

Medicare Outpatient Prospective Payment System Proposed Rule Impact Analysis – Calendar Year 2017

-Version 1, July 2016-

Analysis Description

The calendar year (CY) 2017 Medicare Outpatient Prospective Payment System (OPPS) Proposed Rule Analysis is intended to show providers how Medicare outpatient fee-for-service (FFS) payments will change from CY 2016 to CY 2017 based on the policies set forth in the CY 2017 OPPS proposed rule. The analysis incorporates changes to outpatient payments mandated by Congress and implemented by the Centers for Medicare and Medicaid Services (CMS).

Proposed Rule Impact Analysis

The following changes are modeled in this analysis:

- Marketbasket Update: 2.8% marketbasket increase plus 0.01% due to other budget neutrality (BN) adjustments.
- ACA-Mandated Marketbasket Reductions: Combined 0.5 percentage point productivity reduction and 0.75 percentage point pre-determined reduction to the marketbasket authorized by the Affordable Care Act (ACA) of 2010.
- Pass-through Spending BN Adjustment: CMS' estimate of proposed pass-through spending for drugs, biologicals, and devices for CY 2017 is approximately \$148.3 million, which represents 0.24% of total projected CY 2017 OPPS spending. The rate is adjusted by the difference between the 0.26% estimate of pass-through spending for CY 2016 and the 0.24% estimate of proposed pass-through spending for CY 2017, resulting in a proposed adjustment for CY 2017 of -0.02%.
- Outlier BN Adjustment: Estimated proposed payments for outliers equal 1.0% of total OPPS payments for CY 2017. CMS estimates that outlier payments will be 0.96% of total OPPS payments in CY 2016; the 1.0% for proposed CY 2017 outlier payments would result in a 0.04% increase in payment in CY 2017.
- BN Adjustment for Packaging of Unrelated Laboratory Tests: CMS is proposing to apply a budget neutrality increase of 0.03% to the rate to account for its proposal to package unrelated laboratory tests into OPPS payment.
- Wage Index: Updated wage index values based on the Federal Fiscal Year (FFY) 2017 hospital wage index, including the impact of new wage data; reclassifications; rural and legislated floors, and other adjustments to the wage indexes.
- APC Factor/Updates: This impact represents the changes to the APC assignments and weights proposed for CY 2017. It is inclusive of CMS' policies regarding the creation of comprehensive APCs. The APC Factor is also inclusive of CMS' expansion of the categories of items/services that are packaged into APCs for payment as opposed to separately paid. The anticipated change in outlier payments is also included in this line. This impact is derived by attributing all remaining payment changes to this category (after impact for wage index, marketbasket, etc.).

The impacts provided do not include the 2.0% sequestration reduction to all lines of Medicare payment authorized by Congress and currently in effect through FFY 2025 unless Congress intervenes. The impact of sequester applicable to OPPS-specific payment has been calculated separately and is provided at the bottom of the impact table.

Data Sources

Hospital characteristics, outpatient procedure volumes, and estimated 2016 and 2017 outpatient revenues are from the CMS CY 2017 OPPS proposed rule Impact File (CY 2015 outpatient claims data). OPPS conversion factors are from the CY 2016 final rule and the CY 2017 proposed rule, as published in the *Federal Register*. Wage indexes are based on the wage index tables from the federal fiscal year (FFY) 2016 Inpatient Prospective Payment Systems (IPPS) final rule correction notice (released December 2015) and the FFY 2017 IPPS proposed rule. This analysis was developed to measure the impact of OPPS policy changes only. Hospitals' rural status, volume, and patient mix are held constant at the value published in the CY 2017 Impact File.

Methods

The dollar impact of each component change has been calculated starting with estimated 2016 outpatient payments as provided by CMS in its CY 2017 OPPS proposed rule Impact File. Estimated 2016 outpatient payments include outliers and the rural Sole Community Hospital (SCH) add-on, where appropriate.

