s case mix and surgical procedure mix. The only exclusion is surgeries for patients without continuous enrollment in Medicare FFS Parts A and B in the 1 month after the surgery.

In regards to the cohort, the measure includes Medicare FFS patients aged 65 years and older undergoing same-day surgery (except eye surgeries) in hospitals. “Same-day surgeries” are substantive surgeries and procedures listed on Medicare’s list of covered ASC procedures. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life-threatening. The list for 2016 is posted here (refer to Addendum AA).

The risk-adjustment model includes 25 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following outpatient surgery. The measure risk adjusts for surgical procedure complexity using two variables. First, it adjusts for surgical procedure complexity using the Work Relative Value Units (RVUs). Work RVUs are assigned to each CPT code and approximate procedure complexity by incorporating elements of physician time and effort. Second, it classifies each surgery into an anatomical body system group using the AHRQ Clinical Classification System (CCS) to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

Additional details about this measure are available here.

This measure was endorsed by the NQF in 2015. The MAP also supported the measure for program use citing the vital importance of measures that help facilities reduce unnecessary hospital visits. However, some members cautioned that because the measure was endorsed by NQF before the start of the SDS trial period, the measure should be reexamined during maintenance to determine whether SDS adjustments are needed.

- **OP-37(a-e): Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures.** Currently, there is no standardized survey available to collect information on the patient’s overall experience for surgeries or procedures performed within a hospital outpatient department. The OAS CAHPS Survey was recently developed by HHS and contains 37 questions that cover topics such as access to care, communications, experience at the facility, and interactions with facility staff. The survey also contains two global rating questions and asks for self-reported health status and basic demographic information (race/ethnicity, educational attainment level, languages spoken at home, among others). Questions can be found here under “Questionnaire.”

CMS proposes to adopt five survey-based measures derived from the OAS CAHPS Survey for the
The survey has three administration methods: mail-only; telephone-only; and mixed mode (mail with telephone follow-up of non-respondents). CMS proposes that hospitals contract with a CMS-approved vendor to collect survey data for eligible patients at the hospitals on a monthly basis and report that data to CMS on the hospital's behalf by the quarterly deadlines established for each data collection period. Hospitals may elect to add up to 15 supplemental questions to the OAS CAHPS Survey. These could be questions hospitals develop or use from an existing survey. For all three modes of administration, data collection must be initiated no later than 21 days after the month in which a patient has a surgery or procedure at a hospital, and completed within 6 weeks (42 days) after initial contact of eligible patients begins. CMS proposes that hospitals, via their CMS-approved vendors, must make multiple attempts to contact
eligible patients unless the patient refuses or the hospital/vendor learns that the patient is ineligible to participate in the survey. Survey vendor requirements are discussed starting here.

CMS proposes that the data collection period for the OAS CAHPS Survey measures would be the calendar year 2 years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, hospitals would be required to collect data on a monthly basis, and submit this collected data on a quarterly basis, for January 1, 2018 – December 31, 2018.

CMS further proposes that hospitals will be required to survey a random sample of eligible patients on a monthly basis. A list of acceptable sampling methods can be found in the OAS CAHPS Protocols and Guidelines Manual. CMS also proposes that hospitals would be required to collect at least 300 completed surveys over each 12-month reporting period (an average of 25 completed surveys per month). See discussion below about exemptions to this policy.

- **Applicability**
  Hospital eligibility to perform the OAS CAHPS Survey would be determined at the individual Medicare participating hospital level. In other words, all data collection and submission, and ultimately, also public reporting, for these survey measures would be at the Medicare participating hospital level as identified by the hospital’s CCN (no matter the number of hospital locations of the Medicare participating hospital). Therefore, the reporting for a CCN would include all eligible patients from all locations of the eligible Medicare participating hospital as identified by its CCN.

- **Measure Calculation**
  A discussion of the measure calculations for the composite survey-based measures starts here and for the global survey-based measures can be found here.

- **Cohort**
  The OAS CAHPS Survey is administered to all eligible patients—or a random sample thereof—who had at least one outpatient surgery/procedure during the applicable month. Eligible patients, regardless of insurance or method of payment, can participate. For purposes of each survey-based measure captured, an “eligible patient” is a patient 18 years or older:
  - Who had an outpatient surgery or procedure in a hospital, as defined in the OAS CAHPS Survey Protocols and Guidelines Manual;
  - Who does not reside in a nursing home;
  - Who was not discharged to hospice care following their surgery;
  - Who is not identified as a prisoner; and
  - Who did not request that hospitals not release their name and contact information to anyone other than hospital personnel.
There are a few categories of otherwise eligible patients who are excluded from the measure as follows:

- Patients whose address is not a U.S. domestic address:
- Patients who cannot be surveyed because of State regulations;
- Patient’s surgery or procedure does not meet the eligibility CPT or G-codes as defined in the OAS CAHPS Protocols and Guidelines Manual; and
- Patients who are deceased.

**Exemptions**

CMS acknowledges that some smaller hospitals may not be able to collect 300 completed surveys during a 12-month period; therefore, it proposes an exemption for facilities with lower patient censuses. Hospitals would have the option to submit a request to be exempted from performing the OAS CAHPS Survey-based measures if they treat fewer than 60 survey-eligible patients during the year preceding the data collection period (e.g., for the CY 2020 payment determination, this exemption request would be based on treating fewer than 60 survey-eligible patients in CY 2017, which is the calendar year prior to the data collection period (CY 2018)). To qualify for the exemption, hospitals must submit a participation exemption request form, which will be made available on the OAS CAHPS Survey Web site, on or before May 15 of the data collection calendar year, which aligns with the deadline for submitting Web-based measures and provides hospitals with sufficient time to review the previous years' patient lists and determine whether they are eligible for an exemption.

