# **Medicare Outpatient Prospective Payment System**

### Payment Rule Brief — Calendar Year 2017 Final Rule with Comment Period

#### Overview

The final calendar year (CY) 2017 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was published in the November 14, 2016 *Federal Register (FR)*. The final rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as adopted regulations that implement new policies, among other regular updates and policy changes. The final rule includes policies that will:

- Implement 28 new Comprehensive Ambulatory Payment Classifications (C-APCs) that bundle all payments for certain device-dependent procedures;
- Remove the "Pain Management" dimension from the FFY 2018 Hospital Value-Based Purchasing (VBP) program;
- Establish guidelines for payment to off-campus sites of a hospital providing outpatient services;
- Expand the list of services to be packaged into APCs as opposed to separately paid; and
- Update payment rates and policies for Ambulatory Surgical Centers (ASCs).

A copy of the Federal Register and other resources related to the OPPS are available on the Centers for Medicare and Medicaid Services (CMS) website at <a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending</a>. Comments related to this final rule with comment period are due to CMS by December 31 and can be submitted electronically at <a href="https://www.regulations.gov">https://www.regulations.gov</a> by using the website's search feature to search for file code "1656-FC". Comments are to be limited to the following:

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

An online version of the rule is available at <a href="https://federalregister.gov/a/2016-26515">https://federalregister.gov/a/2016-26515</a>. Page numbers noted in this summary are from the version of the final rule published in the *Federal Register*. A brief summary of the major hospital OPPS sections of the final rule is provided below.

#### **OPPS Payment Rate**

FR pages 79595 -79597, 79867 - 79871

The tables below show the adopted CY 2017 conversion factor compared to CY 2016 and the components of the update factor:

	Final	Final	Percent
	CY 2016 (CN)	CY 2017	Change
OPPS Conversion Factor	\$73.725	\$75.001 (proposed at \$74.909)	+1.73%

Final CY 2017 Update Factor Component	Value
Marketbasket (MB) Update	+2.7% (proposed at 2.8%)
Affordable Care Act (ACA)-Mandated Productivity MB Reduction	-0.3 percentage points (PPT) (proposed at -0.5 PPT)
ACA-Mandated Pre-Determined MB Reduction	-0.75 PPT
Wage Index BN Adjustment	-0.01%

Pass-through Spending BN Adjustment	-0.02%
Outlier BN Adjustment	+0.04%
Cancer Hospital BN Adjustment	+0.03%
BN Adjustment for Packaging of Unrelated	+0.04%
Laboratory Tests	+0.04%
Overall Final Rate Update	+1.73%

### **Adjustments to the Outpatient Rate and Payments**

Wage Indexes (FR pages 79597-79599): As in past years, for CY 2017 OPPS payments, CMS will use the federal
fiscal year (FFY) 2017 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 final year of the three-year hold-harmless 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 2017, CMS will continue to use a labor-related share of 60%.

- Payment Increase for Rural SCHs and EACHs (FR page 79601 79602): CMS will 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 79602 79604): CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals in a budget neutral manner. In order to maintain program budget neutrality, CMS has adopted a +0.03% adjustment to the CY 2017 conversion factor to account for this policy.
- Outlier Payments (FR pages 79604 79605): To maintain total outlier payments at 1.0% of total OPPS payments, CMS has adopted a CY 2017 outlier fixed-dollar threshold of \$3,825. This is an increase compared to the current threshold of \$3,250. 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.

## **Updates to the APC Groups and Weights**

FR pages 79574 - 79595, 79608 - 79678, 79731 - 79732

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 account for 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.

The adopted payment weights and rates for CY 2017 are available in Addenda A and B of the final rule at <a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.</a>

For CY 2017, CMS has adopted two new HCPCS status indicators to replace status indicator "E": "E1" to identify items and services not covered by Medicare, and "E2" to identify those items and services for which pricing/claims data is not available.

