Medicare Outpatient Prospective Payment System

Payment Rule Brief — Calendar Year 2016 Proposed Rule

Overview

The proposed calendar year (CY) 2016 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was published in the July 8, 2015 Federal Register. The proposed rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as proposed regulations that implement new policies:

- Renumbering of APCs in order to better group clinical families;
- Implementation of nine new Comprehensive Ambulatory Payment Classifications (C-APCs) that bundle all payments for certain device-dependent procedures;
- Expansion of the list of services to be packaged into APCs as opposed to separately paid;
- For IPPS, revision of the “2-Midnight Rule” for reasonable expectation requirement and use of Quality Improvement Organizations (QIOs) as the first line for auditing; and
- Updated payment rates and policies for Ambulatory Surgical Centers (ASCs).

A copy of the Federal Register (FR) and other resources related to the OPPS are available on the Centers for Medicare and Medicaid Services (CMS) website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-P.html?DLPage=1&DLEntries=10&DSort=2&DSortDir=descending. Comments on all aspects of the proposed rule are due to CMS by August 31 and can be submitted electronically at http://www.regulations.gov by using the website’s search feature to search for file code “1633-P”.

An online version of the rule is available at https://federalregister.gov/a/2015-16577. Page numbers noted in this summary are from the version of the proposed rule published in the Federal Register. A brief summary of the major hospital OPPS sections of the proposed rule is provided below.

OPPS Payment Rate

FR pages 39,237 - 39,240

The tables below show the proposed CY 2016 conversion factor compared to CY 2015 and the components of the update factor:

<table>
<thead>
<tr>
<th></th>
<th>Final CY 2015</th>
<th>Proposed CY 2016</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPPS Conversion Factor</td>
<td>$74.144</td>
<td>$73.929</td>
<td>-0.29%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposed CY 2016 Update Factor Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketbasket (MB) Update</td>
<td>+2.7%</td>
</tr>
<tr>
<td>Affordable Care Act (ACA)-Mandated Productivity MB Reduction</td>
<td>-0.6 percentage points</td>
</tr>
<tr>
<td>ACA-Mandated Pre-Determined MB Reduction</td>
<td>-0.2 percentage points</td>
</tr>
<tr>
<td>Wage Index Budget Neutrality Adjustment</td>
<td>-0.07 percentage points</td>
</tr>
<tr>
<td>Pass-through Spending Budget Neutrality Adjustment</td>
<td>-0.12 percentage points</td>
</tr>
<tr>
<td>Inflation Adjustment for Excess Packaged Payments for Laboratory Tests</td>
<td>-2.0 percentage points</td>
</tr>
</tbody>
</table>

**Overall Proposed Rate Update**  -0.29%
Inflation Adjustment for Excess Packaged Payments due to Laboratory Tests (FR pages 39,237 – 39,240): CMS observed that OPPS spending for CY 2014 increased by 14%, compared to a typical annual increase of 6-8%. This was found to be due to CMS’ policy of packaging laboratory services into OPPS payment weights, without implementing a comparable reduction in spending for laboratory services that continued to be paid at the clinical laboratory fee schedule (CLFS). In order to address the increased payments resultant of this, CMS is proposing a prospective reduction of 2.0 percentage points to the CY 2016 OPPS conversion factor.

Adjustments to the Outpatient Rate and Payments

Wage Indexes (FR pages 39,240 – 39,242): As in past years, for CY 2016 OPPS payments, CMS is proposing to use the federal fiscal year (FFY) 2016 inpatient PPS wage indexes, including all reclassifications, add-ons, rural floors, and budget neutrality adjustment.

Regarding the new CBSA delineations adopted in FFY 2015, in some very limited circumstances (i.e. urban to rural changes that affect geographic location or Lugar status), this is the 2nd year of the 3-year transition to the new wage index. Hospitals affected by this transition will receive a wage index based on their prior geographic CBSA.

The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2016, CMS is proposing to continue to use a labor-related share of 60%.

Payment Increase for Rural SCHs and EACHs (FR page 39,244): CMS is proposing to continue to apply a 7.1% payment increase for rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs). This payment add-on excludes separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

Cancer Hospital Payment Adjustment and Budget Neutrality Effect (FR pages 39,244 – 39,246): CMS is proposing to continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. This policy will continue to be applied in a budget neutral manner. Because CMS applied a budget neutrality reduction in CY 2012 when this adjustment was first implemented and that adjustment amount has not changed, there is no year-to-year change in the conversion factor as a result of continuing this policy.