For those not eligible for this exemption, CMS also proposes that smaller hospitals that cannot collect 300 completed surveys over a 12-month reporting period will only be required to collect as many completed surveys as possible, during that same time period, with surveying all eligible patients (that is, no sampling). For more information regarding these survey administration requirements, CMS again refers readers to the OAS CAHPS Survey Protocols and Guidelines Manual.

**Risk Adjustment**

The survey-based measures are adjusted for patient characteristics such as age, education, overall health status, overall mental health status, type of surgical procedure, and how well the patient speaks English. These factors influence how patients respond to the survey but are beyond the control of the hospital and are not directly related to hospital performance. More information about patient-mix adjustment for these measures can be found [here](#).

**Public Reporting**

Because CY 2016 is the first year of voluntary national implementation for the OAS CAHPS Survey, CMS is not proposing a format or timing for public reporting of OAS CAHPS Survey data, but will do so in future rulemaking prior to implementation of these measures.
Hospital OQR Program Measures and Topics for Future Consideration (p. 481)

Future Measure Topics
CMS seeks public comment on possible measure topics for future consideration in the Hospital OQR Program. CMS specifically requests comment on any outcome measures that would be useful, as well as any clinical process measures that should be eliminated from the Hospital OQR Program.

Electronic Clinical Quality Measures
CMS seeks public comments on future implementation of specific eCQMs for the Hospital OQR Program. CMS recognizes that considerable work needs to be done by measure stewards and developers to make this possible with respect to the clinical quality measures targeted for electronic specifications (e-specifications) for the outpatient setting.

Possible Future eCQM: Safe Use of Opioids-Concurrent Prescribing
CMS is seeking public comment on a future electronic clinical quality measure concept for the Hospital OQR Program that addresses concerns associated with overlapping or concurrent prescribing of opioids or opioids and benzodiazepines. CMS is in early development of a new eCQM for the Hospital IQR and OQR Programs that would capture the proportion of patients 18 years of age and older who have an active prescription for an opioid and have an additional opioid or benzodiazepine prescribed to them during the qualifying care encounter. This measure is being designed to reduce preventable deaths as well as reduce costs associated with the treatment of opioid-related ED use by encouraging providers to identify patients at high risk for overdose due to respiratory depression or other adverse drug events.

CMS requests public comments on this future measure concept specifically for the Hospital OQR Program setting. CMS also will post this measure concept to the CMS Measures Management System (MMS) Call for Public Comment Web page, available here.

Public Display of Quality Measures (p. 486)
Additionally, beginning with the CY 2018 payment determination, CMS proposes to publicly display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. In addition, the agency proposes that hospitals will generally have approximately 30 days to preview their data. Furthermore, beginning with the CY 2019 payment determination, CMS proposes to update the Extraordinary Circumstances Exemptions (ECE) policy by changing the ECE request deadline from 45 days following an event causing hardship to 90 days following an event causing hardship. This proposal would become effective with ECEs requested on or after January 1, 2017. This timeframe aligns with the ECE request deadlines for the Hospital VBP Program, the Hospital-Acquired Condition Reduction Program, and the.

Prepared by Hart Health Strategies Inc., www.hhs.com
Hospital Readmissions Reduction Program. CMS proposes the same timeline for the ASC Quality Reporting Program later in this rule.

**Proposed Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2017 Payment Determination (p. 502)**

As noted earlier, hospital outpatient facilities will receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these requirements of the Hospital OQR. **CMS proposes not changes to its policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2017 annual payment update factor.**

**ASC Quality Reporting (ASCQR) Reporting Program (p. 507)**

The ASCQR Program is a pay-for-reporting program that requires ambulatory surgical centers (ASCs) to meet administrative, data collection, and reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet the requirements.

**Proposed ASCQR Program Quality Measures for the CY 2020 Payment Determination and Subsequent Years (p. 510)**

**CMS proposes to add seven (7) measures to the ASCQR program measure set for the CY 2020 payment determination and subsequent years.** These measures are discussed below. CMS is not proposing any changes to the CY 2018 and CY 2019 ASCQR Program measure sets, which include 12 measures—11 required and one voluntary.

A table of previously finalized and newly proposed measures for the CY 2020 payment determination are can be found [here](#).

- **ASC-13: Normothermia Outcome.** 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 (PACU). This measure us based on aggregate measure data collected by the ASC and submitted via a CMS Web-based tool (QualityNet).

This proposed measure is not NQF-endorsed. However, it is maintained by the ASC Quality Collaboration, an entity recognized within the community as an expert in measure development for the ASC setting. The MAP reviewed this “intermediate outcome” measure in 2014-2015 and conditionally supported it for the ASCQR Program, pending completion of reliability testing and NQF review and endorsement. However, it agreed that this measure is highly impactful and meaningful to patients. Overall, CMS believes this measure reflects consensus among affected parties and that there is strong evidence that it is reliable.

While there is no literature currently available on variation in rates of normothermia among ASC facilities, variability in maintaining normothermia has been demonstrated in other clinical care settings.
Data Collection
CMS proposes that the data collection period would be two calendar years prior to the applicable payment determination year. For example, for the CY 2020 payment determination, the data collection period would be CY 2018. CMS also proposes that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year.

Measure Calculation
The outcome measured here is 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 (PACU). The numerator is the number of surgery patients with a body temperature equal to or greater than 96.8 degrees Fahrenheit/36 degrees Celsius recorded within 15 minutes of arrival in the PACU. The denominator is all patients, regardless of age, undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes in duration.

Cohort
The measure includes all patients, regardless of age, undergoing surgical procedures under general or neuraxial anesthesia of greater than or equal to 60 minutes’ duration.

The measure excludes: patients who did not have general or neuraxial anesthesia; patients whose length of anesthesia was less than 60 minutes; and patients with physician/advanced practice nurse/physician assistant documentation of intentional hypothermia for the procedure performed.

