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FACT SHEET

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CMS Proposes Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Changes for 2018, and Releases a Request for Information (CMS-1678-P)

On July 13, 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 proposed rule (CMS-1678-P) that includes updates to the 2018 rates and quality provisions, and proposes other policy changes. CMS is proposing a number of policies that would support care delivery; reduce burdens for providers, especially in rural areas; lower beneficiary out of pocket drug costs for several 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 providers can direct their time and resources to patients and improve outcomes. In addition to the payment and policy proposals, CMS is releasing a Request for Information within the proposed rule to solicit ideas for regulatory, policy, practice, and procedural changes to better achieve transparency, flexibility, program simplification, and innovation. This will inform the discussion on future regulatory action related to hospital outpatient services and services performed in ambulatory surgical centers.

In the proposed rule, CMS is proposing to change how Medicare pays hospitals for drugs that are acquired under the 340B Drug Discount Program. In addition, the proposed rule includes a provision that would alleviate some of the burdens rural hospitals experience in recruiting physicians by placing a two-year moratorium on the direct supervision requirement currently in place at rural hospitals and critical access hospitals.

This fact sheet discusses major provisions of the proposed rule, and the Request for Information (RFI) on flexibilities and efficiencies. CMS will accept comments on the proposed rule and the

RFI until September 11, 2017. The proposed rule and the RFI (CMS-1678-P) can be downloaded from the *Federal Register* at: https://www.federalregister.gov/public-inspection.

Request for Information on Flexibilities and Efficiencies

In addition to the payment and policy proposals, CMS is releasing a Request for Information to welcome feedback on positive solutions to better achieve transparency, flexibility, program simplification and innovation. This will inform the discussion on future regulatory action related to outpatient services performed at hospitals and services performed at ambulatory surgical centers.

CMS would like to start a national conversation about improving the healthcare delivery system, how Medicare can contribute to making the delivery system less bureaucratic and complex, and how CMS can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs – thereby making the healthcare system more effective, simple, and accessible while maintaining program integrity and preventing fraud.

CMS is soliciting ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include recommendations regarding payment system re-design; elimination or streamlining of reporting; monitoring and documentation requirements; operational flexibility; and feedback mechanisms and data sharing that would enhance patient care, support the doctor-patient relationship in care delivery, and facilitate patient-centered care within outpatient stays at hospitals and services performed at ambulatory surgical centers. Ideas could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, providers, and suppliers.

In responding to the RFI, commenters should provide CMS with clear and concise proposals that include data and specific examples. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome. CMS will not respond to RFI comment submissions in the final rule, but rather will actively consider all input in developing future regulatory proposals or future sub-regulatory guidance.

OPPS Proposed Payment Policy Changes

Proposed OPPS Payment Update
CMS proposes to update OPPS rates by 1.75 percent for 2018. The change is based on the projected hospital market basket increase of 2.9 percent minus both a 0.4 percentage point adjustment for multi-factor productivity and a 0.75 percentage point adjustment required by law. After considering all other policy changes proposed under the OPPS (except for the 340B drug payment proposal), including estimated spending for pass-through payments, CMS estimates an overall impact of 2.0 percent payment increase for hospitals paid under the OPPS in CY 2018.

Payment for Drugs and Biologicals ("Drugs") Purchased with a 340B Program Discount
In the CY 2009 OPPS/ASC final rule with comment period, CMS solicited comments on whether CMS should implement a payment methodology for participating 340B hospitals and

whether there should be exceptions for certain classes of drugs under this methodology. To address recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries, for CY 2018, CMS is proposing to pay separately payable, non pass-through drugs (other than vaccines) purchased at a discount through the 340B drug pricing program at the average sales price (ASP) minus 22.5 percent rather than ASP plus 6 percent. ASP minus 22.5 percent was the Medicare Payment Advisory Commission's (MedPAC's) estimate of the average minimum discount eligible hospitals received for drugs acquired under the 340B program. Applicable drugs not purchased under the 340B drug program would continue to receive ASP plus 6 percent payment. CMS seeks comment on implementing this proposal in a manner that will bring down out-of-pocket drug costs for Medicare patients and allows providers to best meet their patients' needs.

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 proposed rule, CMS is proposing to reinstate the non-enforcement of direct supervision enforcement instructions for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CYs 2018 and 2019.

Proposed 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, to package all add-on procedures, including drug administration add-on services. In CY 2015, CMS conditionally packaged payment for ancillary services when those ancillary services are assigned to an ambulatory payment classification group with a geometric mean cost of $100 or less, but excluded drug administration services. To continue CMS' work on bundles of payment under the OPPS and encourage hospital efficiencies, CMS is proposing to conditionally package payment for low-cost drug administration services. CMS is also soliciting comment on payment methodologies for drug administration add-on services.

Comment Solicitation on Packaging
CMS is broadly soliciting comments on existing packaging policies under the OPPS, including those related to drugs that function as a supply in a diagnostic test, diagnostic procedure, or surgical procedure. In addition, CMS is interested in stakeholder feedback on common clinical scenarios involving separately payable items and services for which payment would be most appropriately packaged under the OPPS. We are soliciting public comments from a broad cross-section of stakeholders, including beneficiaries, patient advocates, hospital providers, clinicians, manufacturers, and other interested parties.

Inpatient Only List
The Medicare inpatient-only (IPO) list includes procedures that are only paid under the Hospital Inpatient Prospective Payment System. 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 proposing to remove total knee arthroplasty from the IPO list. The CY 2018 OPPS/ASC proposed rule also seeks comment regarding whether partial and total hip arthroplasty should also be removed from the IPO list.

Proposed 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 the associated primary procedure. 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 is proposing 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 proposing 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 the proposal 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.

