Medicare Outpatient Prospective Payment System

Payment Rule Brief — Calendar Year 2019 Proposed Rule with Comment Period

Overview

The proposed calendar year (CY) 2019 payment rule for the Medicare Outpatient Prospective Payment System (OPPS) was released on July 25, 2018. The proposed rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as regulations that implement new policies. The proposed rule includes policies that will:

- Change the rate for biosimilars purchased by hospitals through the 340B program;
- Change the inpatient only list;
- Make payment changes for excepted and non-excepted services furnished in off-campus provider-based departments;
- Extend the 340B drug payment adjustment (ASP – 22.5%) to non-excepted PBDs;
- Change exceptions to 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-1695-P.html. Comments related are due to CMS by September 24, 2018 and can be submitted electronically at http://www.regulations.gov by using the website's search feature to search for file code "1695-P".

An online version of the rule is available at https://www.federalregister.gov/d/2018-15958. Page numbers noted in this summary are from the *Federal Register* (FR) version of the proposed rule. A brief summary of the major hospital OPPS sections of the proposed rule is provided below.

OPPS Payment Rate

FR pages 37,072 – 37,073

The tables below show the proposed CY 2019 conversion factor compared to CY 2018 and the components of the update factor:

	Final CY 2018	Proposed CY 2019	Percent Change
OPPS Conversion Factor	$78.636	$79.546	+1.16%

Proposed CY 2019 Update Factor Component	Value
Marketbasket (MB) Update	+2.80%
Affordable Care Act (ACA)-Mandated Productivity MB Reduction	-0.8 percentage points (PPT)
ACA-Mandated Pre-Determined MB Reduction	-0.75 PPT
Wage Index BN Adjustment	+0.04%
Pass-through Spending / Outlier BN Adjustment	-0.13%
Cancer Hospital BN Adjustment	+0.00%
Overall Proposed Rate Update	**+1.16%**

Adjustments to the Outpatient Rate and Payments

- **Wage Indexes *(FR pages 37,073 – 37,076)*:** As in past years, for CY 2019 OPPS payments, CMS is proposing to use the federal fiscal year (FFY) 2019 inpatient PPS (IPPS) wage indexes, including all reclassifications, add-ons, rural floors, and budget neutrality adjustment.

CMS is using this proposed rule to inform the public that the Census Bureau has created a CBSA for the following MSA:

- Twin Falls, Idaho (CBSA 46300), which is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

CMS is proposing that the imputed rural floor policy will expire after December 31, 2018 with regards to the OPPS.

The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2019, CMS is proposing to continue to use a labor-related share of 60%.

- **Payment Increase for Rural SCHs and EACHs** ***(FR page 37,078)*****:** CMS is proposing to continue 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 37,079 – 37,080):*** CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. Previously, CMS did this by providing a payment adjustment such that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals (and thus the adjustment was budget neutral).

  In order to determine a budget neutrality factor for the cancer hospital payment adjustment, CMS calculated a proposed PCR of 0.89 which, after applying the 1.0 percentage point reduction mandated by the 21st Century Cures Act, results in the proposed target PCR being equal to 0.88 for each cancer hospital, which is equivalent to the target PCR for CY 2018. Therefore, CMS has proposed a +0.00% adjustment to the CY 2019 conversion factor to account for this policy.
- **Outlier Payments** ***(FR pages 37,080 – 37,081)*****:** To maintain total outlier payments at 1.0% of total OPPS payments, CMS is proposing a CY 2019 outlier fixed-dollar threshold of $4,600. This is an increase compared to the current threshold of $4,150. 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 37,055 – 37,072, 37,084 – 37,128, and 37,150

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 2019 are available in Addenda A and B of the proposed rule at https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1695-P-OPPS-Addenda.zip.

CMS is not proposing to remove any codes from the CY 2019 bypass list.

The table below shows the proposed shift in the number of APCs per category from CY 2018 to CY 2019 (Addendum A):

APC Category	Status Indicator	Final CY 2018	Proposed CY 2019
Pass-Through Drugs and Biologicals	G	50	48
OPD Services Paid through a Comprehensive APC	J1	61	63
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	312	319
Partial Hospitalization	P	2	2
Blood and Blood Products	R	36	36
Procedure or Service, No Multiple Reduction	S	77	79

Procedure or Service, Multiple Reduction Applies	T	34	31
Brachytherapy Sources	U	18	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		**714**	**719**

