SUMMARY OF FINAL RULE — DECEMBER 2018

CY 2019 Medicare Outpatient Prospective Payment System

Overview

The Centers for Medicare & Medicaid Services (CMS) issued its final rule addressing rate updates and policy changes to the Medicare outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) prospective payment systems for calendar year (CY) 2019 on November 2, 2018. The final rule was published in the *Federal Register* on November 21.

CHA appreciates members' input, which informed the comments CHA submitted to CMS in response to the proposed rule.

The following is a comprehensive summary of the final rule's provisions. Additional information is available at www.calhospital.org/regulatory-tracker.

For Additional Information

For questions or additional information related to the final rule summary, please contact Alyssa Keefe, vice president federal regulatory affairs, at (202) 488-4866 or akeefe@calhospital.org. For questions related to the CY 2019 OPPS final rule DataSuite reports, please contact Ron Yaw, vice president, finance and economic analysis, at (916) 552-7695 or ryaw@calhospital.org.

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Summary of Key Provisions

The final rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates as well as regulations that implement new policies. The final rule includes policies that will:

- Make payment changes for excepted and non-excepted clinic visits furnished in off-campus provider-based departments (PBDs)
- Extend the 340B drug payment adjustment of average sales price (ASP) minus 22.5 percent to non-excepted PBDs
- Change the rate for biosimilars purchased by hospitals through the 340B program
- Change the inpatient-only list
- Change exceptions to the list of services to be packaged into ambulatory payment classifications (APCs), as opposed to separately paid

CY 2019 OPPS Final Payment Rate Updates and Impact

The tables below summarize the final CY 2019 conversion factor compared to CY 2018 and the components of the update factor.

	Final CY 2018	Final CY 2019	Percent Change
OPPS Conversion Factor	$78.636	$79.490	+1.09%

Final CY 2019 Update Factor Component	Value
Market Basket (MB) Update	+2.90%
Affordable Care Act-Mandated Productivity MB Reduction	-0.8 percentage points (PPT)
ACA-Mandated Pre-Determined MB Reduction	-0.75 PPT
Wage Index Budget Neutrality Adjustment	-0.16%
Pass-through Spending / Outlier Budget Neutrality Adjustment	-0.10%
Cancer Hospital Budget Neutrality Adjustment	+0.00%
Overall Final Rate Update	**+1.09%**

CMS adopts a conversion factor increase of 1.35 percent, based on the hospital inpatient market basket percentage increase of 2.9 percent, minus the multifactor productivity adjustment of 0.8 percentage point minus an additional 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 1.35 percent, while hospitals that do not will be subject to a statutory reduction of two percentage points. CMS determined that 36 hospitals did not meet the requirements to receive the full outpatient department (OPD) fee schedule increase factor. One-half of these hospitals (18 of 36) chose not to participate in the Hospital Outpatient Quality Reporting (OQR) Program for the 2018 payment determination.

CMS estimates that, compared to 2018, its policies will increase total payments under the OPPS by $440 million, including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization and case mix. CMS estimates that OPPS expenditures for 2019 will be approximately $74.1 billion, an

increase of approximately $5.8 billion compared to 2018 OPPS payments. CMS estimates the update to the conversion factor and other adjustments — not including non-budget-neutral adjustments — will increase OPPS payments by 1.3 percent. With all adjustments — including CMS' 2019 policy to control for "unnecessary increases" in the volume of the outpatient services by paying for clinic visits in off-campus PBDs at the physician fee schedule (PFS) equivalent rate — the final rule estimates that OPPS payments will decline by 0.6 percent.

CMS notes the following estimated impacts in Table 62 of the final rule.

Facility Type	2019 Impact
All Hospitals	0.6%
Urban – All	0.7%
Urban – Pacific Region	1.1%
Rural – All	0.5%
Rural – Pacific Region	-0.1%

California estimated impacts provided by CHA DataSuite are noted in the table below; impacts will vary by hospital.

Impact Analysis	Dollar Impact	Percent Change
Estimated CY 2018 OPPS Payments	*$5,102,530,000*	
Market Basket Update	$125,103,900	2.45%
ACA-Mandated Market Basket Reductions	($66,865,800)	-1.31%
Other BN Adjustments	($11,389,200)	-0.22%
Wage Index	$39,521,500	0.77%
APC Factor/Updates	($20,898,000)	0.01%
Estimated CY 2019 OPPS Payments	*$5,168,002,400*	
Total Estimated Change CY 2018 to CY 2019	***$65,472,400***	***1.28%***

The impact shown above does not include the impact of the 2.0% sequestration reduction to all lines of Medicare payment authorized by Congress through FFY 2027. It is estimated that the impact of sequestration on CY 2019 OPPS PPS-specific payments would be: -$103,360,500

Source: CHA DataSuite Analysis, November 2018

Changes to Site-Neutral Payment Policy for Off-Campus Provider-Based Departments

As in the proposed rule, CMS details the history of Medicare inpatient and outpatient hospital payment systems and concerns about expenditure growth in the outpatient department. Section 603 of the Bipartisan Budget Act of 2015 (BBA) partially addressed these concerns by precluding payment under the OPPS effective January 1, 2017, for new off-campus provider based departments (PBDs) that opened after November 2, 2015 (with limited exceptions). CMS generally refers to off-campus PBDs subject to Section 603 as "non-excepted off-campus PBDs." Off-campus PBDs not subject to Section 603 are

referred to as "excepted off-campus PBDs." PBDs on a hospital campus are not subject to Section 603, and are simply referred to as "on-campus PBDs" or "on-campus" departments of a hospital.