Additional methodology and measure development details are available here under “ASC Quality Collaboration Measures Implementation Guide.”

Risk Adjustment
This measure is not risk-adjusted.

- **ASC-14: 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 section of the rule further discusses this measure data sources and calculation.

- **ASC-15(a-e): Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures.** Currently, there is no standardized survey available to collect information on the patient’s overall experience for surgeries or procedures performed within an ASC. CMS proposes five measures that are collected using the OAS CAHPS survey. See earlier discussion under the Hospital OQR summary regarding background on these same five measures being proposed for the ASCQR. **CMS proposes the same survey administration, exemption, data collection, and survey vendor policies for both programs.**
ASCQR Program Measures for Future Consideration (p. 538)

CMS also seeks public comment on a quality measure for future consideration in the ASCQR Program that addresses Toxic Anterior Segment Syndrome (TASS), a complication of anterior segment eye surgery. This measure assesses the number of ophthalmic anterior segment.

Public Reporting (p. 542)

In this rule, beginning with the CY 2018 payment determination, CMS proposes to publicly display data on the Hospital Compare Web site as soon as possible after measure data have been submitted to CMS, consistent with current practice. ASCs will generally have approximately 30 days to preview their data, also consistent with current practice. Lastly, moving forward, the agency proposes to announce the timeframes for each preview period starting with the CY 2018 payment determination on a CMS Web site and/or on our applicable listservs.

Requirements for Data Submitted via a CMS Online Data Submission Tool (p. 546)

CMS proposes to modify the data submission period for measures collected via the CMS online data submission tool from August 15 to May 15 of the year prior to the payment determination year for the CY 2019 payment determination and subsequent years. For example, for the CY 2017 data collection period, ASCs have January 1, 2018 through May 15, 2018 to submit their data for the CY 2019 payment determination.

This proposal would apply to the following measures for the CY 2019 payment determination and subsequent years:

- ASC-6: Safe Surgery Checklist Use;
- ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures;
- ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659); and
- ASC-11: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536)

It would also apply to the following newly proposed measures if finalized:

- ASC-13: Normothermia Outcome, and
- ASC-14: Unplanned Anterior Vitrectomy

CMS previously proposed this change, but did not finalize it due to public concerns that a May 15 deadline would increase ASC administrative burden by giving them less time to collect and report data. CMS believes that the May 15 data submission deadline would align the ASCQR Program with the Hospital OQR Program submission deadline. It also would align the above-listed measures with the submission deadline for ASC-8, resulting in a single deadline for all data submitted via a Web-based tool by ASCs, which CMS believes would reduce the administrative burden associated with submitting and tracking multiple data submission deadlines. CMS also believes implementing the proposed May 15 deadline will enable public reporting of these data by December of the same year, thereby allowing CMS to provide the public with more up-to-date information.
Extraordinary Circumstances Extensions or Exemptions for the CY 2019 Payment Determination and Subsequent Years (p. 554)
Congruent with the Hospital OQR program proposal, CMS proposes to extend the time to submit an extraordinary circumstance extensions or exemptions (ECE) request under the ASCQR from within 45 days of the date that the extraordinary circumstance occurred to within 90 days of the date that the extraordinary circumstance occurred.

Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements Administrative Requirements (p. 557)
Under the ASCQR Program, any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates. CMS is not proposing any changes to these policies.

Transplant Outcomes: Restoring the Tolerance Range for Patient and Graft Survival (p. 561)

Background (p. 561)
The Medicare Conditions of Participation (CoP) for Organ Transplant programs at 42 CFR sections 482.80 and 482.82 contain an outcome requirements standard for one-year patient and graft survival. A transplant program is out of compliance with this standard if all of the thresholds in the standard are crossed. One of the thresholds, the number of observed events divided by the number of expected events, is based on the program’s outcomes in relation to the risk-adjusted national average. Currently, that threshold, which was adopted in 2007, is 1.5. However, as national outcomes for organ transplants have improved over time, the margin for compliance and noncompliance has narrowed.

Because the CMS outcomes requirement is based on a transplant program’s outcomes in relation to the risk-adjusted national average, as national outcomes have improved, it has become much more difficult for an individual transplant program to meet the CMS outcomes standard. CMS believes that the increased percent of unused adult kidneys, combined with an increase in the number of recovered organs, creates an imperative to action, given the lifesaving benefits of organ transplantation.

CMS is concerned that transplant programs may elect not to use certain available organs out of fear that such use would adversely affect their outcome statistics. For instance, CMS observed that the percent of adult kidneys donated and recovered—but not used—increased from 16.6 percent in CY 2006 to 18.3 percent in CY 2007 to 18.7 percent in CY 2014 and 19.3 percent in CY 2015. Even if the number of recovered adult kidneys had remained the same, these percentages of unused kidneys would be of concern.

Furthermore, CMS is concerned with the increase of unused “expanded criteria donor (ECD)” organs. ECD organs are organs that are deemed transplantable but experience lower rates of functional longevity compared to most other organs.11

11 CMS states that characteristics that historically defined an ECD kidney include age of donor at or greater than 60 years, or organs from donors who were aged 50-59 years who also had experienced two of the following: cerebrovascular accident as the
Based on these concerns, CMS is proposing revisions to the performance thresholds for transplant outcomes.

**Proposed Revisions to Performance Thresholds (p. 570)**

**CMS proposes to change the performance threshold from 1.5 to 1.85.** If the threshold is changed, this would mean that transplant programs would not be out of compliance unless the number of observed events (one-year patient deaths or graft failures) divided by the number of expected events exceeds 1.85.