The table below shows the shift in the number of APCs per category from CY 2016 to CY 2017 (Addendum A):

APC Category	Status Indicator	Final CY 2016	Final CY 2017
Pass-Through Drugs and Biologicals	G	38	48
Pass-Through Devices Categories	Н	4	3

OPD Services Paid through a Comprehensive APC	J1	34	61
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	304	313
Partial Hospitalization	Р	4	2
Blood and Blood Products	R	37	36
Procedure or Service, No Multiple Reduction	S	78	77
Procedure or Service, Multiple Reduction Applies	Т	65	34
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	13	11
New Technology	S/T	104	110
Total		699	713

• **New Comprehensive APCs** (FR pages 79580 - 79587): In CY 2014, CMS began adopting a number of refinements to the APC assignments in an effort to create larger payment bundles. For CY 2017, CMS is continuing to create larger payment bundles by expanding its packaging policies and implementing new comprehensive APCs.

Comprehensive APCs (C-APCs) provide all-inclusive payments for certain procedures. A C-APC covers payment for all Part B services that are related to the primary 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 <u>are included</u> in the C-APCs.

The C-APCs do <u>not</u> 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 available in Addendum J to the proposed rule.

For CY 2017, CMS will add 28 new C-APCs, remove 1 C-APC (APC 5166 - Level 6 ENT Procedures), and renumber 3 other C-APCs; bringing the total to 62 C-APCs within 21 clinical families, as listed in Table 1 of the final rule (FR pages 79584 - 79585). The list of renumbered/new C-APCs are:

Adopted New CY 2017 C-APCs	Adopted New CY 2017 C-APC Descriptors	Clinical Families
5072	Level 2 Excision/ Biopsy/ Incision and Drainage	EBIDX
5073	Level 3 Excision/ Biopsy/ Incision and Drainage	EBIDX
5091	Level 1 Breast/Lymphatic Surgery and Related	BREAS
	Procedures Level 2 Breast/Lymphatic Surgery and Related	
5092	Procedures	BREAS
5094 <sup>1</sup>	Level 2 Breast/Lymphatic Surgery and Related	BREAS
	Procedures	5112710
5112	Level 2 Musculoskeletal Procedures	ORTHO
5113 <sup>2</sup>	Level 3 Musculoskeletal Procedures	ORTHO
5114 <sup>2</sup>	Level 4 Musculoskeletal Procedures	ORTHO
5115²	Level 5 Musculoskeletal Procedures	ORTHO
5116¹	Level 6 Musculoskeletal Procedures	ORTHO
5153	Level 3 Airway Endoscopy	AENDO
5154	Level 4 Airway Endoscopy	AENDO
5155	Level 5 Airway Endoscopy	AENDO
5164	Level 4 ENT Procedures	ENTXX
5166³	Cochlear Implant Procedure	COCHL
5194 <sup>1</sup>	Level 4 Endovascular Procedures	VASCX

5200	Implantation Wireless PA Pressure Monitor	WPMXX
5244	Level 4 Blood Product Exchange and Related Services	SCTXX
5302	Level 2 Upper GI Procedures	GIXXX
5303	Level 3 Upper GI Procedures	GIXXX
5313	Level 3 Lower GI Procedures	GIXXX
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5373	Level 3 Urology & Related Services	UROXX
5374	Level 4 Urology & Related Services	UROXX
5414	Level 4 Gynecologic Procedures	GYNXX
5431	Level 1 Nerve Procedures	NERVE
5432	Level 2 Nerve Procedures	NERVE
5491	Level 1 Intraocular Procedures	INEYE
5495 <sup>1</sup>	Level 5 Intraocular Procedures	INEYE
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE

<sup>&</sup>lt;sup>1</sup> Newly Adopted C-APC for CY 2017 not identified by CMS in the Final Rule

Additionally, CMS discontinued the requirement that an add-on code combination also not create a violation of the 2 times rule in the higher level or receiving APC as the rule would not typically apply to complexity-adjusted combinations.