CMS references the Health and Human Services Secretary's authority under section 1833(t)(2)(F) of the Social Security Act to develop a method for controlling unnecessary increases in the volume of covered OPD services. CMS did not establish policy under this authority prior to the proposed rule, instead attempting to address expenditure growth through policies such as increased packaging and the development of comprehensive APCs (C-APCs). However, in response to CMS' assertion that payment differentials in the site of service between physician offices and hospital outpatient provider based departments (PBDs) drive "unnecessary" increases in the volume of clinic visits in hospital PBDs, CMS proposed to pay for clinic visits (G0463) furnished in excepted off-campus PBDs at the same reduced rate they are paid in non-excepted off-campus PBDs.

Despite strong opposition from CHA and other stakeholders, CMS finalizes this proposal, citing its authority to develop a method for controlling unnecessary increases in the volume of covered OPD services. However, in a change from the proposed rule, the policy will be phased in over two years. Specifically, in CY 2019, 50 percent of the reduction will be applied — meaning that for this year, excepted off-campus PBDs will be paid 70 percent of the OPPS rate for clinic visit services (G0463). In CY 2020 and subsequent years, these excepted off-campus PBDs will be paid 40 percent of the OPPS rate for these services, or the same rate as currently paid to non-excepted off campus PBDs. This payment cut will not apply to on-campus clinic visits. CMS indicates that, during the phase in, it will monitor the impact of this policy on access and quality of care for beneficiaries.

For 2019, the standard unadjusted Medicare OPPS payment for the clinic visit is approximately $116. CHA estimates the PFS equivalent rate for Medicare payment for a clinic visit to be approximately $81. CMS will determine 2020 rates in the CY 2020 OPPS rulemaking cycle; however, based on the current standard rate, CHA estimates the PFS equivalent for clinic visits in 2020 would be approximately $46. No changes to hospital billing practices will be required to implement this policy. More specifically, hospitals currently bill for services in off-campus PBDs subject to Section 603 with a "PN" modifier that applies the PFS relativity adjuster of 0.4 to the OPPS payment amount. Excepted off-campus PBDs bill with modifier "PO" that indicates the service was provided in an off-campus PBD, but the PFS relativity adjuster does not apply. Under this policy, CMS will make the system changes necessary to apply the PFS relativity adjuster when a clinic visit is billed in an excepted off-campus PBD with the "PO" modifier.

This payment rate change is not budget neutral. Considering the effects of estimated changes in enrollment, utilization and case mix, this policy results in estimated 2019 savings of approximately $380 million, with approximately $300 million of the savings accruing to Medicare and approximately $80 million saved by Medicare beneficiaries in the form of reduced copayments.

In the table below, CHA DataSuite estimates the impact for California, based on Medicare claims data from the CY 2017 Medicare 100 percent standard analytic file using indicator "PO" to identify

appropriate claims. The portion of CY 2016 OPPS revenue for off-campus PBDs is applied to CY 2019 OPPS estimated payments to determine impacts. Further, it is important to note that CMS uses a different claims file for rate setting and, therefore, hospital-specific impacts will vary.

Estimated Impact of Payment Change to Excepted Off-Campus Provider-Based Departments (PBDs) at 70% of OPPS Rate	Portion of CY 2017 OPPS Revenue for Off-Campus PBDs	Estimated Current Payment for Excepted Off-Campus PBDs	Estimated Final Payment for Excepted Off-Campus PBDs
	1.39%	$71,750,700	$50,225,500
Estimated Impact/Change to CY 2019 OPPS Revenue	($21,525,200)		-30.0%

Source: CHA DataSuite Analysis, November 2018

Expansion of Site-Neutral Payment Policies to Clinical Families of Services at Excepted Off-Campus PBDs

As noted earlier, Section 603 of the BBA excludes from the definition of covered OPD services "applicable items and services" furnished on or after January 1, 2017, by certain off-campus outpatient departments of a provider and provides for payment for services furnished by off-campus PBDs under the applicable payment system (e.g., PFS) for the majority of nonexcepted items and services furnished by nonexcepted off-campus PBDs.