Calculation and Use of Cost-to-Charge Ratios (CCRs) ***(FR pages 37,055 – 37,056)*****:** CMS is proposing to extend the transition policy and remove claims from providers that use a "square footage" cost allocation method in order to calculate CCRs used to estimate costs for the CT and MRI APCs identified below:

- APC 5521: Level 1 Imaging without Contrast;
- APC 5522: Level 2 Imaging without Contrast;
- APC 5523: Level 3 Imaging without Contrast;
- APC 5524: Level 4 Imaging without Contrast;
- APC 5571: Level 1 Imaging with Contrast;
- APC 5572: Level 2 Imaging with Contrast;
- APC 5573: Level 3 Imaging with Contrast;
- APC 8005: CT and CTA without Contrast Composite;
- APC 8006: CT and CTA with Contrast Composite;
- APC 8007: MRI and MRA without Contrast Composite; and
- APC 8008: MRI and MRA with Contrast Composite.

New Comprehensive APCs ***(FR pages 37,057 – 37,058 and 37,059 – 37,063)*****:** Comprehensive Ambulatory Payment Classifications 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).

For CY 2019, CMS is proposing to create three new C-APCs for CY 2019, bringing to total number to 65 C-APCs:

- APC 5163: Level 3 ENT Procedures;
- APC 5183: Level 3 Vascular Procedures; and
- APC 5184: Level 4 Vascular Procedures.

CMS is also proposing to no longer make separate payments for blood and blood products when they appear on the same claim as those services assigned to a C-APC. Finally, in order to ensure that there is sufficient claims data for services assigned to New Technology APCs, CMS is proposing to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a "J1" service assigned to a C-APC.

- **Composite APCs** ***(FR pages 37,063 – 37,067):*** 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 six composite APCs for:
    - Mental Health Services (APC 8010); and
    - Multiple Imaging Services (APCs 8004, 8005, 8006, 8007 and 8008).

  For CY 2019, as in CY 2018, CMS is proposing that when aggregate payment for specified mental health services provided by a hospital to a single beneficiary on single date of service exceed the maximum per diem payment rate for partial hospitalization services, those services will instead be paid through composite APC 8010 for CY 2019. In addition, as with CY 2018, CMS is proposing that the payment rate for composite APC

8010 will be set to that established for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital.

For CY 2019, CMS is otherwise proposing continue its current composite APC payment policies. Table 6, on pages 37,065 – 37,067, displays the HCPCS codes that would be subject to the multiple imaging procedure composite APC policy and their respective families.

- **Payment Policy for Low-Volume New Technology APCs (*FR pages 37,091 – 37,092*):** For CY 2019, in order to promote transparency and stability in payment rates for low volume procedures, CMS is proposing to establish a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims. This new methodology would use up to 4 years of claims data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for each service both for inclusion in the New Technology APC and for assigning the service to a regular APC at the conclusion of payment for the service through a New Technology APC.

- **Packaged Services *(FR pages 37,067 – 37,071 and 37,163 – 37,168)*:** CMS is continuing its efforts to create more complete APC payment bundles over time 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 2019, in order to address the decreased utilization of non-opioid pain management drugs, and to encourage their use rather than that of prescription opioids, CMS is proposing to unpackage, and pay separately, the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. CMS is seeking comment on if the proposed policy would decrease the dose, duration, and/or number of opioid prescriptions that beneficiaries receive during and following an outpatient visit/procedure; as well as if there are other non-opioid alternatives that would have similar effects and may warrant separate payment.

  CMS is also inviting the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorders and improve access to treatment under the Medicare program. This includes the identification of barriers that may inhibit access to non-opioid alternatives for pain treatment and management, or access to opioid use disorder treatment.

- **Payment for Medical Devices with Pass-Through Status *(FR pages 37,097 – 37,107)*:** There are currently no device categories eligible for pass-through payment. CMS has not yet approved any new device pass-through payment applications for CY 2019.

- **Device-Intensive Procedures *(FR pages 37,107 – 37,109)*:** Beginning in CY 2017, CMS defined device-intensive APCs as those procedures which require the implantation of a device, and are assigned an individual HCPCS code-level device offset of more than 40%, regardless of APC assignment.

  For new HCPCS codes describing device implantation procedures that do not yet have associated claims data, CMS applies a device offset of 41% until claims data are available to establish an offset for the procedure. In addition, CMS applies the CY 2016 device coding requirements to newly defined device-intensive procedures. Any device code would satisfy this edit when it is reported on a claim with a device-intensive procedure.