The CY 2016 to CY 2017 percent change, for each outpatient payment change component analyzed, is calculated and applied to estimated CY 2016 payments. The percentage impacts are applied sequentially in order to capture the compounded dollar impacts. For example, the percent change due to the marketbasket update is applied to total CY 2016 payments. Then, the percent change in the ACA-mandated marketbasket reductions is applied to the dollar result of the first change. This method continues for the remaining changes, creating a compounded effect. The difference between the results after each layered component is the impact of that component.

Based on the limitations of CMS' Impact File, an "APC Factor/Updates" adjustment factor is calculated and used to estimate the value of payment changes that cannot be broken out by individual component. This hospital-specific factor/impact is derived by dividing total payments by the wage index and SCH add-on-adjusted conversion factor. The result of the first calculation is divided by the Medicare APC count provided in the OPPS proposed rule Impact File. This factor impact represents the impact of changes to the APC assignments and weights and the outlier threshold.

Note: Individual percentages and dollars shown in this analysis may not add to total due to compounding and rounding. Dollar amounts less than \$50 and percentages less than 0.05% will appear as zeros due to rounding.

This analysis does not include payment estimates for services provided to Medicare Advantage patients or modifications in FFS payments as a result of provider participation in new payment models being tested under Medicare demonstration/pilot programs. Dollar impacts in this analysis may differ from those provided by other organizations/associations due to differences in source data and analytic methods.

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Medicare Outpatient Prospective Payment System

Payment Rule Brief — Calendar Year 2017 Proposed Rule

Overview

The proposed calendar year (CY) 2017 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was published in the July 14, 2016 *Federal Register* (FR). 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, among other regular updates and policy changes. The proposed rule includes policies that would:

- Implement 25 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 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 <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>. Comments on all aspects of the proposed rule are due to CMS by September 6 and can be submitted electronically at <http://www.regulations.gov> by using the website’s search feature to search for file code “1656-P”.

An online version of the rule is available at <https://federalregister.gov/a/2016-16098>. 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 45,630 – 45,631

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

	Final CY 2016 (CN)	Proposed CY 2017	Percent Change
OPPS Conversion Factor	\$73.725	\$74.909	+1.61%
Proposed CY 2017 Update Factor Component		Value	
Marketbasket (MB) Update		+2.8%	
Affordable Care Act (ACA)-Mandated Productivity MB Reduction		-0.5 percentage points (PPT)	
ACA-Mandated Pre-Determined MB Reduction		-0.75 PPT	
Pass-through Spending BN Adjustment		-0.02%	
Outlier BN Adjustment		+0.04%	
BN Adjustment for Packaging of Unrelated Laboratory Tests		+0.03%	
Overall Proposed Rate Update		+1.61%	

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes** (*FR pages 45,631 – 45,633*): As in past years, for CY 2017 OPPS payments, CMS is proposing to 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 3-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 is proposing to continue to use a labor-related share of 60%.

- **Payment Increase for Rural SCHs and EACHs (FR page 45,635):** CMS proposes 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 45,635 – 45,637):** CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals in a budget neutral manner. The proposed increase for CY 2017 was such that CMS has proposed no budget neutrality change to the CY 2017 conversion factor to account for this policy.
- **Outlier Payments (FR pages 45,637 – 45,638):** To maintain total outlier payments at 1.0% of total OPPS payments, CMS has proposed 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 45,615 – 45,630, 45,641 – 45,648, and 45,692

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

For CY 2017, CMS is proposing 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	Proposed CY 2017
Pass-Through Drugs and Biologicals	G	38	38
Pass-Through Devices Categories	H	4	3
OPD Services Paid through a Comprehensive APC	J1	34	61
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	304	297
Partial Hospitalization	P	4	2
Blood and Blood Products	R	37	36
Procedure or Service, No Multiple Reduction	S	78	64
Procedure or Service, Multiple Reduction Applies	T	65	34
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	13	11
New Technology	S/T	104	110
Total		699	674

- **New Comprehensive APCs (FR pages 45,618 – 45,623):** 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 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 available in Addendum J to the proposed rule.