In implementing Section 603, CMS previously proposed to limit the items and services for which payment would be made under the OPPS in an excepted off-campus PBD to items and services furnished before November 2, 2015; items and services not included in that group would be paid under the applicable payment system. CMS did not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish. Stakeholders expressed concerns about the proposal, including that CMS lacked the authority to implement the policy, that limiting service expansion would stifle innovative care delivery and new technologies, and that the proposal was not workable. The agency did not finalize this proposal but indicated it would continue to monitor service line expansion and consider how potential limitations on expansion might work; it sought comments on the issue.

In the CY 2019 proposed rule, citing its previous concerns about expansion of services in excepted off-campus PBDs, CMS again proposed to revise the definition of "excepted items and services" under §419.48 to include only those from certain clinical families of services furnished during certain baseline periods (generally from November 1, 2014, through November 1, 2015). **However, in response to opposition by CHA and other commenters, CMS did not finalize this proposal.** CMS agrees that its proposal was operationally complex and could create an administrative burden for hospitals, CMS and CMS contractors. CMS intends to continue to monitor expansion of services in off-campus PBDs and, if it deems appropriate, may propose to limit expansion of excepted services in future rulemaking.

Thus, an excepted off-campus PBD will continue to receive payments under the OPPS during 2019 for all billed items and services regardless of whether the facility furnished those services before the

enactment of Section 603; this presumes the facility remains "excepted" within the terms of the statute and regulations, including compliance with relocation and change of ownership rules.

Applying the 340B Drug Payment Policy to Non-Excepted Off-Campus PBDs

In CY 2018, CMS finalizes an OPPS policy to reduce payment for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. However, because services furnished in non-excepted off-campus PBDs are no longer considered to be covered OPD services — rather, they are paid under a special PFS rate of 40 percent of the OPPS rate under Section 603 — 340B-acquired drugs furnished in these settings were not subject to this policy and so continued to be paid at ASP plus 6 percent in 2018.

In the CY 2018 OPPS final rule, CMS discussed concerns that not applying the 340B drug payment policy to non-excepted off-campus PBDs incentivizes hospitals to move drug administration services for 340B-acquired drugs to non-excepted off-campus PBDs to receive a higher payment. CMS expressed concern that this payment difference could undermine CMS' goal of reducing beneficiary cost-sharing for these drugs and biologicals and moving toward site neutrality for services paid in non-excepted off-campus PBDs. **To address its concern, CMS finalizes its proposal to pay the adjusted amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program when they are furnished by non-excepted off-campus PBDs of a hospital, effective January 1, 2019.**

CMS will exempt rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from this payment adjustment, consistent with the policy it applies for on-campus PBDs and excepted off-campus PBDs**.** These hospitals will be required to report informational modifier "TB" for 340B-acquired drugs and biologicals, and will continue to be paid ASP plus 6 percent. Because this is an OPPS policy, the payment reduction also will not apply to critical access hospitals.

OPPS Payment Methodology for 340B-Purchased Drugs, Including Biosimilar Biological Products

In the 2018 OPPS/ASC final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP minus 22.5 percent instead of ASP plus 6 percent. CMS has received questions about whether the 340B payment adjustment applies to drugs that are priced using either WAC or average wholesale price (AWP). CMS notes its policy had been to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment by paying WAC minus 22.5 percent and 69.46 percent of AWP for AWP-priced drugs.

In addition, CMS currently pays for biosimilar biological products using policies parallel to those for other drugs and biologicals, with one important distinction — the 6 percent add-on to ASP and the 22.5 percent subtraction from ASP is based on the ASP of the reference product, not the ASP of the

biosimilar. The 6 percent add-on is consistent with the statutory requirement in section 1847A of the Social Security Act that applies to drugs and biologicals furnished in physicians' offices. CMS' policy to subtract 22.5 percent of the reference product's ASP from the ASP of the biosimilar for biosimilars acquired under the 340B program was adopted in the 2018 OPPS final rule when CMS established its 340B drug payment policy.

CMS received concerns about this policy, specifically that 22.5 percent of a biosimilar's reference product ASP is higher than the 22.5 percent of the biosimilar's own ASP because the reference product will generally have a higher price than a biosimilar. Commenters believe it is unfair to subtract a larger amount from the biosimilar's ASP than 22.5 percent of its own ASP. CMS agrees and finalizes its proposal that — when a biosimilar is acquired under the 340B program — Medicare will pay the hospital based on ASP minus 22.5 percent of the biosimilar's ASP and not the reference product's ASP, except where a biosimilar is paid on pass-through. In those circumstances, the biosimilar will continue to receive ASP plus 6 percent of the reference product's ASP.

CHA DataSuite estimates the impact of this policy for California below. Estimates are based on Medicare claims data from the CY 2017 Medicare 100 percent standard analytic file. Hospitals flagged as 340B entities are based on the list maintained by the Health Resources & Services Administration as of November 13, 2018. Currently, the impact of this policy is isolated to HCPCS code Q5101 since the pass-through status for this biosimilar biologic will expire on December 31, 2018.

