CMS finalizes Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System changes for 2019 (CMS-1695-FC)

On November 2, 2018, the Centers for Medicare & Medicaid Services (CMS) finalized changes that removes unnecessary and inefficient payment differences between certain provider and supplier types so patients can have more affordable choices and options. The final rule with comment period updates and revises policies under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System.

The polices in the calendar year (CY) 2019 OPPS and ASC Payment System final rule with comment period will further advance the agency's priority of creating a patient-centered healthcare system by achieving greater price transparency, and significant burden reduction so that hospitals and ambulatory surgical centers can operate with better flexibility and patients have access to the tools they need to become active healthcare consumers.

Increasing Choices and Encouraging Site Neutrality

The final rule with comment period contains a number of policies that reduce payment differences between hospitals and ambulatory surgical centers so that patients may better benefit from high quality care at lower costs, while receiving care that is provided safely and is clinically appropriate.

Method to Control for Unnecessary Increases in Utilization of Outpatient Services
CMS is exercising its authority to utilize a method to control unnecessary increases in the volume of covered hospital outpatient department services by applying a Physician Fee Schedule (PFS)-equivalent payment rate for the clinic visit service when provided at an off-campus provider-based department (PBD) that is paid under the OPPS. The clinic visit is the most common service billed under the OPPS. Currently, Medicare and beneficiaries often pay more for the same type of clinic visit in the hospital outpatient setting than in the physician office setting.

This policy would result in lower copayments for beneficiaries and savings for the Medicare program in an estimated amount of $380 million for 2019, the first year of a two year phase-in we are utilizing to implement this policy. For an individual Medicare beneficiary, current Medicare payment for the clinic visit furnished in an excepted off-campus PBD is approximately $116 with $23 being the average beneficiary copayment. The policy to adjust this payment to the PFS equivalent rate would reduce the OPPS payment rate for the clinic visit to $81 with a beneficiary copayment of $16 (based on a two year phase-in), thus saving beneficiaries an average of $7 each time they visit an off-campus department in CY 2019.

ASC Covered Procedures List
The ASC Covered Procedures List (CPL) is a list of covered surgical procedures that are payable by Medicare when furnished in an ASC. Covered surgical procedures are those procedures that are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety and would not typically be expected to require active medical monitoring and care at midnight following the procedure. Under current policy, covered surgical procedures include those described by certain Common Procedural Terminology (CPT) codes that are within the surgical code range and other codes that directly crosswalk or are clinically similar to CPT codes within the surgical code range.

For CY 2019, CMS is finalizing the proposal to include additional CPT codes outside of the surgical code range that directly crosswalk or are clinically similar to procedures within the CPT surgical code range on the CPL. As a result, CMS is finalizing its proposal to add twelve cardiovascular codes to the ASC CPL and adding five additional codes as a result of stakeholder comments the agency received. Additionally, CMS reviewed all procedures added to the ASC CPL within the past three years to reassess recent experience with the procedures in the ASC and to determine whether such procedures should continue to be on the ASC CPL. CMS is not finalizing any changes to the ASC CPL as a result of that review.

High Cost/Low Cost Threshold for Packaged Skin Substitutes
CMS is finalizing the proposal to continue our policy established in CY 2018 to assign skin substitutes to the low cost or high cost group. In addition, CMS presented several payment ideas to change how skin substitute products are paid under the OPPS and solicited comments on these ideas to be used for future rulemaking.

New Technology Payment Policy for Low-Volume Services
CMS is finalizing the proposal that services assigned to New Technology Ambulatory Payment Classifications (APCs) with fewer than 100 claims annually would be paid under one of several alternative payment methodologies. Specifically, CMS is finalizing the proposal to use up to four years of data to calculate the geometric mean, the median, and the arithmetic mean and to adopt through rulemaking the method that should be used to establish payment for the new technology service for the upcoming year, both for purposes of assigning the service to a new technology APC and ultimately, to a clinical APC. The goal of this policy is to promote transparency and predictability in the payment rates for these low-volume new technology procedures and to mitigate wide variation from year to year for such services.