For CY 2017, CMS proposes to 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 2 of the proposed rule (FR pages 45,621 – 45,622). The list of renumbered/new C-APCs are:

Proposed New CY 2017 C-APCs	Proposed 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 Procedures	BREAS
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS
5094 ¹	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS
5112	Level 2 Musculoskeletal Procedures	ORTHO
5113 ²	Level 3 Musculoskeletal Procedures	ORTHO
5114 ²	Level 4 Musculoskeletal Procedures	ORTHO
5115 ²	Level 5 Musculoskeletal Procedures	ORTHO
5112 ¹	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
5166 ³	Cochlear Implant Procedure	COCHL
5194 ¹	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 ¹	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

¹ Newly Proposed C-APC for CY 2017 not identified by CMS in the Proposed Rule

² C-APC Renumbered for CY 2017 compared to CY 2016 Final Rule

³ Newly Proposed C-APC for CY 2017 that replaces existing C-APC

Additionally, CMS is proposing to discontinue 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 45,623 – 45,627):** 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);
- Mental Health Services (APC 8010); and
- Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008).

For CY 2017, CMS is proposing to continue its current composite APC payment policies. Table 3 on pages 45,625 – 45,627 of the FR shows the HCPCS codes belonging to proposed OPSS imaging families and multiple imaging procedure Composite APCs.

- **Packaged Services (FR pages 45,627 – 45,629):** 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 proposes to 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 OPSS claims spanning multiple days. A list of HCPCS codes that are proposed to be conditionally packaged are displayed in Addendum B of the proposed rule.
- Clinical Diagnostic Laboratory Tests— CMS is proposing to discontinue 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 is proposing to package all laboratory tests appearing on a claim with other hospital outpatient services.

CMS is also proposing to expand 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 proposal.

- **Payment for Medical Devices with Pass-Through Status (FR pages 45,648 – 45,654):**

- Pass-Through Payment Status Eligibility— CMS is proposing to 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 proposing to change 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 is also proposing to increase pass-through payment periods for devices to 3 years, from 2, 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 is proposing to instead use the more specific “Implantable Devices Charged to Patients” CCR to determine device pass-through payments in order to provide more accurate payments, and to help mitigate charge compression. For hospitals where that CCR is unavailable, CMS proposes to continue using the hospital-wide average CCR.

CMS is also proposing 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 45,654 – 45,655):** 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 proposing to change 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 is proposing to 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, CMS is proposing, for CY 2017 and subsequent years, to 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.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices (FR pages 45,655 – 45,656):** 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 proposing to continue reducing OPPS payment, for device-intensive procedures, by the full or partial credit that a provider receives for a replaced device. CMS is also proposing to 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.
- **Payment Policy for Low-Volume Device-Intensive Procedures (FR page 45,656):** CMS is proposing a payment policy for low-volume device-intensive procedures. 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 45,657 – 45,665):** 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 the packaging threshold.

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

CMS is proposing, beginning with pass-through drugs and biologicals newly approved in CY 2017, to 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 is proposing to allow pass-through status to expire for 15 drugs and biologicals, listed in Table 13 of the *FR*; and is continuing pass-through status for 38 others, shown in Table 14 of the *FR*.