Estimated Impact of CMS' Change to Payment Rate for Biosimilars Purchased Through the 340B Drug Pricing Program (Currently only HCPCS Q5101)	*CY 2017 OPPS Revenue for Biosimilar Biological Products*	*Estimated Current Payment for Biosimilars Affected by CMS' 340B Payment Reduction*	*Estimated Final Payment for Biosimilars Affected by CMS' 340B Payment Reduction*
	$747,100	***$579,000***	***$900,800***
Estimated Impact/Change to CY 2019 OPPS Revenue	***$321,800***		***55.6%***

Source: CHA DataSuite Analysis, November 2018

Collecting Data on Services Furnished in Off-Campus PBDs

As noted in the proposed rule, CMS shares concerns similar to those expressed by MedPAC and other entities that higher payment rates for services furnished in off-campus provider-based emergency departments may be a significant factor in the their growth. Higher payment in these settings is due in part to the Section 603 exemption from payment under the applicable payment system (i.e., the PFS) for all services (emergency and nonemergency) furnished in an off-campus provider based hospital emergency department. CMS believes it must collect data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments.

Effective January 1, 2019, CMS will implement a new modifier ("ER" - Items and services furnished by a provider-based off-campus emergency department) for this purpose through the subregulatory Healthcare Common Procedure Coding System (HCPCS) modifier process. The modifier must be

reported with every claim line for outpatient hospital services furnished in off-campus provider-based emergency departments.

The modifier will be reported on the UB-04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals will not have to report this modifier. **Most importantly, the ER modifier will not be applicable in California, as state law prohibits the licensure of provider-based and freestanding emergency departments.**

Recalibration of APC Relative Payment Weights

CMS is largely continuing past policies unchanged. The only changes CMS finalizes are to exclude procedures assigned to new technology APCs from being packaged with C-APCs and to create three new C-APCs for ENT and vascular procedures.

Blood and Blood Products

For 2019, CMS is continuing, without change, to set payment rates for blood and blood products using the blood-specific cost-to-charge ratio (CCR) methodology that it has used since 2005. CMS is also continuing to include blood and blood products in the C-APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of "R" (Blood and Blood Products) in Addendum B of the final rule.

Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

CMS recounts the history and coding, since 2016, of pathogen-reduced platelets and rapid bacterial testing of platelets. In the proposed rule, CMS expressed confidence in the accuracy of the billing for the temporary predecessor codes to P9073 and proposed to use its normal methodology to develop pricing for 2019. Commenters objected to CMS' proposal requesting that it continue the crosswalk through either 2019 or 2020 because of continued concerns about coding errors and confusion and costs in the claims being lower than the actual cost of the services. CMS agreed with the commenters and is continuing its crosswalk methodology for pathogen-reduced platelets for 2019.

Brachytherapy Sources

CMS finalizes no changes to its brachytherapy policy for 2019. The payment rates appear in Addendum B to the final rule and are identified with status indicator "U."

C-APCs for 2019

A C-APC is defined as a classification for a primary service and all adjunctive services provided to support the delivery of the primary service. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are provided during the delivery of the comprehensive service and are integral, ancillary, supportive, dependent and adjunctive to the primary service.

CMS also assigns a C-APC to specific services performed in combination with each other. Applying C-APC policies to these code combinations means that other OPPS-payable services and items reported on the claim are treated as adjunctive to the comprehensive service. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim.

Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Qualifying services are reassigned from the originating C-APC to a higher-paying C-APC in the same clinical family. Currently, code combinations that satisfy the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless the APC reassignment is not clinically appropriate or the primary service is already assigned to the highest cost APC within the C-APC clinical family.

CMS does not create new APCs with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

CMS adds three C-APCs under the existing C-APC payment policy, beginning in CY 2019: C-APC 5163 (Level 3 ENT Procedures), C-APC 5183 (Level 3 Vascular Procedures) and C-APC 5184 (Level 4 Vascular Procedures). Table 7 of the final rule lists all C-APCs for 2019.

Exclusion of Procedures Assigned to New Technology APCs From C-APC Packaging

CMS finalizes its proposal to exclude procedures assigned to new technology APCs from being packaged into C-APCs because of a concern that packaging payment reduces claims for the new technology that is available for APC pricing. The proposed rule indicated that packaging in this circumstance is contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

Composite APCs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS is continuing, without changes, composite policies for mental health services and multiple imaging services for 2019.

Changes to Packaged Items and Services

Drugs that function as a supply, regardless of cost, are packaged under the OPPS and the ASC payment system. These costs are included in the rate-setting methodology for the surgical procedures with which they are billed. The payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services, to the extent they are billed with the procedure.

CMS examined this packaging policy for 2019 in response to a report from the President's Commission on Combating Drug Addiction and the Opioid Crisis. The commission recommended that CMS "…review

and modify rate setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain." The commission's concern is that the policy incentivizes prescription of opioid — rather than non-opioid — medications to patients for post-surgical pain.