Device Intensive Policy
In order for a procedure to be device intensive, the device cost associated with that procedure must exceeds a certain threshold of the total cost of the procedure, among other criteria. In the ASC setting, the device portion of the payment for a device-intensive procedure is based on costs reported under the OPPS. For CY 2019, CMS is finalizing the proposal to lower the device threshold from forty (40) percent to thirty (30) percent. This will allow procedures that use relatively high-cost devices to be better recognized in the OPPS and ASC setting.

Device Pass-through Applications
There were seven device pass-through applications that were reviewed for the CY 2019 final rule with comment period. CMS is approving the remedē® System Transvenous Neurostimulator for device pass-through payment status for CY 2019.

Policy to Apply 340B Drug Payment Policy to Nonexcepted Off-Campus Provider-Based Departments (PBDs)
Section 340B of the Public Health Service Act (Section 340B) allows participating hospitals and other providers to purchase certain covered outpatient drugs at discounted prices from manufacturers. CMS reexamined the appropriateness of the Average Sale Price (ASP) plus 6 percent payment methodology for 340B drugs in the CY 2018 OPPS/ASC final rule with comment period. Beginning January 1, 2018, Medicare pays an adjusted amount of ASP minus 22.5 percent for separately payable, nonpass-through drugs and biologicals that are acquired through the 340B Program by outpatient departments, including excepted off-campus PBDs of a hospital. In the CY 2019 OPPS/ASC final rule with comment period, CMS is finalizing a policy to

pay ASP minus 22.5 percent for 340B-acquired drugs furnished by non-excepted off-campus PBDs paid under the Physician Fee Schedule.

Meaningful Measures/Patients Over Paperwork

This final rule will reduce the number of measures ASCs and hospital outpatient departments are required to report under the Ambulatory Surgical Center Quality Reporting and Hospital Outpatient Quality Reporting Programs. These removals are arrived at after a careful and holistic review of all current, required quality measures. Measures are being finalized for removal after consideration under certain "removal factors": if they do not align with current clinical guidelines or practice, performance or improvement on a measure is not strongly linked to better patient outcomes, they are "topped out" (meaning that the overwhelming majority of providers are performing highly on them), or if their costs are greater than benefits in reporting. The removals are aimed at enabling providers to focus on tracking and reporting the measures that are most impactful on patient care. Overall, the final rule will eliminate a significant number of measures—a total of nine—ASCs and hospital outpatient departments are currently required to report.

Hospital Outpatient Quality Reporting (OQR) Program
The Hospital OQR Program is a pay-for-reporting quality program for services rendered in the outpatient hospital setting. The Hospital OQR Program requires hospitals to meet quality reporting requirements or receive a 2.0 percentage point reduction to the OPD fee schedule increase factor if they fail to meet these requirements. In the CY 2019 OPPS/ASC final rule, CMS is removing certain measures from the Hospital OQR Program. The removal of these measures is consistent with the CMS' commitment to using a smaller set of more meaningful measures and focusing on patient-centered outcomes measures, while taking into account opportunities to reduce paperwork and reporting burden on providers. However, CMS is not finalizing removal of two of the ten measures proposed for removal. In the CY 2019 OPPS/ASC final rule, CMS is finalizing policies to:

1. Update the Code of Federal Regulations to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets.
2. Update the Code of Federal Regulations to use the regular rulemaking process to remove a measure for circumstances that do not raise specific patient safety concerns.
3. Update the Code of Federal Regulations to immediately remove measures as a result of patient safety concerns.
4. Remove one quality measure beginning with the CY 2020 payment determination and seven quality measures beginning with the CY 2021 payment determination. We note that we are not finalizing our proposals to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (OP-29) and the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) measures.
5. Extend the reporting period from one to three years for OP-32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years.
6. Update the Code of Federal Regulations the factors to be considered when removing measures from the program and codify measure removal policies.
7. Change the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years such that they will be released once every twelve months with addenda as necessary – a modification from what was proposed.

8. Update requirements related to participation status, including removal of the Notice of Participation form for the for the CY 2020 payment determination.