For consistency and to avoid unneeded complexity, **CMS proposes to use the same 1.85 threshold for all organ types and for both graft and patient survival.**

CMS states that the current relevant standard specifies that outcomes would not be acceptable if the ratio of observed patient deaths or graft failures divided by the risk-adjusted expected number, or “O/E,” exceeds 1.5. The expected number is based on the national average, adjusted for the patient, organ, and donor risk profile of a transplant program’s actual clientele for individuals who received a transplant in the 2.5-year period under consideration in each SRTR report.

As the national performance has improved, it has become more difficult for transplant programs to maintain compliance with this CoP. CMS believes that a change in the threshold from 1.5 to 1.85 would restore the approximate compliance levels for adult kidney transplants that were allowed in 2007 when national performance was not so high. More specifically, a 1.85 threshold would mean that up to 9.7 graft losses out of 100 transplants (within 1 year of transplant) would remain within the new CMS outcomes range (which is slightly fewer than the 10.7 allowed in 2007 but more than the 7.9 allowed in 2015), and up to 5.7 patient deaths out of 100 transplants (within one year of transplant) would remain within the CMS range (compared to 5.4 in 2007 and 4.6 in 2015).

This is a number that is approximately mid-range between the number that would restore the adult kidney graft tolerance range to the 2007 level, and the number that would do so for adult kidney patient survival.

In addition, **CMS invites comment on whether this proposal is effectively balancing its dual goals of improved beneficiary outcomes and increased beneficiary access.**
Organ Procurement Organizations (OPOs): Changes to Definitions; Outcome Measures; and Documentation Requirements (p. 574)

Background (p. 574)

Organ Procurement Organizations (OPOs)
OPOs are responsible for the identification of eligible donors, recovering organs from deceased donors, reporting information to the UNOS and OPTN, and compliance with all CMS outcome and process performance measures.

Statutory Provisions (p. 574)
Among other provisions, section 1138(b) of the Act also specifies that an OPO must operate under a grant made under section 371(a) of the Public Health Service Act (PHS Act) or must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO within a certain time period. Congress has provided that payment may be made for organ procurement cost “only if” the OPO meets the performance related standards prescribed by the Secretary. Under these authorities, CMS established Conditions for Coverage (CfCs) for OPOs that are codified at 42 CFR Part 486 and set forth the certification and recertification processes for OPOs.

HHS Initiatives Related to OPO Services (p. 575)
in 2012, The Advisory Committee on Organ Transplantation (ACOT) conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs. A CMS discussion of the requirements for OPOs begins on p. 576.

Proposed Provisions (p. 576)

Definition of “Eligible Death” (p. 576)
Existing §486.302 defines this term as “the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy, independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice…,” and who does not exhibit active infections or other conditions, including HIV.

To ensure more consistent requirements, CMS proposes replacing the current definition for “eligible death” at §486.302 with the upcoming revised OPTN definition of “eligible death.” Specifically, the OPTN has approved a change to its “eligible death” definition, which is scheduled to go into effect on January 1, 2017. The changes to the OPTN definition are predicted to increase the availability of transplantable organs by: increasing the maximum age for donation from 70 years of age to 75; replacing the automatic exclusion of patients with Multi-System Organ Failure (MSOF) with clinical criteria for each organ type that specifies such type’s suitability for procurement; and implementing...
policies allowing recovery and transplantation of organs from an HIV positive donor into an HIV positive recipient, consistent with the Hope Act.

_The CMS definition would be revised to include donors up to the age of 75 and replace the automatic exclusion of potential donors with MSOF with the clinical criteria listed in the definition, that specify the suitability for procurement._

**Aggregate Donor Yield for OPO Outcome Performance Measures (p. 578):**

_CMS proposes revising §486.318(a)(3) and §486.318(b)(3) to be consistent with the current OPTN/SRTR aggregate donor yield metric._

These CMS standards measure the number of organs transplanted per standard criteria donor and expanded criteria donor (donor yield). CMS received feedback that the use of this measure has created a hesitancy on the part of OPOs to pursue donors for only one organ due to the impact on the CMS yield measure. The revised metric, currently in use by the OPTN/SRTR, risk-adjusts based on 29 donor medical characteristics and social complexities. CMS believes the OPTN/SRTR yield metric accurately predicts the number of organs that may be procured per donor, and each OPO is measured based on the donor pool in its DSA. CMS believes this methodology is a more accurate measure for organ yield performance and accounts for differences between donor case-mixes across DSAs.

**Organ Preparation and Transport-Documentation with the Organ (p. 579)**

_CMS proposes revising §486.346(b) to no longer require that paper documentation, with the exception of blood typing and infectious disease information, be sent with the organ to the receiving transplant center._

The regulation specifically lists documents that must be copied and sent by the OPO to include: donor evaluations; the complete record of the donor’s management; documentation of consent; documentation of the pronouncement of death; and documentation for determining organ quality. This requirement has resulted in an extremely 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.

_CMS also proposes a revision to §486.346(b) to make it consistent with current OPTN policy at 16.5.A.120 which requires that blood type source documentation and infectious disease testing results be physically sent in hard copy with the organ._

**Transplant Enforcement Technical Corrections and Proposals (p. 580)**

_Technical Correction to Transplant Enforcement Regulatory References (p. 580)_

_CMS corrects a typographical error_ to have the response read as follows: "In the final regulation, at § 488.61(f)(1) and elsewhere, we 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."

Prepared by Hart Health Strategies Inc., www.hhs.com
CMS also proposes amending §488.61(f)(1) which was added in that final rule (79 FR 50359) to correct the same incorrect citations.

Other Proposed Revisions to §488.61 (p. 581)
CMS proposes amending §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 to clarify that the time period for submission of the mitigating factors information is calculated in calendar days (that is, 120 calendar days).

In addition, CMS proposes revising §488.61(h)(2) to clarify that a signed 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, except that CMS, in its sole discretion, CMS-1656-P may shorten the timeframe or allow modification to any portion of the elements of the SIA in such a case.
Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (p. 582)

Background (p. 582)
CMS seeks to reconcile potential differences in electronic reporting requirements for the EHR Incentive Program established in the final rule titled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” from the proposals for the advancing care information in the “Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models” proposed rule.