As a result of CMS' analysis in the proposed rule and in response to public comments, CMS will un-package and pay separately, at ASP plus 6 percent, for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for 2019. This policy will only currently apply to Exparel, which is the only non-opioid pain management drug that functions as a supply when used in a surgical procedure that is covered under Medicare Part B. **However, CMS will not pay separately for these drugs in hospital outpatient departments, despite recommendations from CHA and other stakeholders.**

Area Wage Index

As in past years, for CY 2019 OPPS payments, CMS will use the federal fiscal year (FFY) 2019 inpatient PPS (IPPS) wage indexes, including all reclassifications, add-ons, rural floors and budget neutrality adjustments. The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2019, CMS continues to use a labor-related share of 60 percent. CMS notes that the Census Bureau has created a core-based statistical area (CBSA) for the metropolitan statistical area of Twin Falls, Idaho (CBSA 46300), which is comprised of the principal city of Twin Falls in Jerome County, Idaho and Twin Falls County, Idaho.

In the FFY 2019 IPPS final rule, CMS finalized its proposal to discontinue the imputed floor policy for fiscal year 2019 and subsequent fiscal years. For purposes of the OPPS, CMS discontinues the application of the imputed floor policy to hospitals paid under the OPPS effective for 2019 and subsequent years.

Payment Increase for Rural Sole Community, Essential Access Community Hospitals

CMS continues a 7.1 percent payment increase for rural sole community hospitals and essential access community hospitals. 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

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; thus, the adjustment was budget neutral.

To determine a budget neutrality factor for the cancer hospital payment adjustment, CMS calculated a proposed PCR of 0.89, which, after applying the one percentage point reduction mandated by the 21st

Century Cures Act, results in the target PCR being equal to 0.88 for each cancer hospital, which is equivalent to the target PCR for CY 2018. Therefore, CMS has finalized no adjustment to the CY 2019 conversion factor to account for this policy.

Outlier Payments

To maintain total outlier payments at 1 percent of total OPPS payments, CMS finalizes a CY 2019 outlier fixed-dollar threshold of $4,825 — an increase over the current threshold of $4,150. Outlier payments will continue to be paid at 50 percent 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.

To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied the hospital-specific overall ancillary CCRs available in the October 2018 update to the Outpatient Provider-Specific File after adjustment (using a CCR inflation adjustment factor of 0.9813 to approximate 2019 CCRs) and to charges on 2017 claims. CMS is using the one-year average annualized rate-of-change in charges per case (1.0434) for two years, for a total increase factor of 1.08868, to approximate 2019 charges. The inflation adjustment factors for CCRs and charges are the same used in the FY 2019 IPPS final rule.

Partial Hospitalization Program Services

Partial hospitalization programs (PHPs) are intensive outpatient psychiatric programs that 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 CY 2019 PHP payment rates.

	Final Payment Rate 2018	Final Payment Rate 2019	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$143.30	$120.58	-15.9%
APC 5863: Partial Hospitalization (3+ services) for Hospital-Based PHPs	$208.21	$220.86	+6.1%

For CMHCs, CMS will continue to make outlier payments at 50 percent 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

The inpatient-only list specifies services and procedures that Medicare will pay for only when provided in an inpatient setting. For CY 2019, CMS finalizes 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 [reassignment to APC 5153]
- CPT code 01402 — Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty
- 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)

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

The complete list of procedure codes on the IPO list for 2019 is in Addendum E of the final rule. Table 49 contains the final changes to the IPO list for 2019.

Payment for Medical Devices With Pass-Through Status

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 Procedure Policy for 2019

In the 2017 OPPS final rule, CMS finalized a change in its methodology to assign device-intensive status. CMS assigns device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. All procedures that meet these requirements are identified as device-intensive, and are subject to the device edit and no cost/full credit and partial credit device policies.

In the 2018 OPPS final rule, CMS clarified that — to be identified as device-intensive procedures and subject to all applicable policies — procedures must require the implantation of a device and meet the following 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, at least temporarily, after the procedure's conclusion.

- The device offset amount must be "significant," which is defined as exceeding 40 percent of the procedure's mean cost.

In response to stakeholders' comments, and as part of an effort to better capture costs for procedures with significant device costs, for 2019 CMS modifies the criteria for device-intensive procedures. CMS no longer believes that whether a device remains in the patient's body should affect its designation as a device-intensive procedure. In addition, to allow a greater number of procedures to qualify as device-intensive, CMS finalizes its proposal to lower the device offset percentage threshold from 40 to 30 percent. CMS believes this will help ensure these procedures receive more appropriate payment in the ASC setting. CMS also states this change will help to ensure more procedures containing relatively high-cost devices are subject to device edits, which leads to correct coding and greater accuracy in the claims data.

Specifically, for 2019 and subsequent years, CMS finalizes that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code.
- The required devices (including single-use devices) must be surgically inserted or implanted.
- The device-offset amount must be "significant," which is defined as exceeding 30 percent of the procedure's mean cost.