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services (FR pages 45,667 – 45,678):** 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 proposing to combine the existing two-tiered PHP APCs into a single APC for each setting. Payments for the new APCs would 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 would 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 proposed CY 2017 PHP payment rates:

		Payment Rate	% Change (2017)
Proposed CY 2017	APC 5853: Partial Hospitalization (3+ services) for CMHCs	\$129.45	-
Final CY 2016	APC 5851: Level 1 Partial Hospitalization (3 services) for CMHCs	\$94.49	+37.0%
	APC 5852: Level 2 Partial Hospitalization (4+ services) for CMHCs	\$143.00	-9.5%
Proposed CY 2017	APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	\$184.25	-
Final CY 2016	APC 5861: Level 1 Partial Hospitalization (3 services) for Hospital-based PHPs	\$183.41	+0.5%
	APC 5862: Level 2 Partial Hospitalization (4+ services) for Hospital-based PHPs	\$212.67	-13.4%

For CMHCs, CMS proposes to 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 states 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 45,678 – 45,681):** The inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2017, CMS is proposing to remove the following six services from the inpatient-only list:

- 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 osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure);
- CPT code 31584—Laryngoplasty; with open reduction of fracture; and
- CPT code 31587—Laryngoplasty, cricoid split.

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

In addition, CMS is seeking public comment on the possible future removal of Total knee arthroplasty (TKA) (CPT code 27447) from the Inpatient Only list. Specifically, CMS is seeking comment 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.

- **Payment for Off-Campus Outpatient Departments (FR pages 45,681 – 45,691):** 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). CMS has issued a number of proposals regarding this, 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 use “exempt”:
 - All exempt off-campus provider-based departments (PBDs) would continue to bill for exempt services under the OPPS. These include those furnished in a dedicated emergency department (ED), in an on-campus PBD, or within 250 yards from a remote location of a hospital facility. Exempt services include those covered OPD services furnished by the PBD prior to November 2, 2015, and all those within the same clinical family of services. The proposed clinical families of service are presented in Table 21 on page 45,685 – 45,686 of the proposed rule.
 - Services furnished in a new off-campus PBD, established after November 2, 2015, or new lines of service (beyond those within the same clinical families) provided in an existing exempt off-campus PBD after this date would instead bill under the MPFS. CMS is also proposing that an off-campus PBD will lose its exempt status if it changes location. 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.
 - The MPFS will be the “applicable payment system” for the majority of nonexempt items and services furnished in an off-campus PBD. This payment proposal would be a 1-year transitional policy 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.

CMS is seeking 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 an applicable payment system. CMS is also seeking comment on whether a clearly defined, limited relocation exception process should be developed in cases of disaster or extraordinary circumstances.

- **Changes for Payment for Film X-Ray (FR page 45,691):** For CY 2017 and subsequent years, due to the Consolidated Appropriations Act of 2016, CMS is proposing to reduce OPPS payment for imaging services utilizing film-based X-rays (including the X-ray component of a packaged service) by 20%. This reduction is not budget neutral. CMS is proposing to establish a new modifier 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 45,709 – 45,727

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).

The CY 2017 OPPS proposed 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 45,720 of the proposed rule *FR*.

Organ Transplants

- **Transplant Outcomes** (*FR pages 45,740 – 45,743*): 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:

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

If all three thresholds were crossed over in a single SRTR report, the program was determined to not be in compliance with the CMS standard.

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 is proposing to

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** (*FR pages 45,743 – 45,744*): CMS is proposing 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 certain 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 45,744 – 45,745*): CMS is proposing 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, 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 45,745 – 45,755

In order to advance certified EHR technology utilization, CMS is proposing to:

- Eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program for Modified Stage 2 and Stage 3;
- 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 proposed changes would not apply to eligible hospitals and CAHs that attest to meaningful use under their State’s Medicaid EHR Incentive Program.
- 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;
- Require 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 to attest to the Modified Stage 2 objectives and measures by October 1, 2017;
- 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 45,755 – 45,757

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 is proposing to remove the HCAHPS Pain Management survey dimension from the Inpatient Hospital Value-Based Purchasing program for FFY 2018 and subsequent years. As this removal would reduce the number of measures in the FFY 2018 Patient- and Caregiver-Centered Experience of Care/Care Coordination domain from 9 to 8, CMS proposes to 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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