Table 1: Hospital Quality Measures Being Removed from Hospital OQR Program

Measure Name	Removal Rationale
Chart-Abstracted Measures	
Median Time to ECG (OP-5)	The costs associated with the measure outweigh the benefit of its continued use in the program.
Claims-Based Measures	
Mammography Follow-up Rates (OP-9)	Measure does not align with current clinical guidelines or practice.
Thorax Computed Tomography (CT) Use of Contrast Material (OP-11)	Measure performance is “Topped-Out”.
Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (OP-14)	Measure performance is “Topped-Out”.
Web-based Tool Measures	
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (OP-12)	Performance or improvement on a measure is not strongly linked to better patient outcomes.
Tracking Clinical Results between Visits (OP-17)	Performance or improvement on a measure is not strongly linked to better patient outcomes.
Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (OP-30)	The costs associated with the measure outweigh the benefit of its continued use in the program.
Federal Data Registry Preventative Care Measures	

Influenza Vaccination Coverage Among Healthcare Personnel (OP-27)	The costs associated with the measure outweigh the benefit of its continued use in the program.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program
The ASCQR Program is a pay-for-reporting quality program that requires ASCs to meet quality reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these requirements. In the CY 2019 OPPS/ASC final rule, CMS is removing certain measures from the ASCQR Program. The removal of these measures is consistent with the CMS' commitment to using a smaller set of more meaningful measures and focusing on patient-centered outcomes measures, while taking into account opportunities to reduce paperwork and reporting burden on providers. In the CY 2019 OPPS/ASC final rule, CMS is finalizing policies to:

1. Remove one quality measure beginning with the CY 2020 payment determination and one quality measure beginning with the CY 2021 payment determination. CMS is not finalizing proposals to remove the Mammography Follow-up Rates (ASC-9) and Thorax Computed Tomography (CT) Use of Contrast Material (ASC-11).
2. Extend the reporting period from one to three years for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years.
3. Update the factors to be considered when removing measures from the program and update the Code of Federal Regulations to better reflect measure removal policies.

CMS is not finalizing its proposals to remove the following four ASCQR patient safety measures (1) (ASC-1) Patient Burns; (2) (ASC-2) Patient Falls; (3) (ASC-3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (4) (ASC-4) All-Cause Hospital Transfer/Admission. CMS is retaining these measures in the ASCQR Program and suspending their data collection beginning with the CY 2021 payment determination until further action in rulemaking with the goal of updating the measures.

Table 2: Hospital Quality Measures Being Removed from ASCQR Program

Measure Name	**Removal Rationale**
Web-based Tool Measures	
Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (ASC-10)	The costs associated with the measure outweigh the benefit of its continued use in the program.
Federal Data Registry Preventative Care Measures	

Influenza Vaccination Coverage Among Healthcare Personnel (ASC-8)	The costs associated with the measure outweigh the benefit of its continued use in the program.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program
The PCHQR Program is a quality reporting programthat began with the Fiscal Year 2014 program year. The PCHQR Program collects and publishes data from 11 PPS-exempt cancer hospitals (PCHs) on an announced set of quality measures. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41613), CMS announced that it would defer a final decision on its proposed removal of two NHSN measures from the PCHQR Program in order to conduct additional data analyses to assess measure performance based on new information provided by the Centers for Disease Control and Prevention (CDC). In the CY 2019 OPPS/ASC final rule, CMS is not finalizing the removal of these two NHSN measures. The specific measures are:

- Catheter-Associated Urinary Tract Infection Outcome Measure (CAUTI) (NQF #0138)
- Central Line-Associated Bloodstream Infection Outcome Measure (CLABSI) (NQF #0139)

Updates to OPPS Payment Rates

In accordance with Medicare law, CMS is updating OPPS payment rates by 1.35 percent. This update is based on the hospital market basket increase of 2.9 percent minus both a 0.8 percentage point adjustment for multifactor productivity (MFP) and a 0.75 percentage point adjustment required by law.

Partial Hospitalization Program (PHP) Rate Setting
The CY 2019 OPPS/ASC final rule updates Medicare payment rates for PHP services furnished in hospital outpatient departments and Community Mental Health Centers (CMHCs). The PHPs are structured intensive outpatient programs consisting of a group of mental health services paid on a per diem basis under the OPPS, based on PHP per diem costs.