- Composite APCs (FR pages 79587 79592): 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 seven composite APCs for:
  - Low-Dose Rate (LDR) Prostate Brachytherapy (APC 8001);
  - o Mental Health Services (APC 8010); and
  - o Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008).

For CY 2017, CMS will continue its current composite APC payment policies. Table 3 on pages 79590 – 79592 of the *FR* shows the HCPCS codes belonging to the adopted OPPS imaging families and multiple imaging procedure Composite APCs.

- **Packaged Services** (FR pages 79592 79595): For CY 2017, CMS is continuing its efforts to create more complete APC payment bundles by expanding 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. For CY 2017, CMS will align the packaging logic for all conditional packaging status indicators, and to change the logic for status indicators "Q1" and "Q2" so that packaging would occur at the claim level, instead of based on date of service, to ensure that items and services are packaged appropriately for OPPS claims spanning multiple days. A list of HCPCS codes that will be conditionally packaged are displayed in Addendum B of the final rule.
  - Clinical Diagnostic Laboratory Tests— CMS is discontinuing the unrelated laboratory test exception ("L1" modifier) as it believes that these tests are not significantly different than packaged laboratory tests, and that hospitals are often unable to determine when to apply the "L1" modifier to a claim. As a result, CMS will package all laboratory tests appearing on a claim with other hospital outpatient services.

CMS is also expanding the laboratory packaging exemption applicable to molecular pathology tests to also apply to all advanced diagnostic laboratory tests (ADLTs) that meet certain criteria as these may have different patterns of clinical use than more conventional laboratory tests. CMS will assign status indicator "A" to ADLTs as a result of this change.

Payment for Medical Devices with Pass-Through Status (FR pages 79648 – 79657):

<sup>&</sup>lt;sup>2</sup> C-APC Renumbered for CY 2017 compared to CY 2016 Final Rule

<sup>&</sup>lt;sup>3</sup> Newly Adopted C-APC for CY 2017 that replaces existing C-APC

- Pass-Through Payment Status Eligibility— CMS will remove HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) from the list of medical devices currently provided pass-through payment status on December 31, 2016. As a result, the costs of these devices will be packaged into the costs related to the procedures with which HCPCS code C2624 is reported. The HCPCS codes for devices still on the pass-through payment list are:
  - C1822 Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system;
  - C2613 Lung biopsy plug with delivery system; and
  - C2623 Catheter, transluminal angioplasty, drug-coated, non-laser.

CMS is also changing the start date of the period for which a device is eligible for pass-through payments to align with the first date on which pass-through payment is made, rather than when pass-through status was established. Additionally, CMS will increase the pass-through payment periods for devices to three years, from two, and to also have these periods expire on a quarterly basis to correspond with CMS' current quarterly pass-through status application policy.

- Pass-Through Payment Provisions— Currently, medical device pass-through payments are
  determined using average, hospital-wide cost-to-charge ratios (CCRs). For CY 2017, CMS will instead
  use the more specific "Implantable Devices Charged to Patients" CCR to determine device passthrough payments in order to provide more accurate payments, and to help mitigate charge
  compression. For hospitals where that CCR is unavailable, CMS will continue using the hospital-wide
  average CCR.
  - CMS also adopted for 2017, that for each device-intensive procedure payment the portion of the Medicare OPD fee schedule amount to be deducted from pass-through payment will be calculated to reflect the cost of an associated pass-through device at the HCPCS level, rather than APC.
- **Device-Intensive Procedures** (FR pages 79657 79659): CMS defines device-intensive APCs as those procedures which require the implantation of a device, and are assigned to an APC with a device offset of more than 40%. For CY 2017, CMS is changing the requirements for this status such that a procedure must have an individual HCPCS code-level device offset of more than 40%, regardless of APC assignment. CMS no longer believes that device-intensive status should be based on an APC assignment as APC groupings are based on clinically similar procedures, which does not necessarily factor into similarity of device costs.