To align the device-intensive policy with the criteria used for device pass-through status, CMS finalizes its proposal that, for 2019 and subsequent years, a device-intensive procedure must involve a device that:

- Has received Food and Drug Administration (FDA) marketing authorization, has received an FDA Investigational Device Exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, 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
- Is not:
    a. Equipment, an instrument, apparatus, implement or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the *Medicare Provider Reimbursement Manual* (CMS Pub. 15-1)
    b. A material or supply furnished incident to a service (e.g., a suture, customized surgical kit or a clip, other than a radiological site marker)

For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, in the 2017 OPPS final rule, CMS finalized a policy to apply a device-

intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. CMS also finalized that in certain rare instances, such as in the case of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer.

In accordance with the proposal to lower the device offset percentage threshold from 40 to 30 percent, CMS finalizes its proposal to apply a 31 percent HCPCS code-level offset to new HCPCS codes that describe procedures requiring the implantation of medical devices that do not yet have associated claims data, until such data are available. CMS will continue its current policy of temporarily assigning a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer.

The full listing of the final 2019 device intensive procedures is included in Addendum P to the final rule.

Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit in the amount portion for value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the device's cost.

For 2019 and subsequent years, CMS proposes to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the proposed modified criteria discussed above.

Payment Policy for Low-Volume Device-Intensive Procedures

For 2019, CMS will continue its policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For 2019, there are no procedures to which this policy would apply.

Payment for Drugs, Biologicals and Radiopharmaceuticals

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. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved since CY 2017 to grant a pass-through period as close to three full 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 finalizes 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 ASP plus 6 percent.

For separately payable drugs and biological products that do not have pass-through status and are not acquired under the 340B program, CMS finalizes its proposal to reduce wholesale acquisition cost (WAC)-based drug payments from WAC plus 6 percent to WAC plus 3 percent for CY 2019 and future years. This policy was advanced by MedPAC in its June 2017 *Report to Congress: Medicare and the Health Care Delivery System* and is consistent with policies finalized in the CY 2019 physician fee schedule final rule.

Finally, CMS will allow the pass-through status to expire on December 31, 2018, for 23 drugs and biologicals listed in Table 37 of the final rule, and continue pass-through status in CY 2019 for 49 others, shown in Table 38.

High Cost/Low Cost Threshold for Packaged Skin Substitutes

CMS divides skin substitutes into high-cost and low-cost groups 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 finalizes is proposal 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 2019. The list of packaged skin substitutes and their group assignments may be found in Table 41 of the final rule.

In the CY 2018 OPPS final rule, CMS requested public comment about refinements that could be made to the existing payment methodology for packaged skin substitutes to stabilize payments for these products. The four potential methodologies CMS is reviewing are:

- *Establish a lump-sum "episode-based" payment for a wound care episode*. Under this option, a hospital would receive a lump sum payment for an "episode" (such as 12 weeks) for all wound care services involving procedures using skin substitutes. Quality metrics could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.
- *Eliminate the high-cost/low-cost categories.* Under this option, CMS would establish a single payment category that has a payment rate between the current rates paid for high-cost and low-cost skin substitute procedures.
- *Pay add-ons based on the size of the skin graft*. Under this option, payment for skin substitutes would be made based on the size of the skin substitute product being applied.

- *Change the threshold used to assign skin substitutes in the high-cost or low-cost groups*. Under this option, CMS would consider fixing the MUC or PDC threshold at an amount from a prior year or setting global payment targets for high-cost and low-cost skin substitutes and establishing a threshold that meets the payment targets.

CMS will continue the current skin substitute payment policy for CY 2019, but is considering implementing one of these methodologies — taking into consideration public comments on the proposed rule — in CY 2020 rulemaking.

Hospital Outpatient Quality Reporting Program

In support of its Meaningful Measures Initiative, CMS removes eight measures from the Outpatient Quality Reporting (OQR) Program. The total number of mandatory measures would be reduced from 21 previously adopted for the 2020 and 2021 payment determinations to 20 measures for 2020 and 13 measures for 2021 payment.

CMS also modifies the factors it considers when removing measures from the OQR program, removes the requirement that hospitals submit a notice of participation form, notes that it will update the measure specifications manual less frequently and lengthens the reporting period for one claims-based measure.

Policies for Removal of Quality Measures From the OQR Program

Currently, CMS uses a set of seven factors to determine whether to remove a measure from the OQR program. Removal of measures meeting any of the criteria is not automatic and is made on a case-by-case basis. In this rule, CMS modifies the wording of one of the current seven factors to better align it with the ASC quality reporting program, clarifies its calculations for determining topped-out measures and adopts an eighth factor.

The newly adopted "Factor 8" allows for the removal of a measure when CMS determines the costs associated with a measure outweigh the benefit of its continued use in the program. CMS reviews a number of different costs associated with measures, including provider and clinician information collection and reporting burden, as well as the costs to CMS associated with program implementation and oversight.