Update to PHP Per Diem Rates
The CY 2019 OPPS/ASC final rule maintains the methodology established in CY 2017, which implemented a unified rate structure with a single PHP APC for each provider type for days with 3 or more services per day. In establishing the final rates for CY 2019, CMS used CY 2017 claims data to calculate the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing regulations.

Proposed Update to the PHP APC Code Set
New, revised, and deleted CY 2019 Category I and III CPT codes were included in Addendum B of the CY 2019 OPPS/ASC proposed rule for the 2019 OPPS update. While PHP is a part of the OPPS, PHP providers may not have seen those proposed changes because CMS did not also include them in the PHP section of the proposed rule. As a result, the CY 2019 OPPS/ASC final rule includes proposals to delete six existing codes from the PHP allowable code set for CMHC APC 5853 and hospital-based PHP APC 5863, and to replace them with nine new codes starting January 1, 2019. We are soliciting comments on these proposals and seek to finalize our proposed actions in the CY 2020 OPPS/ASC final rule with comment period.

Updates to ASC Payment Rates

CMS historically updated ASC payment rates annually by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). In the CY 2018 OPPS/ASC proposed rule, CMS solicited recommendations and ideas on ASC payment system reform. For the CY 2019 OPPS/ASC proposed rule, in response to the comments received, CMS proposed to update ASC payment rates using the hospital market basket rather than the CPI-U for CY 2019 through CY 2023. We also sought comment on an alternative proposal to maintain CPI-U while collecting evidence to justify a different payment update, or adopting the new proposed payment update based on the hospital market basket permanently.

We are finalizing this proposal without modification. Using the hospital market basket, CMS is updating ASC rates for CY 2019 by 2.1 percent. The change is based on the hospital market basket increase of 2.9 percent minus a 0.8 percentage point adjustment for MFP. This change will help to promote "site-neutrality" between hospitals and ASCs and encourage the migration of services from the hospital setting to the lower cost ASC setting.

New Clinical Families of Services at Off-Campus Provider-Based Departments (PBDs) Excepted from Section 603 of the Bipartisan Budget Act of 2015

In CY 2019 OPPS/ASC proposed rule, CMS proposed a policy that off-campus PBDs excepted from Section 603 of the Bipartisan Budget Act of 2015 could continue to be paid at OPPS rates for items and services in each of 19 proposed "clinical families of services" if a PBD furnished and billed for a service in that clinical family of services prior to November 2, 2015. CMS is not finalizing this proposal in the CY 2019 OPPS/ASC final rule with comment period, but we will continue to monitor the expansion of services in excepted off-campus PBDs.

Combating the Opioid Crisis

In response to recommendations from the *President's Commission on Combatting Drug Addiction and the Opioid Crisis,* to comply with the requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271), and to avoid any potential unintended consequences, under the Hospital Inpatient Quality Reporting (IQR) Program, CMS is finalizing the proposal to update the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey measure by removing the three recently revised pain communication questions. The removal of these questions is effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years, earlier than proposed. As a related modification, CMS will not publicly report the three revised Communication About Pain questions.

In addition, the *President's Commission on Combating Drug Addiction and the Opioid Crisis* also recommended that CMS review its payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. Payment for drugs that function as a supply in surgical procedures or diagnostic tests is packaged under the OPPS and ASC payment systems. In response to this recommendation as well as stakeholder requests and peer-reviewed evidence, for CY 2019, CMS is finalizing the proposal to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as a supply when used in a covered surgical procedure performed in an ASC.

CMS sought feedback in the proposed rule on whether other non-opioid alternatives for acute or chronic pain have evidence demonstrating that they lead to a decrease in opioid prescriptions and addiction and may, therefore, warrant separate payment under the OPPS and ASC payment systems. CMS will continue to analyze this issue as the agency implements section 6082 of the SUPPORT for Patients and Communities Act which requires review and adjustment of payments under the OPPS and ASC payment systems to avoid financial incentives to use opioids instead of non-opioid alternative treatments.

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