Outlier Payments (FR pages 39,246 – 39,247): To maintain total outlier payments at 1.0% of total OPPS payments, CMS has set a proposed CY 2016 outlier fixed-dollar threshold of $3,650. This is an increase compared to the current threshold of $2,775. Outlier payments will continue to be paid at 50% of the amount by which the hospital’s cost exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

Effect of Sequestration (no FR page reference): The proposed rule does not specifically address the 2.0% sequester reductions to all Medicare payments (authorized by Congress and currently in effect through FFY 2024). Sequester is not applied to the payment rate; instead, it is applied to Medicare claims after determining co-insurance, any applicable deductibles, and any applicable Medicare secondary payment adjustments. Other Medicare payment lines such as graduate medical education (GME), bad debt, and electronic health record (EHR) incentives are also affected by the sequester reductions. Payments from MA plans should not be automatically impacted by sequester.

Updates to the APC Groups and Weights


As required by law, CMS must review and revise the APC relative payment weights annually. CMS must also revise the APC groups each year to take into account drugs and medical devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services, and new cost data.

For CY 2016, CMS is proposing two new status indicators: “J2” to identify certain combinations of services proposed to be paid through C-APC 8011 (Comprehensive Observation Services), and “Q4” to identify conditionally packaged laboratory tests.

In order to better identify and group consecutive APC levels within a clinical family, CMS is proposing to renumber 218 APCs for CY 2016. CMS has provided a crosswalk of current APC numbers to the new 2016 numbers in Addendum Q of the proposed rule.

The table below shows the shift in the number of APCs per category from CY 2015 to CY 2016:

<table>
<thead>
<tr>
<th>APC Category</th>
<th>Status Indicator</th>
<th>Final CY 2015</th>
<th>Proposed CY 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic or Emergency Department Visit</td>
<td>V</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>Procedure or Service, Multiple Reduction Applies</td>
<td>T</td>
<td>129</td>
<td>65</td>
</tr>
<tr>
<td>Procedure or Service, No Multiple Reduction</td>
<td>S</td>
<td>134</td>
<td>80</td>
</tr>
<tr>
<td>Pass-Through Devices Categories</td>
<td>H</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>OPD Services Paid through a Comprehensive APC</td>
<td>J1</td>
<td>25</td>
<td>33</td>
</tr>
<tr>
<td>Observation Services</td>
<td>J2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Non-Pass-Through Drugs/Biologicals</td>
<td>K</td>
<td>289</td>
<td>280</td>
</tr>
<tr>
<td>Partial Hospitalization</td>
<td>P</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Blood and Blood Products</td>
<td>R</td>
<td>34</td>
<td>34</td>
</tr>
<tr>
<td>Brachytherapy Sources</td>
<td>U</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Pass-Through Drugs and Biologicals</td>
<td>G</td>
<td>35</td>
<td>32</td>
</tr>
<tr>
<td>New Technology</td>
<td>S/T</td>
<td>82</td>
<td>100</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>766</strong></td>
<td><strong>663</strong></td>
</tr>
</tbody>
</table>

**New Comprehensive APCs (FR pages 39,222 – 39,228):** Starting CY 2014, CMS began adopting a number of refinements to the APC assignments in an effort to create larger payment bundles. For CY 2016, CMS is proposing to continue creating larger payment bundles by expanding its packaging policies and implementing new comprehensive APCs.

Comprehensive APCs (C-APCs) are applicable for certain medical device implantation procedures. A C-APC covers payment for all Part B services that are related to the device-dependent procedure (including items currently paid under separate fee schedules). The C-APC encompasses diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un-coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs.

The C-APCs do not include payments for services that are not covered by Medicare Part B or are not payable under OPPS such as: certain mammography and ambulance services; brachytherapy sources; pass-through drugs and devices; and charges for self-administered drugs (SADs). A full list of excluded services is provided in Table 5 of the proposed rule (page 39,224).

For CY 2016, CMS is proposing the addition of nine new C-APCs, bringing the total to 34 C-APCs within 14 clinical families, as listed in Table 6 of the proposed rule (pages 39,225 – 39226). The list of 9 new C-APCs are:
Included in these is a proposal to pay for all qualifying extended assessment and management non-surgical encounters with a high-level visit and 8 or more hours of observation through a newly created “Comprehensive Observation Services” C–APC (C–APC 8011).

- **Composite APCs (FR pages 39,228 – 39,232):** Composite APCs are another type of packaging to provide a single APC payment for groups of services that are typically performed together during a single outpatient encounter. Currently, there are eight composite APCs for:
  - Low-Dose Rate (LDR) Prostate Brachytherapy (APC 8001);
  - Mental Health Services (APC 0034);
  - Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008); and
  - Extended Assessment and Management (EAM) Services (APC 8009).