Summary of Proposals Included in this Proposed Rule (p. 584)
These proposed changes would not apply to eligible hospitals and CAHs that attest to meaningful use under their State’s Medicaid EHR Incentive Program. These eligible hospitals and CAHs would continue to attest to their State Medicaid agencies on the measures and objectives finalized in the 2015 EHR Incentive Programs Final Rule.

CMS proposes to make the following changes to the Medicare and Medicaid EHR Incentive Program:

1. CMS proposes eliminating the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Modified Stage 2 and Stage 3 for 2017 and subsequent years.

2. CMS also proposes reducing the thresholds of a subset of the remaining objectives and measures in Modified Stage 2 for 2017 and in Stage 3 for 2017 and 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program.

3. CMS proposes changing the EHR reporting period in 2016 for all returning EPs, eligible hospitals and CAHs that have previously demonstrated meaningful use in the Medicare and Medicaid EHR Incentive Programs.

4. CMS proposes requiring EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year and 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 attest to the Modified Stage 2 objectives and measures.

5. CMS proposes 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.

6. CMS proposes to change the policy on measure calculations for actions outside the EHR reporting period for the Medicare and Medicaid EHR Incentive Programs. Specifically, for all meaningful use measures, unless otherwise specified, CMS is proposing 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.

Further details on these proposals are described below.
Proposed Revisions to Objectives and Measures for Eligible Hospitals and CAHs (p. 586)

Removal of the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs (p. 586)

To reduce hospital administrative burden, CMS proposes to remove the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measure for eligible hospitals and CAHs.

CMS notes that the CDS and CPOE objectives and associated measures that CMS is proposing to remove for eligible hospitals and CAHs would still be required as part of the eligible hospital or CAH’s CEHRT. However, eligible hospitals and CAHs attesting to meaningful use under Medicare would not be required to report on those measures under this proposal.

Rationale for removal of the CPOE objective and measures. CMS applied the following two criteria to determine whether these objectives were topped out, which are similar to the criteria used in the Hospital IQR and Hospital VBP Programs (79 FR 50203):

- Statistically indistinguishable performance at the 75th and 99th percentile; and
- Performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold.

In applying these criteria to the objectives and measures for Modified Stage 2 and Stage 3, CMS determined that the CPOE objective and measures are topped out.

Based on the 2015 attestation data, CMS determined that there is widespread adoption among eligible hospitals and CAHs and CMS is proposing to remove them from the Medicare EHR Incentive Program to reduce hospital administrative burden.12

Rationale for removal of the CDS objective and measures. CMS also considers this objective and measures to be “topped out.” Specifically, CMS notes that 99 percent of eligible hospitals and CAHs have attested “yes” to meeting these measures based on attestation data for 2015.

Reduction of Measure Thresholds for Eligible Hospitals and CAHs for 2017 and 2018 (p. 589)

CMS proposes to reduce a subset of the thresholds for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for EHR reporting periods in CY 2017 for Modified Stage 2 and in CYs 2017 and 2018 for Stage 3.

Proposed Changes to the Objectives and Measures for Modified Stage 2 (42 CFR 495.22) in 2017 (p. 591). For eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program:

12 CMS performed an analysis at the 25th, 50th, and 75th percentiles to determine the distribution regarding the percentage above the required thresholds attested by eligible hospitals and CAHs. Eligible hospitals and CAHs at the 25th percentile have attested to performance rates of over 75 percent for the measures associated with this objective. Eligible hospitals and CAHs at the 50th percentile have attested to performance rates of over 87 percent for the measures associated with this objective. Eligible hospitals and CAHs at the 75th percentile have attested to performance rates of over 95 percent for the measures associated with this objective.
• CMS is proposing to revise section 495.22(e) to specify that the current Modified Stage 2 meaningful use objectives and measures apply for EPs for 2015 through 2017, for eligible hospitals and CAHs attesting under a State’s Medicaid EHR Incentive Program for 2015 through 2017 and for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for 2015 and 2016.

• CMS proposes to add a new section 495.22(f) that includes the meaningful use objectives and measures with the proposed modifications discussed below that would be applicable only to eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for an EHR reporting period in calendar year 2017.

• CMS also proposes a new naming convention for certain measures (shown in the table summarizing the Proposed Modified Stage 2 Objectives and Measures in 2017 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, below).

• Patient Electronic Access (VDT) (proposed 42 CFR 495.22(f)(8)(ii)(B)) View Download Transmit (VDT) Measure: For eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, CMS proposes to reduce the threshold of the VDT Measure from more than 5 percent to at least one patient, because CMS has heard from stakeholders including hospitals and hospital associations that they have faced significant challenges in implementing the objectives and measures that require patient action.

### Proposed Modified Stage 2 Objectives and Measures in 2017 for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program

<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 Measure</td>
<td>Yes/No attestatio</td>
</tr>
<tr>
<td>*CDS (Clinical Decision Support)</td>
<td>Measure 1</td>
<td>Clinical Decision Support Interventions Measure</td>
<td>Five CDS</td>
</tr>
<tr>
<td></td>
<td>Measure 2</td>
<td>Drug Interaction and Drug-Allergy Checks Measure</td>
<td>Yes/No</td>
</tr>
<tr>
<td>*CPOE (Computerized Provider Order Entry)</td>
<td>Measure 1</td>
<td>Medication Orders Measure</td>
<td>&gt;60%</td>
</tr>
<tr>
<td></td>
<td>Measure 2</td>
<td>Laboratory Orders Measure</td>
<td>&gt;30%</td>
</tr>
<tr>
<td></td>
<td>Measure 3</td>
<td>Radiology Orders Measure</td>
<td>&gt;30%</td>
</tr>
<tr>
<td>eRx (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 Measure</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 Measure</td>
<td>&gt;50%</td>
</tr>
<tr>
<td></td>
<td>Eligible Hospital/CAH Measure 1</td>
<td>Patient Access Measure</td>
<td>&gt;50%</td>
</tr>
</tbody>
</table>
Objectives and Measures for Stage 3 (42 CFR 495.24) in 2017 and 2018 (p. 595). CMS proposes, beginning in 2017, to update the measures for EPs, eligible hospitals and CAHs with a new naming convention to allow for easier reference to a given measure, and to align with the measure nomenclature proposed for the MIPS (as specified in the Stage 3 table below).