Removal of Measures Beginning With 2020 and 2021 Payment Determinations

CMS removes the following eight measures from the OQR program. One measure would be removed beginning with the 2020 payment year and the others beginning with the 2021 payment year.

- **OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431):** CMS removes the measure beginning with the 2020 payment determination based on Factor 8. CMS notes that some hospital outpatient departments are required to participate in the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) reporting

system only for the purpose of reporting this measure. However, the vast majority of facilities participating in the OQR program report this measure for these other programs, and the inpatient version of the measure captures the vast majority of hospital personnel.

- **OP-5: Median Time to Electrocardiogram (ECG) (NQF #0289)**: CMS removes the measure beginning with the 2021 payment determination based on Factor 8. CMS has determined that the measure shows minimal performance variation, despite not meeting the definition of "topped out." The median time to ECG differs from the 75th and 90th percentile times by less than two minutes, and the difference between the 25th and 75th percentiles is only five-and-a-half minutes. CMS does not consider these differences meaningful in helping beneficiaries make informed care decisions.
- **OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659):** CMS removes the measure beginning with the 2021 payment determination under proposed Factor 8. In addition to the general burden of chart abstraction, CMS believes this measure is uniquely burdensome because it requires facilities to conduct extensive patient histories and to contact other facilities to document a patient's history of adenomatous polyps. CMS notes that it is retaining a related measure on this topic, OP-29, which is less burdensome to report.
- **OP-9: Mammography Follow-up Rates**: CMS removes this measure beginning with the 2021 payment determination because the measure does not align with current clinical guidelines or practice. Specifically, the measure does not take into account more recent guidelines and literature on the clinical benefits of diagnostic digital breast tomosynthesis (DBT), for which CMS cites various studies and the American College of Radiology breast cancer screening appropriateness criteria. CMS will investigate re-specification of this measure to capture a broader spectrum of mammography services, including DBT.
- **OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513) and OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT:** CMS removes the measures beginning with the 2021 payment determination because measure performance is topped out.
- **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 and OP-17: Tracking Clinical Results between Visits**: CMS removes the measures beginning with the 2021 payment because performance or improvement does not result in better patient outcomes. CMS notes that these measures assess functionality of health information technology and do not address patient outcomes and, as a result, are not consistent with the goals of its Meaningful Measures Initiative.

CMS did not finalize its proposal to remove the following two measures under Factor 8:

- **OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)**: CMS was persuaded by commenters that this measure provides distinct and valuable information for beneficiaries about the outpatient hospital setting

where a high volume of colonoscopies is performed, and is less burdensome to report than OP-30, which is being removed.

- **OP 31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)**: CMS has concluded that, although only a small number of facilities report this measure (between 52 and 66 for the 2017 through 2019 payment determinations), it is meaningful to those that do. In addition, no other OQR program measure addresses cataract surgery, a common outpatient hospital procedure. Finally, because the measure is voluntary, CMS concludes it is inherently not burdensome.

A table showing the OQR measure set through 2021 is included in the appendix to this summary. Specifications for OQR Program measures are available on the QualityNet website.

Notice of Participation Form

CMS removes the requirement that hospitals submit a notice of participation form for the OQR program, as submission of any OQR program data would indicate a hospital's status as a program participant. A hospital must register on the QualityNet website before beginning to report data, identify and register a QualityNet security administrator and submit data.

Frequency of OQR Program Specifications Manual Release

Beginning with 2019, CMS will update the OQR program measure specifications manual every 12 months — and addenda as necessary — rather than maintaining its current semi-annual update schedule. CMS had proposed to update the manual every six to 12 months but agrees with commenters that such an ad hoc schedule could be confusing.

Extension of Reporting Period for OP-32: Facility Seven-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

CMS finalizes a change to the reporting period for the claims-based measure OP-32 from one year of data to three years of data because it believes that better information will be provided to beneficiaries. While its analysis of data from the 2015 dry run of this measure has supported the finding that using one year of data provides sufficient reliability for measure calculation, CMS also found that using a three-year reporting period increases the measure's reliability and precision. In addition, the longer period is estimated to increase the number of HOPDs with eligible cases for this measure by 5 percent, adding 235 facilities to the measure calculation.

The reporting period for OP-32 will be changed beginning with the 2020 payment determination and will use claims from calendar years 2016, 2017 and 2018 instead of 2018 alone. A similar pattern will be used for later payment determinations. Because CMS adds prior years, it says payment determinations and public display of the measure will not be disrupted. For example, public display for the 2020 payment determination will occur in January 2020.

Payment Reduction for Hospitals That Fail to Meet the OQR Program Requirements for 2019 Payment

CMS continues to apply existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the hospital OQR program requirements for 2019. The reduction ratio for hospitals that fail to meet OQR program requirements, called the "reporting ratio," is 0.98.

