CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC)

On November 1, 2017, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule with comment period (CMS-1678-FC), which includes updates to the 2018 rates and quality provisions, and other policy changes. CMS adopted a number of policies that will support care delivery; reduce burdens for health care providers, especially in rural areas; lower beneficiary out of pocket drug costs for certain drugs; enhance the patient-doctor relationship; and promote flexibility in healthcare.

CMS is committed to transforming the healthcare delivery system – and the Medicare program – by putting a strong focus on patient-centered care, so health care providers can direct their time and resources to patients and improve outcomes. In the final rule, CMS is adjusting the amount Medicare pays hospitals for drugs that are acquired under the 340B Drug Discount Program. In addition, the final rule includes a provision that would alleviate some of the burdens rural hospitals experience in recruiting physicians by placing a two-year moratorium on enforcement of the direct supervision requirement currently in place at rural hospitals and critical access hospitals.

Patients over Paperwork Initiative

CMS recently launched the Patients Over Paperwork Initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. Through the Patients Over Paperwork Initiative, CMS, along with its partners and stakeholders, is committed to removing regulatory obstacles that get in the way of providers spending time with patients. Among the efforts to reduce regulatory burden in the Hospital Outpatient Prospective Payment System final rule include:

- CMS is reinstating the non-enforcement of direct supervision requirements for outpatient therapeutic services for Critical Access Hospitals and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019.
- CMS is finalizing the removal of three Ambulatory Surgical Center Quality Reporting (ASCQR) Program quality measures for the CY 2019 payment determination and subsequent years. Removal of these measures would alleviate maintenance costs and administrative burdens to the ASCs, resulting in a burden reduction of 1,314 hours and saving $48,066 in CY 2019.
- CMS is also finalizing the removal of 6 Hospital Outpatient Quality Reporting (OQR) Program quality measures, resulting in a burden reduction of 457,490 hours and saving $16.7 million in CY 2020 for hospitals.

OPPS Final Payment Policy Changes for 2018

OPPS Payment Update

CMS is increasing the OPPS payment rates by 1.35 percent for 2018. The change is based on the hospital market basket increase of 2.7 percent minus both a 0.6 percentage point adjustment for multi-factor productivity and a 0.75 percentage point adjustment required by law. After considering all other policy changes under the final rule, including estimated spending for pass-through payments, CMS estimates an overall impact of 1.4 percent payment increase for providers paid under the OPPS in CY 2018.

Payment for Drugs and Biologicals ("Drugs") Purchased through the 340B Drug Pricing Program

To address recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries, CMS is finalizing a change to the payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for Medicare beneficiaries.

In CY 2018, CMS is adopting a policy to pay for separately payable, nonpass-through drugs and biologicals (other than vaccines) purchased through the 340B Program at the average sales price (ASP) minus 22.5 percent rather than ASP plus 6 percent. Rural Sole Community Hospitals, PPS-exempt Cancer Hospitals, and Children's Hospitals will be excepted from this policy for CY 2018. Drugs not purchased under the 340B drug program will continue to be paid for at a rate of ASP plus 6 percent. CMS is implementing this policy in a budget neutral manner by offsetting the projected decrease in drug payments of $1.6 billion by redistributing an equal amount for non-drug items and services across the OPPS. CMS may revisit these policies for CY 2019 and is especially interested in exploring policies addressing the needs of safety net

hospitals, which play a critical role in serving the most vulnerable populations.

Supervision of Hospital Outpatient Therapeutic Services

In the CY 2009 and CY 2010 OPPS/ASC proposed rule and final rule with comment period, CMS clarified that direct physician supervision is generally required for hospital outpatient therapeutic services that are furnished in hospitals, critical access hospitals (CAHs), and in provider-based departments of hospitals. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this final rule, CMS is reinstating the non-enforcement of direct supervision requirements for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019.

Packaging of Low-Cost Drug Administration Services

A tenet of a prospective payment system is to package payment of all integral, ancillary, supportive, dependent, or adjunctive services into payment for primary services. In CY 2014, CMS proposed but did not finalize a policy to package all add-on procedures, including drug administration add-on services. In CY 2015, CMS conditionally packaged payment for ancillary services assigned to an ambulatory payment classification group with a geometric mean cost of $100 or less, but excluded certain low-cost drug administration services from this policy. To continue CMS' work toward bundling payments under the OPPS and encouraging hospital efficiencies, CMS is finalizing its proposal to conditionally package payment for low-cost drug administration services.