Additionally, for new HCPCS codes describing device implantation procedures that do not yet have associated claims data, CMS will apply a device offset of 41% until claims data are available to establish an offset for the procedure.

Regarding the effect that this change has on the device edit policy, for CY 2017 and subsequent years, CMS will apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. In addition, any device code would satisfy this edit, when it is reported on a claim with a device-intensive procedure. CMS has created HCPCS code C1889 to recognize those devices provided during a device intensive procedure that are not descripted by a specific Level II HCPCS Category C-code. Reporting of this code with a device intensive procedure will also satisfy the edit requirement.

Payment Adjustment for No Cost/Full Credit and Partial Credit Devices (FR pages 79659 – 79660): 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 2017, CMS is continuing to reduce OPPS payment, for device-intensive procedures, by the full or partial credit that a provider receives for a replaced device. CMS will also determine the procedures to which this policy would apply using three criteria:

- 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 (even if temporarily); and
- The procedure must be device-intensive (defined as devices exceeding 40% of the procedure's average cost).
- Payment Policy for Low-Volume Device-Intensive Procedures (FR page 79660 79661): CMS has adopted a
  payment policy for low-volume device-intensive procedures with this final rule. Under this policy, for any
  device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the
  APC, the payment rate for that procedure will be calculated using the median cost, instead of the geometric
  mean cost, as the median is less impacted by cost outliers. For CY 2017, the only procedure to which this
  policy would apply is CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline
  lens or intraocular lens prosthesis), which is currently assigned to APC 5495.
- Payment for Drugs, Biologicals and Radiopharmaceuticals (FR pages 79661 79676): CMS pays for drugs and biologicals that <u>do not</u> 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 the packaging threshold.

For CY 2017, CMS adopted a packaging threshold of \$110. Drugs, biologicals and radiopharmaceuticals that are above the \$110 threshold are paid separately using individual APCs; the final payment rate for CY 2017 is the average sales price (ASP) + 6%.

Beginning with pass-through drugs and biologicals newly approved in CY 2017, CMS will allow for a quarterly expiration of pass-through payment status in order to grant a pass-through period as close to a full three years as possible, and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

Finally, CMS will allow pass-through status to expire on December 31, 2016 for 15 drugs and biologicals, listed in Table 35 of the *FR*; and will provide pass-through status for 47 others, shown in Table 36 of the *FR*, as of January 1, 2017.

#### **Other OPPS Policies**

Partial Hospitalization Program (PHP) Services (FR pages 79678 – 79695): 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.

Beginning with CY 2017, CMS is combining the existing two-tiered PHP APCs into a single APC for each setting. Payments for the new APCs will be calculated by combining the geometric mean per diem costs for existing Level 1 and Level 2 PHP APCs into a single value for the new, aggregated APCs. CMS states that these newly combined APCs will avoid further cost inversion issues (Level 1 geometric mean per diem cost greater than that of Level 2), and would thus generate more appropriate payment for the services provided. Another reason behind the aggregation is the decrease in the number of PHPs, particularly CMHCs, as in a smaller pool of providers, data from the large providers would have a more pronounced effect on the calculated payment rates; and is magnified further by splitting services into separate levels of APCs.

The table below compares the final CY 2016 and final CY 2017 PHP payment rates:

		Rate	% Change (2017)
Final CY 2017	APC 5853: Partial Hospitalization (3+ services) for CMHCs	\$121.48	-
Final	APC 5851: Level 1 Partial Hospitalization (3 services) for CMHCs	\$94.49	+28.6%

CY 2016	APC 5852: Level 2 Partial Hospitalization (4+ services) for CMHCs	\$143.00	-15.0%
Final	APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	\$207.27	_
CY 2017 Final	APC 5861: Level 1 Partial Hospitalization (3 services) for Hospital-based PHPs	\$183.41	+13.0%
CY 2016	APC 5862: Level 2 Partial Hospitalization (4+ services) for Hospital-based PHPs	\$212.67	-2.5%

For CMHCs, 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 highest CMHC PHP APC payment rate implemented for that calendar year.