  For CY 2019, CMS is proposing to allow procedures that involve surgically inserted/implanted, single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures regardless of if the device remains in the patient's body post-procedure. CMS is also proposing to lower the device offset percentage threshold from 40% to 30% (resulting in a 31% device offset for new HCPCS device codes) to allow more procedures to qualify as device-intensive.

  In addition, to align the device-intensive policy with the criteria used for device pass-through status, CMS is proposing for CY 2019 and subsequent years that, for the purpose of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

  - Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA, or meets another appropriate FDA exemption from premarket review;
  - Is an integral part of the service furnished;
  - Is used for one patient only;

- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
  - Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or
  - A material or supply furnished incident to a service.

Finally, CMS is proposing that for CY 2019 and subsequent years, in the limited instances where a new HCPCS code does not have a predecessor CPT code, but describes a procedure previously described by an existing code, that CMS will use clinical discretion to identify those HCPCS codes that are clinically related or similar to the new HCPCS code, but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code.

- **Payment Adjustment for No Cost/Full Credit and Partial Credit Devices *(FR pages 37,109 – 37,110)*:** 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.

  CMS determines the procedures to which this policy applies 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).

  For CY 2019, CMS is proposing to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive.

- **Payment Policy for Low-Volume Device-Intensive Procedures (*FR pages 37,110 – 37,111*):** In the CY 2017 final rule CMS adopted a policy where, 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. For CY 2019 the only procedure to which this policy would apply continues to be 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 37,111 – 37,117 and 37,121 – 37,126)*:** 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. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved since CY 2017 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.

  For CY 2019, CMS is proposing a packaging threshold of $125. Drugs, biologicals and radiopharmaceuticals that are above the $125 threshold are paid separately using individual APCs; the baseline payment rate for CY 2018 is the average sales price (ASP) + 6%.

  For separately payable drugs and biological products that do not have pass-through status and are not acquired under the 340B program, CMS is also proposing to reduce wholesale acquisition cost (WAC)-based drug payments from WAC+6% to WAC+3% for CY 2019 and future years, which was also proposed by MedPAC in their June 2017 Report to Congress.

  Finally, CMS is proposing to allow the pass-through status to expire on December 31, 2018 for 23 drugs and biologicals, listed in Table 19 on page 37,112; and to continue pass-through status in CY 2019 to 49 others, shown in Table 20 on pages 37,113 – 37,114.

- **High Cost/Low Cost Threshold for Packaged Skin Substitutes** ***(FR pages 37,117 – 37,121)*****:** CMS divides skin substitutes into a high cost group and a low cost group in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a products per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group.

  CMS is proposing to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high cost group in CY 2018 to the high cost group in CY 2019 as well. CMS will also assign those with pass-through payment status to the high cost category, however there are no skin substitutes with pass-through payment for CY 2018.

  The list of packaged skin substitutes, and their group assignments, may be found in Table 23 on pages 37,119 – 37,120.

  In the CY 2018 OPPS final rule, CMS had requested public comment about refinements that could be made to the existing payment methodology for packaged skin substitutes in order to stabilize payments for these products. The four potential methodologies brought up that CMS is currently looking in to are (page 37,119):

  - Establishing a lump-sum "episode-based" payment for a wound care episode;
  - Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products;
  - Allow for the payment of current add-on codes or create additional procedure codes to pay for skin-graft services between 26 cm^2 and 99 cm^2 and substantially over 100 cm^2; and
  - Keep the high cost/low cost skin substitute categories, but change the threshold used to assign skin substitutes in the high-cost or low-cost group.

  CMS is proposing to continue the current skin substitute payment policy for CY 2019, but is considering one of these methodologies (or any new ones with the current comment period) for implementation in CY 2020.

- **Payment for Drugs Purchased under the 340B Drug Discount Program** ***(FR pages 37,123, 37,125 – 37,126, and 37,143 – 37,146)*****:** The 340B Drug Pricing Program, administered by the Health Resources & Services Administration (HRSA), allows participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers.

  In CY 2018, due to a correlation between increases in drug spending and hospital participation in the 340B program, as well as CMS' belief that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs, CMS changed the Medicare Part B drug payment methodology for 340B hospitals.

  Specifically, CMS now pays a reduced rate of ASP - 22.5%, rather than the current rate of ASP + 6% for nonpass-through separately payable drugs and biosimilar biological products purchased under the 340B program. CMS believes that 22.5 percent below the ASP reflects the average minimum discount that 340B hospitals receive for drugs acquired under the 340B program.

  Rural sole-community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are exempt from the 340B adjustment, and receive drug payments based on ASP + 6%.