The reporting ratio would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services. All other applicable standard adjustments to the OPPS national unadjusted payment rates apply, and OPPS outlier eligibility and outlier payment are based on the reduced payment rates. Beneficiaries and secondary payers share in the reduced payment to hospitals that are subject to the payment reduction.

CMS reports that for 2018 payment, 36 hospitals out of about 3,300 failed to meet the OQR program requirements for a full update factor; half of these hospitals chose not to participate in the program.

Inpatient Quality Reporting Program HCAHPS Pain Question Policies

CMS finalizes a change to the Inpatient Quality Reporting Program in addition to those that were included as part of the FFY 2019 IPPS final rule issued in August 2018. In a change from the proposed rule — and to implement a provision of the recently passed Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patient and Communities Act — CMS removes the three "communication about pain" questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure beginning with October 2019 discharges (for FY 2021 payment). Further, CMS finalizes that there will be no public reporting of these questions.

CMS had proposed later removal of the questions (January 2022 for the FY 2024 payment determination) but in light of the SUPPORT Act requirements and public comments, CMS has determined that it is operationally feasible to remove the questions beginning with October 2019 discharges. Instead of continuing public reporting of measure data until October 2022 as it had proposed, CMS finalizes that it will not report any of these data publicly in keeping with the SUPPORT Act and the concerns about how the questions might encourage inappropriate opioid prescribing.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program Policies

As part of the IPPS rulemaking for FFY 2019, CMS proposed removal of two measures from the PCHQR program beginning with the FFY 2021 program year. Both are infection measures from the CDC NHSN and were proposed for removal under the new cost removal Factor 8. The two measures are NHSN Central Line-Associated Bloodstream Infection (CLABSI) (NQF #0139) and NHSN Catheter Associated Urinary Tract Infection (CAUTI) (NQF #0138).

In its proposal to remove these two measures, CMS noted that both the reporting burden and the low volume of results make the measures unavailable for public reporting and, therefore, of no use to beneficiaries. However, in the IPPS final rule for FFY 2019, CMS deferred a final decision on removal of

these measures and stated that it was conducting additional data analyses to assess measure performance based on new information provided by the CDC.

In this rule, CMS announces its decision to retain the measures. The CLABSI and CAUTI measures were recently updated to use new standardized infection ratio calculations that allow for stratified patient care locations within the PPS-exempt cancer hospitals and no predictive models or comparisons are used in the rate calculations. CMS believes these measures could provide valuable information to beneficiaries on performance of the 11 PCHs and intends to propose to use these updated measures in future rulemaking. Until then, it believes the current measures should be retained in the PCHQR program. Public display will continue to be deferred until CMS has evaluated performance data from the updated versions of these measures, and will occur as soon as practicable.

The final rule includes a table summarizing the public display requirements for the PCHQR program for FFY 2021, which indicates that public reporting is deferred for the CLABSI and CAUTI measures and that it will begin as soon as practicable for other NHSN measures related to Methicillin-resistant Staphylococcus aureus, *Clostridium difficile* infection, surgical site infections and influenza vaccine among health care personnel. CMS also indicates that it plans to propose a time frame for public reporting of the measure of patients receiving outpatient chemotherapy in IPPS rulemaking for FFY 2020.

Requests for Information

In the proposed rule, CMS included three requests for information (RFIs) that solicited public comments to inform future policymaking on:

- Promoting interoperability and electronic health care information exchange
- Improving beneficiary access to provider and supplier charge information
- Leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center Model

In the final rule, CMS neither summarizes nor responds to comments submitted on these RFIs, and does not comment on any future policymaking action it will take. However, on October 25, 2018, CMS released an advanced notice of proposed rulemaking requesting comment on a potential model that combines elements of the CAP with an international price index and other delivery system reforms for Part B drugs. Public comments on that advanced notice are due December 31 by 2 p.m. (PT).

Appendix

Summary Table—OQR Measures for Payment Determination Years 2018-21
(X= Adopted)

NQF	Measure Title	2018	2019	2020	2021
0287*	OP-1: Median Time to Fibrinolysis	X	X	Removed	
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X
0286*	OP-4: Aspirin at Arrival	X	X	Removed	
0289*	OP-5: Median Time to ECG	X	X	X	Removed
0514	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X
	OP-9: Mammography Follow-up Rates	X	X	X	Removed
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	X	X	Removed
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	X	X	X	Removed
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	X	X	Removed
0491*	OP-17: Tracking Clinical Results between Visits	X	X	X	Removed
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X
	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	X	X	Removed	
0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	Removed	
0499*	OP-22: ED- Left Without Being Seen	X	X	X	X
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X
	OP-25: Safe Surgery Checklist Use	X	X	Removed	
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	X	X	Removed	
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel	X	X	Removed	
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	X	X	X	Removed

1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary			
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	X	X	X
	OP-35 Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy			X	X
2687	OP-36 Hospital Visits After Hospital Outpatient Surgery			Voluntary	
	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				
	OP-37e: OAS CAHPS – Recommendation of Facility				

*NQF endorsement removed