- **Objective: Patient Electronic Access to Health Information (proposed 42 CFR 495.24(c)(5)) Proposed Modification to the Patient Access Measure Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program (p. 595)**
  - **Patient Access Measure**: CMS proposes reduce the threshold for the Patient Access measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 80 percent to more than 50 percent. CMS is proposing to reduce the threshold based on the concerns voiced by these vendors and believe the Modified Stage 2 threshold of more than 50 percent is reasonable.
  - **Patient-Specific Education Measure**: CMS proposes to reduce the threshold for the Patient-Specific Education measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 35 percent to more than 10 percent.

- **Objective: Coordination of Care Through Patient Engagement (proposed 42 CFR 495.24(c)(6)) (p. 600).**
  - **Proposed Modification to the View, Download, Transmit (VDT) Threshold**: CMS is proposing to reduce the threshold of the View, Download Transmit (VDT) measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 5 percent to at least one patient, because CMS has heard from stakeholders, including hospitals and hospital associations, that they have faced significant challenges in implementing the objectives and measures that require patient action. These challenges include but are not limited to, patients who have limited knowledge of, proficiency with and access to information technology as well as patients declining to access the portals provided by the eligible hospital or CAH to view, download, and transmit their health information via this platform.
  - **Proposed Modification to the Secure Messaging Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program**: CMS is proposing to reduce
the threshold of the Secure Messaging measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 25 percent to more than 5 percent. CMS has heard that, for patients who are in the hospital for an isolated incident, the hospital may not have significant reason for a follow up secure message. In addition, CMS has heard concerns from these same stakeholders that these same patients may decline to access the messages received through this platform.

- **Objective: Health Information Exchange (HIE) (proposed 42 CFR 495.24(c)(7))** (p. 603)
  - Proposed Modification to the Patient Care Record Exchange Measure for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program: CMS proposes to reduce the threshold for the Patient Care Record Exchange measure for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program from more than 50 percent to more than 10 percent. Stakeholders have emphasized that while the majority of hospitals are now engaging in health IT supported health information exchange, achieving high performance will require further saturation of these health IT supports throughout the industry. CMS notes that it will likely raise the bar over time as providers gain experience with health IT supported information exchange and as barriers to interoperability are lessened.
  
  - Proposed Modification to the Request/Accept Patient Care Record Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program: CMS proposes to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Request/Accept Patient Care Record Measure from more than 40 percent to more than 10 percent. Hospital and hospital association feedback on the 2015 EHR Incentive Programs Final Rule, as well as recent reports and surveys of hospital participants show that there are still challenges to achieving wide scale interoperable health information exchange.
  
  - Proposed Modification to the Clinical Information Reconciliation Threshold for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program: CMS is proposing, to reduce the threshold for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for the Clinical Information Reconciliation Measure from more than 80 percent to more than 50 percent, because there are challenges to achieving wide scale interoperable health information exchange.

- **Objective: Public Health and Clinical Data Registry Reporting (proposed 42 CFR 495.24(c)(8))** (p. 609)
  
  - Proposed Modification to the Public Health and Clinical Data Registry Reporting Requirements for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program: CMS is proposing to reduce the reporting requirement for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Public Health and Clinical Data Registry Reporting to the Modified Stage 2 requirement of any combination of three measures from any combination of six measures in alignment with
Modified Stage 2 requirements (80 FR 62870). CMS received written correspondence from hospitals and hospital associations indicating that it is often difficult to find registries that are able to accept data that will allow them successfully attest.

**Proposed Stage 3 Objectives and Measures for 2017 and 2018 for Eligible Hospitals and CAHs Attesting Under the Medicare EHR Incentive Program**

