MEMORANDUM

Date: November 10, 2017

Re: CMS Releases CY 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rules

The Centers for Medicare & Medicaid Services (CMS) on Nov. 1, 2017, published a Final Rule that updates payment rates and policy changes in the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. The Final Rule will be published in the Federal Register on Nov. 13, 2017. These policy changes and payment rates are effective as of Jan. 1, 2018.

Public comments on this Final Rule are due to CMS by 5 p.m. ET on Dec. 31, 2017. For further details, see the OPPS/ASC Final Rule and the related CMS Fact Sheet.

Of significance, the Final Rule reduces hospital payment for drugs purchased through the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. However, Rural Sole Community Hospitals, PPS-exempt Cancer Hospitals and Children’s Hospitals will be exempted from this policy for Calendar Year (CY) 2018. This change to Medicare drug payment policy is both significant and controversial. Within hours of the Final Rule's release, three major hospital associations – the American Hospital Association, the Association of American Medical Colleges and America’s Essential Hospitals – announced that they intend to sue CMS to stop implementation of this provision.

The rule also makes revisions to the laboratory date of service that will allow manufacturers that develop certain Advanced Diagnostic Laboratory Tests (ADLTs) to bill Medicare directly for those tests, thus eliminating the need to contract with hospitals.

Additional Key Highlights

Proposed Hospital Outpatient Department (HOPD) Payment Updates: CMS finalized a 1.35 percent increase in the conversion factor (CF). CMS anticipates that the CY 2018 CF update – along with changes in enrollment, utilization and case-mix – will result in total payments of approximately $70 billion to HOPD providers, an increase of approximately $5.8 billion from CY 2017 payment estimates. HOPDs failing to meet quality-reporting requirements will continue to receive a 2.0 percent reduction in payments for OPPS services.

Proposed ASC Payment Updates: For ASCs meeting quality reporting requirements under the Ambulatory Surgical Center Quality Reporting (ASCQR) program, CMS finalizes a 1.2 percent increase, based on a projected Consumer Price Index for All Urban Consumers (CPI-U) update of 1.7 percent minus the 0.5 percentage point multi-factor productivity (MFP) adjustment required by the Affordable Care Act (ACA). CMS estimates that this finalized update will result in approximately $4.62 billion in total payments to ASCs, an increase of approximately $130 million compared to estimated CY 2017 payments.

CMS will continue to solicit comments broadly on potential reforms to the current ASC payment system, including but not limited to:
- the rate update factor applied to ASC payments
- whether and how ASCs should submit data relating to costs
- whether ASCs should bill on the institutional claim form as opposed to the professional claim form
- other ideas to improve payment accuracy for ASCs

**Payment Changes for the 340B Program:** CMS implemented a significant Medicare Part B payment reduction for separately payable, non-pass-through drugs provided in the hospital outpatient setting. In 2018, CMS will cut Part B reimbursement for certain 340B drugs from ASP plus 6 percent to ASP minus 22.5 percent. The reduction applies to separately payable, non-pass-through drugs with status indicator "K."

CMS selected the reimbursement rate of ASP minus 22.5 percent (versus the current payment rate of ASP plus 6 percent) based on previous analysis by the Medicare Payment Advisory Commission (MedPAC). Interestingly, even MedPAC commented on the proposed rule, reiterating its recommendation that payment rates for all separately payable drugs provided in 340B hospitals should be reduced by only 10 percent of the ASP (or -4 percent).

Select facilities, including Rural Sole Community Hospitals, Children's Hospitals and PPS-exempt Cancer Hospitals, are excluded from the modified 340B reimbursement rates for CY 2018. The Final Rule does not apply to critical access hospitals (CAHs). Non-excepted provider-based sites under Section 603 of the Bipartisan Budget Act are also exempt from CMS' Part B drug reimbursement reductions and will continue to be paid at ASP plus 6 percent. CMS indicated that it will revisit this policy in CY 2019.