  Effective January 1, 2018, in order to implement this payment adjustment, CMS established modifiers "JG" and "TB". Modifier "JG" is used by non-exempt hospitals to report separately payable drugs that were acquired through the 340B program, and thus paid the reduced rate. Modifier "TB" is used by hospitals exempt from the 340B payment adjustment to report separately payable drugs that were acquired through the 340B program.

  For CY 2019 and subsequent years, CMS is proposing to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5% of the biosimilar's ASP, instead of the biosimilar's ASP minus 22.5% of the reference product's ASP.

  CMS clarifies that the 340B payment adjustment also applies to those drugs for which pricing is determined based on WAC and average wholesale price (AWP). Drugs acquired under WAC pricing will be paid at WAC minus 22.5%, while those acquired under AWP pricing will be paid at 69.46% of AWP.

  CMS is proposing to extend the ASP – 22.5% payment rate to 340B drugs (excluding vaccines and drugs on pass-through payment status) provided at non-excepted off-campus provider-based departments. This

proposed policy would not apply to rural sole community hospitals, children's hospitals, or to PPS-exempt cancer hospitals.

Other OPPS Policies

- **Partial Hospitalization Program (PHP) Services** ***(FR pages 37,128 – 37,136)*****:** 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 final CY 2018 and proposed CY 2019 PHP payment rates:

	Final Payment Rate 2018	Proposed Payment Rate 2019	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$143.30	$117.35	-18.1%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	$208.21	$216.55	+4.0%

  For CMHCs, CMS is proposing 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.

- **Updates to the Inpatient-Only List** ***(FR pages 37,136 – 37,137)*****:** The inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. For CY 2019, CMS is proposing to make the following changes to the services included on the inpatient-only list:

  Remove:

  - CPT code 31241— Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery [proposed assignment to APC 5153]; and
  - CPT code 01402 — Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty.

  Add:

  - HCPCS code C9606 — Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, and combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel.

  In addition, the public is asked to comment on whether CPT code 0266T ("Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed") should also be removed from the inpatient only list.

- **Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments** ***(FR pages 37,137 – 37,138)*****:** MedPAC's June 2017 Report to Congress states that there has been significant growth recently in the number of health care facilities located apart from hospitals that are devoted primarily to emergency department services; including both OPPS-eligible off-campus provider-based emergency departments and OPPS-ineligible freestanding emergency departments not affiliated with a hospital. MedPAC is concerned that the payment incentives linked to operating off-campus emergency departments may be the driver of this growth.

  In order to track this CMS is, through the subregulatory process, requiring that effective January 1, 2019, a HCPCS modifier "ER" (Items and services furnished by a provider-based off-campus emergency department) be reported with every claim line for outpatient hospital serviced furnished in an off-campus provider-based emergency department. The modifier would be reported on the UB-04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals would be exempt from reporting this modifier.

- **Payment for Off-Campus Outpatient Departments** ***(FR pages 37,138 – 37,143 and 37,146 – 37,150)*****:** 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):

- All excepted off-campus provider-based departments (PBDs) may bill for excepted services under the OPPS (using the claim line indicator "PO"). 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.
- Excepted off-campus PBDs are allowed to relocate (temporarily or permanently), without loss of excepted 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. Excepted status is 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 is the "applicable payment system" for the majority of nonexcepted items and services furnished in an off-campus PBD. These services will be paid under the MPFS at these newly established rates (or 40% of the amount paid under OPPS), which will continue to be billed on the institutional claim, and will require the new claim line modifier "PN" which will flag the service as nonexcepted, 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.

In CY 2019, in order to control what CMS deems an unnecessary increase in OPPS service volume for a basic clinic visit representing a large share of the services provided at off-campus PBDs, CMS is proposing to expand the MPFS payment methodology to excepted off-campus PBDs (currently paid under the OPPS rates), for HCPCS code G0463. These excepted PBDs would continue to bill HCPCS code G0463 with modifier "PO". CMS is further proposing that this payment method would be implemented in a non-budget neutral manner.

In addition to this proposal, CMS is seeking public comment on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services, as well as on how to expand the application of the application of the Secretary of Health and Human Services' authority to additional items and services paid under the OPPS that may represent unnecessary increases in OPD utilization.