<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>Security Risk Analysis Measure</td>
<td>Yes/No attestation</td>
<td></td>
</tr>
<tr>
<td>eRx (electronic prescribing)</td>
<td>e-Prescribing</td>
<td>&gt;25%</td>
<td></td>
</tr>
<tr>
<td>*CDS (Clinical Decision Support)</td>
<td>Clinical Decision Support Interventions Measure</td>
<td>Five CDS</td>
<td></td>
</tr>
<tr>
<td>Measure 1</td>
<td>Drug Interaction and Drug-Allergy Checks Measure</td>
<td>Yes/No</td>
<td></td>
</tr>
<tr>
<td>*CPOE (Computerized Provider Order Entry)</td>
<td>Medication Orders Measure</td>
<td>&gt;60%</td>
<td></td>
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<tr>
<td>Measure 2</td>
<td>Laboratory Orders Measure</td>
<td>&gt;60%</td>
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<tr>
<td>Measure 3</td>
<td>Diagnostic Imaging Orders Measure</td>
<td>&gt;60%</td>
<td></td>
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<tr>
<td>Patient Electronic Access to Health Information</td>
<td>**Patient Access Measure</td>
<td>&gt;50%</td>
<td></td>
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<tr>
<td>Measure 2</td>
<td>**Patient-Specific Education Measure</td>
<td>&gt;10%</td>
<td></td>
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<tr>
<td>Coordination of Care through Patient Engagement</td>
<td>**View, Download Transmit (VDT) Measure</td>
<td>&gt;At least 1 patient</td>
<td></td>
</tr>
<tr>
<td>Measure 2</td>
<td>**Secure Messaging</td>
<td>&gt;5%</td>
<td></td>
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<tr>
<td>Measure 3</td>
<td>Patient Generated Health Data Measure</td>
<td>&gt;5%</td>
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<tr>
<td>Health Information Exchange</td>
<td>**Patient Care Record Exchange Measure</td>
<td>&gt;10%</td>
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<tr>
<td>Measure 2</td>
<td>**Request/Accept Patient Care Record Measure</td>
<td>&gt;10%</td>
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<tr>
<td>Measure 3</td>
<td>**Clinical Information Reconciliation Measure</td>
<td>&gt;50%</td>
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<tr>
<td>Public Health and Clinical Data Registry Reporting</td>
<td>Immunization Registry Reporting</td>
<td>Immunization Registry Reporting</td>
<td>Report to 3 Registries or claim exclusions</td>
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<tr>
<td>Immunization Registry Reporting</td>
<td>Syndromic Surveillance Reporting</td>
<td>Case Reporting</td>
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<td>Immunization Registry Reporting</td>
<td>Public Health Registry Reporting</td>
<td>CLINICAL DATA REGISTRY REPORTING</td>
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<td>Immunization Registry Reporting</td>
<td>Electronic Reportable Laboratory Result Reporting</td>
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<td>Public Health Registry Reporting</td>
<td>Case Reporting</td>
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</table>

*CMS notes that CMS is proposing to remove CDS and CPOE for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program in section XVIII.C.1. of this proposed rule. These objectives are included in the table to demonstrate what their measures and thresholds would be if we were not to finalize the proposal to remove them.

** CMS notes that CMS is proposing to reduce the thresholds for these measures.

**Additional request for comments.**

- **CMS seeks public comments on how measures of meaningful use under the EHR Incentive Program can be made more stringent in future years.**
- **CMS seeks comments on the proposed thresholds or whether different thresholds would be more appropriate.**
- **CMS seeks public comment on new and more stringent measures for future years of the EHR Incentive Program.**

**Proposed Revisions to the EHR Reporting Period in 2016 for EPs, Eligible Hospitals and CAHs (p. 614)**

**Definition of “EHR Reporting Period” and “EHR Reporting Period for a Payment Adjustment Year” (p. 614)**

**CMS proposes to change the EHR reporting periods in 2016 for returning participants from the full CY 2016 to any continuous 90-day period within CY 2016.** This would mean that all EPs, eligible hospitals and CAHs may attest to meaningful use for an EHR reporting period of any continuous 90-day period from January 1, 2016 through December 31, 2016. The applicable incentive payment year and payment adjustment years for the EHR reporting period in 2016, as well as the deadlines for attestation and other related program requirements, would remain the same as established in prior rulemaking.
CMS has received feedback from stakeholders that more time is needed to accommodate some of the updates from the 2015 EHR Incentive Programs Final Rule. These updates include, but are not limited to, system changes to the CEHRT, including implementation of an API which is a unique user interface that allows patients, through an application of their choice (including third-party applications), to pull certain components of their unique health data directly from the provider’s CEHRT.

Clinical Quality Measurement (p. 617)
In connection with the proposal to establish a 90-day EHR reporting period in 2016, and for the reasons discussed in the preceding section, CMS also proposes a 90-day reporting period for clinical quality measures (CQMs) for all EPs, eligible hospitals, and CAHs that choose to report CQMs by attestation in 2016. In 2016, CMS proposes that providers may:

- Report CQM data by attestation for any continuous 90-day period during calendar year 2016 through the Medicare EHR Incentive Program registration and attestation site; or
- Electronically report CQM data in accordance with the requirements established in prior rulemaking.

CMS notes that, for EPs, eligible hospitals and CAHs, CQM data submitted via attestation can be submitted for a different 90-day period than the EHR reporting period for the meaningful use objectives and measures.

Proposal to Require Modified Stage 2 for New Participants in 2017 (p. 617)
CMS proposes that any EP or eligible hospital new participant seeking to avoid the 2018 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation system, or any CAH new participant seeking to avoid the FY 2017 payment adjustment by attesting for an EHR reporting period in 2017 through the EHR Incentive Program Registration and Attestation System, would be required to attest to the Modified Stage 2 objectives and measures.

In early 2018, these returning eligible hospitals and CAHs will be transitioned to other reporting systems to attest for 2017, such as the Hospital IQR Program reporting portal.

Due to cost and time limitation concerns related specifically to 2015 Edition CEHRT updates in the EHR Incentive Program Registration and Attestation System, CMS notes 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.

CMS is proposing corresponding revisions to the regulations\(^\text{13}\) to require new participants to attest to the Modified Stage 2 objectives and measures for 2017. In addition, CMS proposes an editorial correction to the introductory language to correct the inadvertent omission of the word “satisfy” after the term “CAH must.”

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\(^{13}\) These regulations are proposed to appear at 42 CFR 495.40(a)(2)(i)(F) and 42 CFR 495.40(b)(2)(i)(F).
Proposed Significant Hardship Exception for New Participants Transitioning to MIPS in 2017 (p. 619)

*CMS proposes to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment as authorized under section 1848(a)(7)(B) of the Act.* CMS is limiting this proposal only to EPs who have not successfully demonstrated meaningful use in a prior year, intend to attest to meaningful use for an EHR reporting period in 2017 by October 1, 2017 to avoid the 2018 payment adjustment, and intend to transition to MIPS and report on measures specified for the advancing care information performance category under the MIPS in 2017.