CMS also finalized establishing two modifiers to identify 340B purchased drugs: one for hospitals subject to the payment adjustment and the other for those facilities exempted from the new reimbursement rate. Non-exempt hospitals must report modifier "JG" on all OPPS claims for 340B-acquired drugs; exempt hospitals must report modifier "TB" for all 340B-acquired drugs (excluding CAHs). CMS may alter this policy for CY 2019 and seeks to explore policies to address the needs of safety net hospitals.

CMS expects this policy will allow for redistribution of the estimated $1.6 billion decrease in drug payments to non-drug items and services across OPPS to ensure that implementation is budget neutral. CMS will increase the non-drug OPPS conversion factor for all hospitals in 2018 by 3.2 percent. CMS believes the overall OPPS payment increase in 2018 will be 1.4 percent (1.3 percent urban; 2.5 percent rural). Effectively, 340B entities will face substantial decreases in drug reimbursement, and these dollars will be allocated to all hospitals (for-profit and nonprofit).

**Laboratory Date of Service:** In response to concerns that the current date of service (DOS) policy, also known as the "14-Day Rule," creates operational burden for hospitals and laboratories, CMS finalized its proposal to allow laboratories to bill Medicare directly for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs). These services are currently excluded from the OPPS packaging policy under the following conditions: 1) ordered less than 14 days following the date of the patient’s discharge from the hospital and 2) collected in the hospital outpatient during a hospital outpatient encounter. The CY 2018 revised policy provides an exception to the general laboratory DOS rule whereby the DOS for these tests is the date that the laboratory test was performed.
Hospital Inpatient List: The Medicare inpatient-only (IPO) list includes procedures that are only paid for under the Hospital Inpatient Prospective Payment System. Each year, CMS reviews the list to determine whether any procedures should be taken off of the list.

This year, CMS finalized a policy to remove total knee arthroplasty (TKA) from the Medicare IPO for procedures reimbursed only under IPPS. This move will allow Medicare to reimburse TKAs performed on an outpatient basis, likely resulting in a shift of thousands of procedures from inpatient to outpatient. With CMS' reimbursement rate of $12,384 for inpatient TKAs and $10,122 for outpatient TKAs, a shift of 48 percent of Medicare TKA cases to outpatient settings would result in an 18 percent decrease in reimbursement for providers and $311 million in savings for Medicare.

In addition, CMS is precluding the recovery audit contractor (RAC) from reviewing the TKA procedures for "patient status" (i.e., site of service) for a period of two years and noted that it will monitor changes in site of service to determine whether changes may be necessary to the Comprehensive Care for Joint Replacement (CJR) or the Bundled Payment for Care Improvements (BPCI) models. After receiving public comments for additions and removals to the IPO list, CMS is also removing five other procedures (Current Procedural Terminology (CPT) code 27447 for total knee arthroplasty and CPT codes 4382, 43772, 43773 and 43774 for laparoscopy) and is adding one procedure to the IPO list (CPT code 92941 for percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel).

Supervision of Outpatient Therapeutic Services in CAHs and Small Rural Hospitals: CMS has extended its non-enforcement instruction for Medicare Administrative Contractors (MACs) to not evaluate or enforce direct supervision requirements for therapeutic services provided to outpatients in CAHs and small rural hospitals with 100 or fewer beds. Though the direct supervision requirement has been applicable to CAHs and small rural hospitals for a number of years, the requirement has not historically been enforced due to CMS instructions or legislative action and stakeholder concerns regarding the difficulty in staff recruiting, particularly with specialty services, for these types of providers.

Low-Cost Drug Administration Services: CMS proposes to include drug administration into the bundle payment finalized in CY 2015 for add-on procedures with a geometric mean cost of $100 or less.

High/Low Cost Thresholds for Packaged Skin Substitutes: CMS finalized its proposal to continue the current policy of assigning skin substitute products with a geometric mean unit (MUC) or per-day cost (PDC) above the MUC or PDC thresholds to the high-cost group. CMS also finalized its proposal to keep products currently in the high-cost group that do not exceed the MUC or PDC threshold in the same group while it continues to analyze if reforms to the current payment methodology are warranted.