Potential Revisions to the Laboratory Date of Service Policy
For a clinical diagnostic laboratory test, the date of service (DOS) is often the date the specimen was collected, unless certain conditions are met. For example, if the physician orders the test at least 14 days after a patient's discharge from the hospital and certain other requirements are met, the DOS is the date the test is performed (instead of the date the specimen was collected). Under the current DOS policy, if the test is ordered less than 14 days after the date of the patient's discharge from the hospital, the hospital must bill Medicare for the test and then pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

CMS has received feedback from stakeholders that the DOS policy creates unintentional operational burden for hospitals and the laboratories that perform molecular pathology tests and certain advanced diagnostic laboratory tests (ADLTs). Therefore, CMS is considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for molecular pathology tests and 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. We are seeking information from stakeholders on whether these tests, by their nature, are appropriately separable from the hospital stay that preceded the test and therefore, should have a DOS that is the date of performance rather than the date of collection.

Partial Hospitalization Program (PHP) Rate Setting
The CY 2018 OPPS/ASC proposed 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.

The CY 2018 OPPS/ASC proposed rule maintains 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 Proposed Payment Policy Provisions

ASC Payment Update
ASC payments are annually updated 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 projected to be 2.3 percent. The MFP adjustment is projected to be 0.4 percent, resulting in a proposed MFP-adjusted CPI-U update factor of 1.9 percent.

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 (56 percent in 2017), CMS is soliciting comments on ways to improve payment accuracy to ASCs and seeking comments on the collection of ASC cost data.

ASC Covered Procedures List
For CY 2018, CMS is proposing to add three procedures to the ASC covered procedures list (CPL). In addition, CMS is soliciting comment on whether total knee arthroplasty, partial hip arthroplasty, and total hip arthroplasty meet the criteria to be added to the ASC-CPL. CMS is also soliciting 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.

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 data collection requirements in order to avoid a reduction of 2.0 percentage points to their annual payment update.

In the CY 2018 OPPS/ASC Proposed Rule, CMS prepared proposals that balance the value of quality data with efforts to limit provider burden. CMS proposes to remove 6 measures, resulting in a burden reduction of 152,680 hours and $5.6 million for the CY 2020 payment determination and 304,810 hours and $11.1 million for the CY 2021 payment determination. The measures proposed to be 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 proposed to be removed 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 proposed to be removed 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 is proposed to be removed beginning with the CY 2021 payment determination.

- 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 is proposed to be removed beginning with the CY 2021 payment determination.

- 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 is proposed to be removed beginning with the CY 2021 payment determination.

- 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 is proposed to be removed beginning with the CY 2021 payment determination.

CMS is also seeking public comment on future development of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival as an electronic clinical quality measure (eCQM) and proposing the eCQM in future rulemaking.

Additionally, CMS is proposing 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 for CY 2018 data collection. However, hospitals that would like to continue to administer the survey under the voluntary national implementation, may do so in CY 2018.

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 proposing to formalize chart-abstracted measures validation educational review procedures, updates to include a corrections process, and make corresponding regulatory updates to reflect these proposals. Additional proposals include changes to the Notice of Participation (NOP) deadline and alignment of the naming of the Extraordinary Circumstances Exceptions (ECE) policy with other quality reporting programs and corresponding regulatory updates to the to reflect these proposals.

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, and reporting 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 proposed rule, CMS invites public comments on its proposal to add three measures to the ASCQR program measure set for the CY 2021 and CY 2022 payment determinations and subsequent years. In addition to meeting statutory requirements for reflecting consensus among affected parties during measure development, CMS has focused on measures that have a high impact on and support HHS' and CMS' priorities for improved healthcare outcomes, quality, safety, efficiency, and satisfaction for patients. Specifically, the proposed new measure set includes procedure-type specific measures that will provide patients with more valuable ASC performance data and address the clinical areas that are critical to providers. The three proposed measures are:

- ASC-16: Toxic Anterior Segment Syndrome (TASS) measure, which is based on aggregate measure data collected by the ASC via chart abstraction and assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within two days of surgery (beginning with the CY 2021 payment determination).

- 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.

CMS also invites public comment on its 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 for the CY 2019 payment determination. The three measures proposed for removal 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.

For the CY 2020 payment determination (CY 2018 data collection) and subsequent years, CMS is proposing 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 for CY 2018 data collection. CMS also invites public comment on measures (ASC-15a-e). Under this proposal, ASCs that would like to continue to administer the survey under the voluntary national implementation, may do so in CY 2018.

CMS also invites public comment on the Ambulatory Breast Procedure Surgical Site Infection Outcome measure (NQF #3025) for potential inclusion in the ASCQR Program in future rulemaking. This measure assesses the risk-adjusted Standardized Infection Ratio (SIR) for all surgical site infections (SSIs) following breast procedures conducted at ASCs among adult patients and reported to the CDC's National Healthcare Safety Network. Surgical site infection (SSI) is one of the most common healthcare-associated infections and contributes greatly to mortality and cost burden. Breast procedures are increasingly common at ASCs, and there is strong evidence that measurement and feedback of SSIs lead to lower SSI rates.

Additionally, CMS is inviting public comments on 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. 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. If finalized, logistics on batch data submission would be included in the Specifications Manual in the future. Lastly, CMS is also proposing to align the naming of the Extraordinary Circumstances Exceptions (ECE) policy and make corresponding regulatory updates to reflect this proposal.

CMS will accept comments on the proposed rule until September 11, 2017, and will respond to comments in a final rule on or about November 1, 2017. The proposed rule will publish in the July 20, 2017, Federal Register and can be downloaded from the Federal Register at: https://www.federalregister.gov/public-inspection.

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