Finally, CMS stated that it is concerned by the low frequency of individual therapy, and will continue monitoring for it. CMS believes that appropriate PHP treatment includes some individual therapy and encourages providers to ensure that patients are receiving all of the services that they may need.

- Updates to the Inpatient-Only List (FR pages 79695 79699): The inpatient list specifies services/procedures that
  Medicare will only pay for when provided in an inpatient setting. For CY 2017, CMS is removing the following
  seven services from the inpatient-only list:
  - CPT code 22585—Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy, and decompression of spinal cord and/or nerve roots; each additional interspace (List separately in addition to code for primary procedure);
  - CPT code 22840—Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure);
  - CPT code 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 code 22845—Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure);
  - CPT code 22858—Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure);
  - o CPT code 31584—Laryngoplasty; with open reduction of fracture; and
  - o CPT code 31587—Laryngoplasty, cricoid split.

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

In addition, CMS sought public comment on the possible future removal of Total knee arthroplasty (TKA) (CPT code 27447) from the Inpatient Only list. Specifically, CMS was looking for stakeholder input on how to reflect the shift of some Medicare beneficiaries from inpatient TKA to outpatient TKA regarding the Bundled Payments for Care Improvement Initiative (BPCI) and Comprehensive Care for Joint Replacement (CJR) methodologies. These comments are published on pages 79697 – 79699 of the FR.

- Payment for Off-Campus Outpatient Departments (FR pages 79699 79729): The Bipartisan Budget Act of 2015 restricted OPPS payments for services provided by certain off-campus outpatient departments (OPDs) of providers on or after January 1, 2017. Covered OPD services provided in these off-campus OPDs prior to November 2, 2015 would continue to be paid under OPPS, while those added after that date would be paid under the Medicare Physician Fee Schedule (MPFS). Please note that CMS uses the word "excepted" in reference to those off-campus sites that will be allowed to continue to bill under OPPS, here we instead use "exempt." Please be aware that CMS did not adopt the proposal to limit exempt services to those provided at the site on or before November 2, 2015:
  - All exempt off-campus provider-based departments (PBDs) will continue to bill for exempt services under the OPPS. These include those furnished in a dedicated emergency department (ED), in an oncampus PBD, or within 250 yards from a remote location of a hospital facility.
  - CMS adopted an adjusted form of its proposal that an off-campus PBD would lose its exempt status if it changes location. Instead, exempt off-campus PBDs will be allowed to relocate (temporarily or

permanently), without loss of exemption status, in the rare event of extraordinary circumstances outside of the hospital's control, such as natural disasters, seismic building code requirements, or significant public health and safety issues. Relocation requests will be evaluated by the CMS Regional Offices and either approved or denied. CMS adopted its proposal that exempt status would also be lost if ownership of the off-campus PBD changes, unless the new owner also acquires the main hospital and adopts the existing Medicare provider agreement.

o The MPFS will be the "applicable payment system" for the majority of nonexempt items and services furnished in an off-campus PBD. This payment policy would result in a 1-year transitional period while CMS explores operational changes that would allow an off-campus PBD to bill Medicare for its services under a Part B system other than the OPPS beginning in CY 2018.

In the proposed rule, CMS also sought comment for CY 2018 on regulatory and operational changes that could be made to allow an off-campus PBD to bill and be paid for services under the MPFS; CMS' responses to these comments may be found on pages 79718 - 79729 of the FR. As a result of comments received, CMS is attempting to establish a way for hospitals to report and receive payment under the MPFS for services furnished at nonexempt off-campus PBDs.