Finally, for CY 2019 and subsequent years, CMS is proposing that if an excepted off-campus PBD furnishes services from any clinical family of services (Table 32 on page 37,150), that it did not provide under OPPS during the baseline period of November 1, 2014 through November 1, 2015, then the items and services from the new clinical families of service would not be covered OPD services and thus be paid under the MPFS. If an excepted off-campus PBD did not furnish services under OPPS until after November 1, 2014, CMS is proposing that the one-year baseline period begins on the first date the PBD furnished covered OPD services prior to November 2, 2015. For providers meeting the mid-build requirement, the proposal is to establish a one-year baseline period beginning on the first date that the off-campus PBD furnished a service under OPPS.

CMS is seeking public comment on whether a different baseline period should be used for off-campus PBDs that began providing services and billing after November 1, 2014, or those that met the mid-build requirement. CMS is also asking for public comments on alternate methodologies to limit the expansion of excepted services in excepted off-campus PBDs for CY 2019.

Updates to the Hospital Outpatient Quality Reporting (OQR) Program

FR pages 37,175 – 37,193

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.

In the CY 2019 OPPS proposed rule, CMS is proposing the removal of ten measures from the Hospital Outpatient Quality Reporting Program:

The one measure to be removed for CY 2020 payment determinations is:

- OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431);

The nine measures to be removed for CY 2021 payment determinations are:

- OP-5: Median Time to ECG (NQF #0289);
- OP-31: Cataracts – Improvements in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536);
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659);
- OP-9: Mammography Follow-up Rates;
- OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513);
- OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data;
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; and
- OP-17: Tracking Clinical Results between Visits.

A table listing the 26 measures to be collected for CY 2020 payment determinations is available on *Federal Register* pages 37,186 – 37,187 of the CY 2019 proposed rule.

A table listing the 17 measures to be collected for CY 2021 payment determinations is available on *Federal Register* page 37,187 of the CY 2019 proposed rule.

Additionally, CMS is proposing to remove submission of the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program beginning with the CY 2020 payment determination, as CMS has concluded that it does not provide CMS with any unique information and thus is unnecessarily burdensome for hospitals to complete.

CMS is also proposing to change the reporting period for *OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* from one year, to three years, beginning with CY 2020 payment determinations in order to improve the reliability of the measure.

CMS Request for Information (RFI): Promoting EHR Interoperability

FR pages 37,209 – 37,211

With this proposed rule, CMS is issuing an RFI on "Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid- Participating Providers and Suppliers." This RFI solicits feedback on positive solutions to better achieve interoperability on the sharing of healthcare data between providers. Submissions will be considered in developing future regulatory proposals or sub-regulatory guidance.

CMS RFI: Price Transparency

FR pages 37,211 – 37,212

Effective January 1, 2019, CMS is updating its guidelines to require hospitals to make a list of their current standard charges available via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate. This could take the form of the chargemaster itself, or another form of the hospital's choice, as long as the information is in a machine readable format.

In order to further its objective of hospital price transparency, CMS is seeking public comment on a number of topics, including:

- The definition of "standard charges" in provider and supplier settings;
- The types of information most beneficial to patients, how hospitals can best enable patients to use charge and cost information, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces for this data;

- Requirements for providers to inform patients of their out-of-pocket costs prior to performing a service, improvements to patient out-of-pocket cost transparency; and
- Requirements for providers and suppliers to provide patients with information on what Medicare pays for a given service.

CMS RFI: Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals

FR pages 37,212 – 37,217

CMS is seeking additional public feedback on a potential model design that would accelerate the move to a value-based health care system building on the Competitive Acquisition Program (CAP). Topics for comments include, but are not limited to:

- Design features, such as the potential model's scope;
- Which providers and suppliers should be included or excluded from the model;
- The types of Medicare Part B drugs and biologicals that should be included or excluded;
- The role of private-sector vendors in the model;
- A defined population of beneficiaries to be addressed by the model;
- Appropriate beneficiary protections;
- Possible inclusion of other payers; and
- Options for Model payments.

CMS is also interested in how to best handle Medicare payment for the new high-cost therapies, and if a CAP-like model could be appropriate for these drugs and biologicals. Finally, CMS is soliciting comments on how a model could be structured to advance the goals of the President's Blueprint to lower Drug Prices so as to increase competition, strengthen negotiation, create incentives for lower list prices, and to lower out-of-pocket costs.

Additional Inpatient Quality Reporting (IQR) Program Policies

FR pages 37,217 – 37,220

In order to reduce the potential pressure on hospital staff to prescribe opioids to patients, CMS is proposing to update the HCAHPS Survey by removing the "Communication About Pain" questions effective with January 2022 discharges, for the FFY 2024 payment determination and subsequent years.

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