As part of its overall APC restructuring and renumbering CMS is proposing to change APC 0034 to APC 8010. In addition, to ensure alignment with the C-APC policies, CMS is proposing to discontinue one of these composite APCs: APC 8009, which will be replaced by C-APC 8011 (Comprehensive Observation Services). Table 7 on pages 39,230 – 39,232 of the FR shows the HCPCS codes that are eligible for Composite APC assignment.

- **Packaged Services (FR pages 39,233 – 39,236):** For CY 2016, CMS is continuing its efforts to create more complete APC payment bundles by proposing to expand its packaging policies to the following services/items:
  - Ancillary services— CMS’ stated intention, over time, is to package more ancillary services when they occur on a claim with another service, and only pay for them separately when performed alone. There are three additional ancillary services (Table 8; page 39,234) currently paid separately under the OPPS that CMS is proposing to package in CY 2016 under certain conditions. Other ancillary services will remain separately paid (assigned a status indicator of S or T) because CMS has identified them as not being clinically similar to those services currently packaged, or as services that are preventative or psychiatry/counseling-related. A list of HCPCS codes proposed to be conditionally packaged are displayed in Addendum B of the proposed rule.
  - Drugs and Biologicals Functioning as Supplies for a Surgical Procedure— CMS is proposing to package payment for four drugs (Table 10; page 39,235), that are currently paid separately, based on their primary function as a supply in surgical procedures. CMS is proposing to package an additional drug (HCPCS code C9447) in CY 2018, once its pass-through payment status expires.
  - Clinical Diagnostic Laboratory Tests— CMS is proposing to exclude, from the packaging policy, all current and future codes that describe molecular pathology tests as these are considered to be less tied to other primary outpatient services. CMS is also proposing to make separate payments for preventative laboratory tests in order to maintain alignment with the exclusions for ancillary services. Finally, also being proposed is an expansion of the current conditional payment policy to laboratory tests provided during an outpatient stay, rather than specifically provided on the same date as the primary service, except when ordered for a different purpose and by a different practitioner.
Payment for Medical Devices with Pass-Through Status *(FR pages 39,264 – 39,267)*: CMS is proposing to remove HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) from the list of medical devices currently provided pass-through payment status, so that payments for these devices will be packaged with related procedures. The HCPCS codes for devices still on the pass-through payment list are:
- C2613 - Lung biopsy plug with delivery system;
- C2623 - Catheter, transluminal angioplasty, drug-coated, non-laser; and
- C2624 - Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components.

Payment Adjustment for No Cost/Full Credit and Partial Credit Devices *(FR pages 39,268 – 39,269)*: For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital received a credit from the manufacturer. The offset can be 100% of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer; or 50% when a hospital receives partial credit of 50% or more.

For CY 2016, CMS is proposing that hospitals must continue to report any credits received if they are 50% or more of the cost of the device. CMS is also proposing to no longer specify lists of devices to which this payment adjustment would apply. Instead, CMS is proposing to apply this adjustment “to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.”

Payment for Drugs, Biologicals and Radiopharmaceuticals *(FR pages 39,270 – 39,285)*: CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on a price threshold.

For CY 2016, CMS has proposed a packaging threshold of $100. Drugs, biologicals and radiopharmaceuticals that are above the $100 threshold are paid separately using individual APCs; the payment rate for CY 2016 is the average sales price (ASP) + 6%.

CMS is proposing to allow pass-through status to expire for 12 drugs and biologicals, listed in Table 39 of the *FR*; and is continuing pass-through status for 32 others, shown in Table 40 of the *FR*.

Payment for Chronic Care Management Services *(FR pages 39,288 – 39,290)*: CMS is proposing additional requirements for hospitals to bill and receive payment for CPT code 99490 (“Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month”). The primary points of this proposal are:
- The patient must have registered to the hospital as either an inpatient or outpatient within the last 12 months, and for whom the hospital provided therapeutic services;
- The hospital is required to have documented in the medical record that the services were explained and offered to the beneficiary, and that the beneficiary either agreed to or declined the services; or that this agreement is provided in a medical record accessible to the hospital;
- That during a single calendar month service period, only one hospital may furnish, and be paid, for those services described by CPT code 99490; and
- That additional requirements listed on page 39,290 of the *FR* be provided; including the recording of demographics and potential complications, full-time access to care management services, that there be continuity of care for any routine appointments to follow, and a requirement for the use of EHR technology.

Other OPPS Policies

Partial Hospitalization Program (PHP) Services *(FR pages 39,290 – 39,299)*: The PHP is an intensive outpatient psychiatric program to provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding Community Mental Health Center (CMHC).
PHP providers are paid on a per diem basis with payment rates calculated using CMHC- or hospital-specific data. The table below compares the CY 2015 and proposed CY 2016 PHP payment rates.