- O Payment Rates under the MPFS for Nonexempt PBDs (FR pages 79720 79729): CMS is establishing interim final site-specific rates under the MPFS for the technical component of services provided at nonexempt PBDs. These services will be paid under the MPFS at these newly established rates, which will continue to be billed on the institutional claim, to be passed through the Outpatient Code Editor into the OPPS PRICER, and will require the new claim line modifier "PN" which will flag the service as nonexempt. For CY 2017, the payment rate for these services will generally be set at 50% of the OPPS rate, with some exceptions:
  - Items and services assigned status indicator "A" will continue to be reported on an institutional claim and paid under the MPFS, Clinical Laboratory Fee Schedule (CLFS), or the Ambulance Fee Schedule, as appropriate, will not receive reduced payments.
  - Drugs and biologicals that are separately payable under the OPPS (status indicators "G" and "K") will continue to be paid at ASP +6%. Those that are always packaged (status indicator "N") will be bundled into the MPFS payment, and will not be paid separately.
  - CMS stated that additional exceptions were to be found in Table X.B.2 of the Federal
    Register. However, this table is not included in the current version of the final rule and it
    is expected to be published with a correction notice in the future.

Exclusively for services provided in these nonexempt PBDs, CMS is establishing new geographic practice cost indices (GPCIs) under the MPFS that will be used to adjust payments to hospitals. The wage areas and values of these new GPCIs will, for CY 2017, be identical to those used under the OPPS. In addition, CMS is adopting the same packaging payment rates and multiple procedure payment reduction (MPPR) percentage as are applicable under the OPPS. However, CMS is not adopting several payment adjustments for use with this program. Those adjustments include, but are not limited to: outlier payments, rural SCH adjustments, cancer hospital adjustments, transitional outpatient payments, OQR reductions, and the inpatient hospital cap on deductibles for single hospital outpatient services.

For partial hospital services, CMS will pay nonexempt PBDs based on the CMHC per diem rate.

CMS is seeking public comments on the new payment mechanisms and rates detailed in this rule and will make adjustments as necessary to the payment mechanisms and rates that could be effective for CY 2017.

Changes for Payment for Film X-Ray (FR page 79729 – 79730): For CY 2017 and subsequent years, due to the
Consolidated Appropriations Act of 2016, CMS will reduce OPPS payment for imaging services utilizing filmbased X-rays (including the X-ray component of a packaged service) by 20%. This reduction is not budget
neutral. CMS has established a new modifier ("FX") to be required on claims for imaging services for X-rays
taken using film, the use of which would result in the 20% payment reduction for the service.

The Consolidated Appropriations Act of 2016 also stipulates that OPPS payments for X-ray services taken using computed radiography (including the X-ray component of a packaged service) be reduced by 7% for the years CY 2018 through CY 2022, and by 10% for CY 2023 and subsequent years. CMS will address this separate payment reduction in future rulemaking.

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

FR pages 79753 - 79797

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 2017 payment determinations were established in prior years' rulemaking and the 25 required quality measures are listed in the final CY 2016 FR (page 70,505).

A table that lists the 26 measures CMS is currently collecting for the CY 2018 payment determinations is available in the final CY 2016 FR (page 70,510), while the 26 measures to be collected for CY 2019 payment determinations are available on pages 79754 – 79755 of this final rule FR.

The CY 2017 OPPS final rule establishes OQR program changes for CY 2020 payment determinations. The changes to the measures are as follows:

Addition of two claims-based measures:

- OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

Addition of five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures:

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

A table listing the 33 measures CMS is collecting for CY 2020 payment determinations is available on page 79784 of the final rule FR.

## **Organ Transplants**

• Transplant Outcomes (FR pages 79826–79830): The Scientific Registry of Transplant Recipients (SRTR) is a registry required by the 1984 National Organ and Transplantation Act (NOTA) that supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation. The SRTR contains data on current and past information about transplant activity, transplant recipients, and survival statistics.