Inpatient Only List

The Medicare inpatient-only (IPO) list includes procedures that are typically only provided in the inpatient setting and therefore are not paid under the OPPS. Each year, CMS uses established criteria to review the IPO list and determine whether or not any procedures should be removed from the list. For CY 2018, CMS is removing total knee arthroplasty from the IPO list as well as five other procedures. CMS is also adding one procedure to the IPO list in response to public comments. In addition, CMS is precluding the Recovery Audit Contractors from conducing "site of service" reviews of outpatient total knee arthroplasty procedures for a period of two years.

High Cost/Low Cost Threshold for Packaged Skin Substitutes

Under the OPPS, payment for skin substitutes — products used to aid in wound healing — is packaged into the payment for their associated surgical procedures. These products are assigned to either a "high cost group" or a "low cost group" depending on how costly they are relative to certain cost thresholds. Consistent with current policy, CMS proposed to assign skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition for CY 2018, CMS is finalizing its proposal that a skin substitute product that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, will be assigned to the high cost group for CY 2018. The goal of this policy is to maintain similar levels of payment for skin substitute products for CY 2018 while CMS analyzes the current skin substitute payment methodology to determine whether refinements to the existing methodologies may be warranted.

Revisions to the Laboratory Date of Service Policy

For a clinical diagnostic laboratory test, the date of service (DOS) is typically the date the specimen was collected, unless certain conditions are met. CMS considered potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for molecular pathology tests and certain ADLTs which are excluded from the OPPS packaging policy and ordered less than 14 days following the date of the patient's discharge from the hospital.

After considering the public comments received, we added an additional exception to the current laboratory DOS regulations, effective January 1, 2018. This new exception to the laboratory DOS policy generally permits laboratories to bill Medicare directly for ADLTs and molecular pathology tests excluded from OPPS packaging policy if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient's discharge from the hospital outpatient department.

Partial Hospitalization Program (PHP) Rate Setting

The CY 2018 OPPS/ASC final rule with comment period 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.

For 2018, we are maintaining the methodology established in CY 2017. In CY 2017, CMS implemented a unified rate structure with a single PHP payment rate for each provider type for days with 3 or more services per day.

ASC Payment Policy Provisions

ASC Payment Update

CMS updates ASC payments annually by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). The Medicare statute specifies a multi-factor productivity (MFP) adjustment to the ASC annual update. For CY 2018, the CPI-U update is 1.7 percent. The MFP adjustment is 0.5 percent, resulting in a CY 2018 MFP-adjusted CPI-U update factor of 1.2 percent. Including enrollment, case-mix, and utilization changes, total ASC payments are projected to increase approximately 3 percent in 2018.

Comment Solicitation on ASC Payment Reform

Currently, ASC payment rates are tied to data derived from the OPPS. Given concerns about the difference between OPPS payments relative to ASC payments (55 percent in 2018), CMS solicited comments on ways to improve payment accuracy for ASCs, including the possibility of collecting ASC cost data, as well as other ideas for ASC payment reform. CMS will continue to take commenters' feedback into consideration in future policy development.

ASC Covered Procedures List

For CY 2018, CMS is finalizing its proposal to add three procedures to the ASC covered procedures list (CPL). In addition, CMS solicited comments on whether total knee arthroplasty, partial hip arthroplasty, and total hip arthroplasty meet the criteria to be added to the ASC-CPL. CMS also solicited comments from stakeholders on whether there are codes outside of the AMA-CPT surgical code range that, nonetheless, should be considered to be a surgical procedure. CMS will continue to take commenters' feedback into consideration in future policy development.

Hospital Outpatient Quality Reporting (OQR) Program

The Hospital OQR Program is a quality reporting program for outpatient hospital services. The Hospital OQR Program requires hospital outpatient facilities to submit data on quality measures and meet certain program requirements to avoid a reduction of 2.0 percentage points to their annual payment update.

In the CY 2018 OPPS/ASC final rule, CMS is finalizing proposals that balance the value of quality data with efforts to limit provider burden. CMS is finalizing the removal of 6 measures for this setting, resulting in a burden reduction of 457,490 hours and $16.7 million with respect to requirements for the CY 2020 payment determination. The measures being removed are:

- OP-21: Median Time to Pain Management for Long Bone Fracture, which measures the median time from emergency department (ED) arrival to time of initial oral, nasal, or parenteral pain medication (opioid and non-opioid) administration for emergency department patients with a principal diagnosis of long bone fracture. This measure is being finalized for removal beginning with the CY 2020 payment determination.
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures, which assesses the aggregate count of selected, higher volume, surgical procedures performed in Hospital Outpatient Departments. This measure is being finalized for removal beginning with the CY 2020 payment determination.
- OP-1: Median Time to Fibrinolysis, which assesses the median time from ED arrival to administration of fibrinolytic therapy in ED patients with ST-segment elevation on the ECG performed closest to ED arrival and prior to transfer. This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.
- OP-4: Aspirin at Arrival, which assesses the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival or before transferring from the emergency department. This measure was proposed to be removed beginning with the CY 2021 payment determination, but is

being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.

- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, which assesses the time from ED arrival to provider contact for emergency department patients. This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.
- OP-25: Safe Surgery Checklist Use, which assesses whether a hospital employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period. This measure was proposed to be removed beginning with the CY 2021 payment determination, but is being finalized for removal beginning with the CY 2020 payment determination in response to public comments requesting earlier removal.

Additionally, CMS is finalizing the proposal to delay the mandatory implementation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) under the Hospital OQR Program beginning with the CY 2018 data collection.

CMS also provides clarification on the procedures for validation of chart-abstracted measures to note that 50 outlier hospitals, based on poor measure scoring, will be targeted for validation. CMS is finalizing: policy to formalize the chart-abstracted measures validation educational review procedures, updates to include a corrections process, and corresponding regulatory updates to reflect these policies. In addition, CMS is finalizing its proposal to align the first quarter for which to submit data for hospitals that did not participate in the previous year's Hospital OQR Program and make corresponding regulatory updates. CMS is also finalizing a proposal to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy with other quality reporting programs and corresponding regulatory updates to reflect these policies. CMS is also finalizing, with modification, its proposal to publicly report OP-18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients Psychiatric/Mental Health Patients. Lastly, CMS is not finalizing its proposal to extend the Notice of Participation (NOP) deadline and make corresponding changes to the CFR.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program

The ASCQR Program is a pay-for-reporting program that requires ambulatory surgical centers (ASCs) to meet administrative, data collection, reporting, and other program requirements, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these program requirements.

In the CY 2018 OPPS/ASC final rule, CMS is finalizing the addition of two measures of hospital events following specified surgical procedures to the ASCQR program measure set for the CY 2022 payment determinations and subsequent years. Data for the two measures are collected via administrative claims and do not add provider burden to the program. The measures finalized for addition are:

- ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, which assesses all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC (beginning with the CY 2022 payment determination). For the purposes of this measure, "hospital visits" include emergency department visits, observation stays, and unplanned inpatient admissions.
- ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures, which assesses all-cause, unplanned hospital visits occurring within seven days of the urology procedure performed at an ASC (beginning with the CY 2022 payment determination). For the purpose of this measure, "hospital visits" include emergency department visits, observation stays, and unplanned inpatient admissions.

The adoption of one measure proposed in the CY 2018 OPPS/ASC proposed rule, ASC-16: Toxic Anterior Segment Syndrome (TASS), is not being finalized. CMS is finalizing proposals to remove a total of three measures for the CY 2019 payment determination and subsequent years. Removal of these measures would alleviate maintenance costs and administrative burdens to the ASCs, resulting in a burden reduction of 1,314 hours and $48,066 with respect to requirements for the CY 2019 payment determination. The three measures being removed are:

- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing, which assesses whether intravenous antibiotics given for prevention of surgical site infection were administered on time.
- ASC-6: Safe Surgery Checklist Use, which is a structural measure of facility process that assesses whether an ASC employed a safe surgery checklist that covered each of the three critical perioperative periods (prior to administering anesthesia, prior to skin incision, and prior to patient leaving the operating room) for the entire data collection period.
- ASC-7: ASC Facility Volume Data on Selected Procedures, which is a structural measure of facility capacity that collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting.

Beginning with the CY 2020 payment determination (CY 2018 data collection), CMS is finalizing the proposal to delay the mandatory implementation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) under the ASCQR Program.

Additionally, CMS is finalizing its proposal to expand the CMS online data submission tool, QualityNet, to also allow for batch submission of ASCQR Program measure data beginning with data submitted during CY 2018, and make corresponding regulatory updates. Batch submission is submission of data for multiple facilities simultaneously using a single, electronic file containing data from multiple facilities submitted via one agent QualityNet account. Logistics on batch data submission will be included in the Specifications Manual. Lastly, CMS is finalizing a proposal to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make corresponding regulatory updates to reflect this policy.

The final rule will publish in the November 13, 2017, Federal Register and can be downloaded from the Federal Register.