<table>
<thead>
<tr>
<th>Former APC</th>
<th>New APC</th>
<th>Group Title</th>
<th>CY 2015 Payment Rate</th>
<th>Proposed CY 2016 Payment Rate</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>0175 5861</td>
<td>0176 5862</td>
<td>Hospital-Based PHPs-Level I PHP (3 services)</td>
<td>$179.11</td>
<td>$185.27</td>
<td>+3.4%</td>
</tr>
<tr>
<td>0172 5851</td>
<td>0173 5852</td>
<td>Hospital-Based PHPs-Level II PHP (4 or more)</td>
<td>$195.62</td>
<td>$207.24</td>
<td>+5.9%</td>
</tr>
<tr>
<td>0172 5851</td>
<td>0173 5852</td>
<td>CMHCs-Level I PHP (3 services)</td>
<td>$96.51</td>
<td>$100.17</td>
<td>+3.8%</td>
</tr>
<tr>
<td>0172 5851</td>
<td>0173 5852</td>
<td>CMHCs-Level II PHP (4 or more)</td>
<td>$114.23</td>
<td>$139.62</td>
<td>+22.2%</td>
</tr>
</tbody>
</table>

For CMHCs, for APCs 5851 and 5852, CMS will continue to make outlier payments for 50% of the amount by which the cost for the PHP service exceeds 3.4 times the payment rate.

- **Updates to the Inpatient-Only List (FR pages 39,299 – 39,300):** The inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2016, CMS is proposing to remove the following seven services from the inpatient-only list:
  - CPT code 0312T—Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming;
  - CPT code 20936—Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision;
  - CPT code 20937—Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision);
  - CPT code 20938—Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision);
  - CPT code 22552—Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophysectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace;
  - CPT code 54411—Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including the irrigation and debridement of infected tissue; and
  - CPT code 54417—Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative sessions, including irrigation and debridement of infected tissue;

The full list of inpatient-only procedures is available in Addendum E.

**Updates to the Hospital Outpatient Quality Reporting (OQR) Program**

*FR pages 39,325 – 39,340*

The OQR program is mandated by law; hospitals that do not successfully participate are subject to a 2.0 percentage point reduction to the OPPS marketbasket update for the applicable year. The required OQR measures for CY 2016 payment determinations were established in prior years’ rulemaking and the 27 required quality measures are listed in the final CY 2015 FR (page 66,944).

A table that lists the 25 measures CMS is currently collecting for the CY 2017 payment determinations is available on page 39,326 of the proposed rule *FR*.

The CY 2016 OPPS proposed rule establishes OQR program changes for CYs 2017, 2018, and 2019 payment determinations. The changes to the measures are as follows:

- Elimination of one chart-abstracted process measure:
  - OP-15—Use of Brain Computed Tomography (CT) in the ED for Atraumatic Headache. (**CY 2017**)
Addition of two new web-based measures:

- OP-33—External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (CY 2018); and
- OP-34—Emergency Department Transfer Communication (EDTC) (NQF #0291) (CY 2019).

**Two-Midnight Policy for Inpatient Stays**

*MFR pages 39,348 – 39,353*

CMS is using this OPPS proposed rule to update its proposal for IPPS related to the two-midnight rule. CMS is not proposing any changes to the two-midnight presumption – meaning hospital stays that are expected to be two midnights or longer will continue to be presumed appropriate for inpatient admission and will not be subject to medical necessity reviews. However, CMS acknowledges that certain procedures may have intrinsic risks, recovery impacts or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A, regardless of the length of hospital time the admitting physician expects a particular patient to require.

For stays expected to last less than two midnights – CMS proposes the following:

- Stays for which the physician expects the patient to need less than two midnights of hospital care (and the procedure is not on the inpatient only list or otherwise listed as a national exception), an inpatient admission would be payable under Medicare Part A on a case-by-case basis based on the judgment of the admitting physician. The documentation in the medical record must support that an inpatient admission is necessary, and is subject to medical review.
  - CMS reiterates that it would be rare and unusual for a beneficiary to require inpatient hospital admission for a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for a period of time that is only for a few hours and does not span at least overnight. CMS will monitor the number of these types of admissions and plans to prioritize these types of cases for medical review.

- In addition, CMS states that it plans to change the medical review strategy, and have QIO contractors be responsible for conducting reviews of short inpatient stays in place of the Medicare Audit Contractors (MACs), by October 1st, 2015. Under the QIO process, claim denials will be referred to the MACs, followed by the QIO providing education about the claims denied and collaborating with hospitals to improve organizational processes. Hospitals that consistently have high denial rates, fail to adhere to the 2-midnight rule, or fail to improve their performance after QIO educational intervention will then be referred to the RACs for further auditing.