In 2007, CMS issued a final rule setting out Conditions of Participation (CoPs) for solid organ transplant programs. The regulations specified that a transplant program would not be in compliance with the COPs for patient and graft survival if three thresholds were all crossed:

- o If patient deaths or graft failures were 1.5 times the risk-adjusted expected number ((O/E ratio exceeded 1.5);
- o The results were statistically significant (p<.05); and
- o The results were numerically meaningful (that is, the number of observed events minus the expected number is greater than 3).

Because CMS' outcome 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. Therefore, CMS has adopted a

change the tolerance limit for patient and graft survival from 1.5 to 1.85 in an attempt to balance their dual goals of improved beneficiary outcomes and increased beneficiary access.

- Organ Procurement Organizations (OPOs) (FR pages 79830-79835): CMS adopted the following changes to OPOs:
  - Change the definition of "eligible death" to include donors up to the age of 75 (from 70) and replace the automatic exclusion of potential donors with multi-system organ failure with the clinical criteria that specify the suitability for procurement;
  - Change the definition of the aggregate donor yield metric to that used by the OPTN/SRTR, a
    more accurate measure for organ yield performance and accounts for differences between
    donor case-mixes across areas; and
  - No longer require donor information documentation be transported to the transplant center together with an organ. Blood type source documentation and infectious disease testing results must be physically sent with the organ.
- Noncompliance Enforcement Provisions (FR pages 79835 79836): CMS will extend the due date for
  programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar
  days, to clarify that the time period for submission of the mitigating factors information is calculated in
  calendar days, and to explain that CMS' has discretion regarding Systems Improvement Agreements.

### **Medicare and Medicaid EHR Incentive Programs**

FR pages 79836- 79855

In order to advance certified EHR technology utilization, CMS has finalized policies to:

- Eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry objectives and measures for eligible hospitals and CAHs attesting under the Medicaid and Medicare EHR Incentive Programs for Modified Stage 2 and Stage 3 for 2017 and subsequent years;
- Reduce 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;
  - These changes do not apply to eligible hospitals and CAHs that attest to meaningful use under their State's Medicaid EHR Incentive Program.
  - o The Modified Stage 2 Objective and Measure requirements for 2017 may be found on page 79841 of the *FR*, while the Stage 3 Objective and Measure requirements for 2017 and 2018 may be found on page 79850 of the *FR*.
- Change the EHR reporting period in 2016 for all returning eligible professionals (EPs), eligible hospitals and CAHs that have previously demonstrated meaningful use in the Medicare and Medicaid EHR Incentive Programs. Instead of the prior requirement that participants report EHR compliance for a full calendar year, CMS will now only require that reporting be for any continuous 90-day period between January 1 and December 31;
- Require EPs, eligible hospitals, and CAHs not successfully demonstrating meaningful use in a prior year to attest to the Modified Stage 2 objectives and measures by October 1, 2017 in order to avoid the 2018 payment adjustment must;
- Implement 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; and
- Change the measure calculation policy whereby for all meaningful use measures, unless otherwise specified, 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.

## **Inpatient Hospital Value-Based Purchasing (VBP)**

FR pages 79855-79862

Due to stakeholder concerns over the pressure that the HCAHPS Pain Management dimension places on hospital staff to prescribe more opioids in order to attain a higher score, and potential confusion about the appropriate use of the measure, CMS will remove the HCAHPS Pain Management survey dimension from the Inpatient Hospital

Value-Based Purchasing program for FFY 2018 and subsequent years. As this removal reduces the number of measures in the FFY 2018 Patient- and Caregiver-Centered Experience of Care/Care Coordination domain from 9 to 8, CMS will assign each measure 10 points which, in addition to the available 20 HCAHPS Consistency Points, would allow for a hospital's HCAHPS score to range from 0 to 100 points, similar to the program's earlier years.

CMS states that when modified Pain Management questions for the HCAHPS Survey become available, it intends to adopt them for use in the Hospital VBP Program in future rulemaking.

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