Partial Hospitalization Program (PHP) Rates: CMS finalized its proposal to maintain the consolidated payment from last year's Final Rule for PHP services performed in HOPDs or Community Mental Health Centers (CMHC) at a single PHP payment for three or greater services per day.

Changes for Payment for X-Ray Services Taken Using Radiography Technology: CMS finalized its proposal to establish a new modifier, "FY" (X-ray taken using computed radiography technology/cassette-based imaging), to be used on claims to identify those Healthcare Common Procedure Coding System (HCPCS) codes that describe X-rays taken using computed radiography
technology. CMS also finalized the phased-in payment reductions to be taken when this payment modifier is reported. The reduction in payments will be 7 percent for services furnished in CY 2018-2022 and 10 percent for services in or after CY 2023.

**Additional Measures to the Hospital Outpatient Quality Reporting (OQR) Program:** CMS finalized removal of six process measures to "alleviate maintenance costs with retaining them."

For 2018, CMS will remove two measures from the Hospital OQR Program for the 2020 payment determination and subsequent years:

- OP-21: Median time to pain management for long bone fracture
- OP-26: Hospital outpatient volume data on selected outpatient surgical procedures

For 2019, CMS will remove four measures from the Hospital OQR Program for the 2021 payment determination and subsequent years:

- OP-1: Median time to fibrinolysis
- OP-4: Aspirin at arrival
- OP-20: Door to diagnostic evaluation by a qualified medical professional
- OP-25: Safe surgery checklist use

CMS also finalized delayed implementation of the Outpatient Ambulatory Surgery Hospital Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey measures beginning with the 2018 data collection until action in further rulemaking. CMS did not finalize its plans to change the Notice of Participation (NOP) submission deadlines such that hospitals are required to submit the NOP any time prior to registering on the QualityNet website, rather than by the deadlines specified in the previous rule.

**Accounting for Social Risk Factors in the Hospital OQR Program:** CMS is exploring updating the risk-adjustment calculation process for the Hospital OQR program to account for social risk factors (e.g., income, education, race and ethnicity, employment, disability, community resources and social support) as part of future rulemaking. CMS' objective is to meet the goal of reducing health disparities and ensuring quality of care is assessed fairly. CMS requested public comment in the proposed rule on whether and how to implement this change as well as social risk factors that might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. CMS responded to several comments in the Final Rule and noted that all feedback will be taken into consideration as part of future rulemaking. CMS will await further analyses from the ongoing National Quality Forum (NQF) two-year trial to determine whether to move forward and welcomes public comment on operational considerations for which CMS should account.

**Additional Measures to the Ambulatory Surgical Center Quality Reporting (ASCQR) Program:** For CY 2019, CMS finalized the adoption of two out of the three proposed measures (see ASC-17 and ASC-18 below) in the ASCQR program. Two of the new measures are not NQF-endorsed.

- ASC-16: Toxic Anterior Segment Syndrome (TASS)
- ASC-17: Hospital visits after Orthopedic Ambulatory Surgical Center procedures
• ASC-18: Hospital visits after Urology Ambulatory Surgical Center procedures

CMS noted that the two new measures are collected via administrative claims and do not add provider burden to the program. The third proposed measure (ASC-16) would have been submitted via QualityNet.

CMS also finalized the removal of the following three measures beginning with the CY 2019 payment determination and subsequent years:

• ASC-5: Prophylactic intravenous (IV) antibiotic timing
• ASC-6: Safe surgery checklist use
• ASC-7: ASC facility volume data on selected procedures

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.

**Payment for Clinic and Emergency Department Services:** CMS finalized its proposal to continue with and make no changes to the current clinic and emergency department hospital outpatient visit payment policies.

**Payment for Critical Care Services:** CMS finalized its proposal to continue with and make no changes to the current critical care services payment policies.