To apply for this significant hardship exception, an EP would submit an application by October 1, 2017 (or a later date specified by CMS) to CMS that includes sufficient information to show that they are eligible to apply for this particular category of significant hardship exception. The application must also explain why, based on their particular circumstances, demonstrating meaningful use for the first time in 2017 under the EHR Incentive Program and also reporting on measures specified for the advancing care information performance category under the MIPS in 2017 would result in a significant hardship. EPs should retain all relevant documentation of this hardship for six years post attestation.

In the MIPS and APMs Proposed Rule, CMS proposed calendar year 2017 as the first MIPS performance period. As established in the 2015 EHR Incentive Programs Final Rule, 2017 is also the last year in which new participants may attest to meaningful use (for a 90-day EHR reporting period in 2017) to avoid the 2018 payment adjustment. CMS believes this overlap of reporting and performance periods in 2017 could be confusing to EPs who are new participants in the EHR Incentive Program and are also making the transition to MIPS because although both programs require the use of certified EHR technology, the measures and other requirements for meaningfully using that technology under the EHR Incentive Program are different from the measures and other requirements proposed under the advancing care information performance category of the MIPS. In addition, there are also different systems in which participants will have to register and attest.

In the event CMS does not to finalize the MIPS and APM proposal, CMS may determine that this proposed significant hardship exception is not necessary.

Proposed Modifications to Measure Calculations for Actions Outside the EHR Reporting Period (p. 622)

*CMS proposes 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 it 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 CY 2017, the action must occur between January 1 and December 31, 2017, but does not have to occur within the 90-day EHR reporting period timeframe

In the 2015 EHR Incentive Programs Final Rule, CMS referenced FAQ 8231 which states that 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. CMS notes that this open-ended timeframe could be confusing to providers and could vary widely among providers as their date of attestation could fall anywhere from January 1
through February 28 (or other date specified by CMS) after the year in which their EHR reporting period occurs.

Proposed Additional Hospital Value-Based Purchasing (VBP) Program Policies (p. 624)

Proposed Removal of the HCAHPS Pain Management Dimension from the Hospital VBP Program Beginning with the FY 2018 Program Year (p. 627)

One of the HCAHPS Survey dimensions that CMS has adopted for the Hospital VBP Program is Pain Management. Three survey questions that are used to construct this dimension are as follows:

12. During this hospital stay, did you need medicine for pain?
13. During this hospital stay, how often was your pain well controlled?
14. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

CMS is developing alternative questions for the Pain Management dimension in order to remove any potential ambiguity in the HCAHPS Survey. While CMS awaits the results of ongoing research and the modifications to the Pain Management dimension questions, CMS proposes to remove the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain beginning with the FY 2018 program year.

CMS received feedback that some stakeholders are concerned about the Pain Management dimension questions being used in a program where there is any link between scoring well on the questions and higher hospital payments. In addition, CMS is concerned that they have heard some hospitals may be disaggregating their raw HCAHPS data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. CMS notes that the HCAHPS Survey was never intended to be used in these ways.

In addition, CMS is in the early stages of developing the following measures:

- An electronically specified process measure for the inpatient and outpatient hospital settings that would measure concurrent prescribing of an opioid and benzodiazepine.
- A process measure that would assess whether inpatient psychiatric facilities are regularly monitoring for adverse drug events of opioid and psychotropic drugs.

If the proposal to remove the Pain Management dimension is finalized, this would leave eight dimensions in the HCAHPS Survey for use in the Hospital VBP Program:

1) Communication with Nurses
2) Communication with Doctors
3) Responsiveness of Hospital Staff
4) Communication About Medicines
5) Hospital Cleanliness & Quietness
6) Discharge Information
7) 3-Item Care Transition
8) Overall Rating of Hospital

In order to adjust for the removal of the HCAHPS Pain Management dimension from the Hospital VBP Program, **CMS proposes to continue to assign Achievement Points (0 to 10 points) and Improvement Points (0 to 9 points) to each of the remaining CMS-1656-P eight dimensions in order to create the HCAHPS Base Score (0 to 80 points)**. Each of the remaining eight dimensions would be of equal weight, so that the HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would then be calculated, and would range from 0 to 20 points. The Consistency Points would consider scores across the remaining eight dimensions, and would not include the Pain Management dimension. The final element of the scoring formula would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and would range from 0 to 100 points. The performance standards for the other eight dimensions would remain unchanged, as the table below illustrates.

<table>
<thead>
<tr>
<th>HCAHPS Survey Dimension</th>
<th>Floor* (percent)</th>
<th>Achievement Threshold** (percent)</th>
<th>Benchmark*** (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication with Nurses</td>
<td>55.27</td>
<td>78.52</td>
<td>86.68</td>
</tr>
<tr>
<td>Communication with Doctors</td>
<td>57.39</td>
<td>80.44</td>
<td>88.51</td>
</tr>
<tr>
<td>Responsiveness of Hospital Staff</td>
<td>38.40</td>
<td>65.08</td>
<td>80.35</td>
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<tr>
<td>Pain Management</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Communication about Medicines</td>
<td>43.43</td>
<td>63.37</td>
<td>73.66</td>
</tr>
<tr>
<td>Hospital Cleanliness &amp; Quietness</td>
<td>40.05</td>
<td>65.60</td>
<td>79.00</td>
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<tr>
<td>Discharge Information</td>
<td>62.25</td>
<td>86.60</td>
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<td>3-Item Care Transition</td>
<td>25.21</td>
<td>51.45</td>
<td>62.44</td>
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<tr>
<td>Overall Rating of Hospital</td>
<td>37.67</td>
<td>70.23</td>
<td>84.58</td>
</tr>
</tbody>
</table>

* Floor is defined as the 0th percentile of the baseline (76 FR 26519).
** Achievement threshold is defined as the 50th percentile of hospital performance in the baseline period (76 FR 26519)

*** Benchmark is defined as the mean of the top decile of hospital performance on each dimension (76 FR 26517).