Holland & Knight

MEMORANDUM **April 29, 2019**

Re: CMS Releases Fiscal Year (FY) 2020 Inpatient Prospective Payment System (IPPS) Proposed Rule

On April 23, 2019, the Centers for Medicare and Medicaid Services (CMS) released the Fiscal Year (FY) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule. The proposed rule will affect discharges occurring on or after October 1, 2018. It will be published in the *Federal Register* on May 3rd. **Comments on the proposed rule are due June 24, 2019.**

Click here for the CMS fact sheet, here for the proposed rule.

Key Takeaways

- The proposed payment rate increase for FY 2020 would be the largest in a decade. CMS projects that total Medicare spending on inpatient hospital services, including the capital, will increase by about $4.7 billion in FY 2020, leading to an average increase in overall payments by 3.2%.
- CMS has proposed substantial modifications to the wage index calculation methodology to address payment disparities between rural and urban facilities with the ultimate goal of increasing payment rates for hospitals in the lowest-cost areas of the country. Notably, these changes are budget neutral and thus creates "winners and losers."
- CMS proposes an increased Medicare reimbursement for hospitals administering Chimeric Antigen Receptor (CAR-T) cancer drugs, although it does not yet create a billing code for the therapies.
- CMS sets out several proposals to revise policies related to new technology add-on payments and increase payment rates (maximum new technology add-on payment increased from $186,500 to $242,450).
- CMS continues to streamline its quality measure program as it removes topped out measures and consolidates others, along with a renewed focus on opioid-related measures.
- For the Medicare and Medicaid Interoperability Programs, CMS will continue a minimum 90-day reporting period. CMS proposes new measures and seeks comments on improving the use of electronic health records (EHRs), among other topics.

Proposed Changes to Inpatient Payment Rates

CMS projects that the rate increase, together with other proposed changes to IPPS payment policies, will increase IPPS operating payments by approximately 3.5% overall. When combined with proposed changes in uncompensated care payments, new technology add-on payments, low-volume hospital payments, and capital payments, which are expected to increase payments by an additional 0.2%, CMS estimates a total increase in IPPS payments of approximately 3.7%.

CMS projects that total Medicare spending on inpatient hospital services, including the capital, will increase by about $4.7 billion in FY 2020. The proposed changes would apply to approximately 3,300 acute care hospitals and affect discharges occurring on or after October 1, 2019.

Proposed Change in Wage Index Calculation to Address Disparities

To increase payments to rural hospitals, CMS is proposing to increase the wage index for certain low-wage hospitals. As these changes are budget-neutral, this sets up a "winners vs. losers" scenario, with some hospitals in high-cost areas expected to see reduced payment rates. The increase would affect the hospitals in the bottom 25th percentile of the wage index; under the new policy, those hospital's wage index would be increased by 50% of the difference between current policy and the wage index for the 25th percentile for all hospitals. Hospitals with a wage index in the 75th percentile or higher would see their wage index decreased to offset the higher spending. If finalized, the payment changes will be phased in over four years. CMS also proposes to place a 5% cap on the reduction of any hospital's wage index in a given year.

We anticipate "winners and losers" across service lines as well. Service lines such as neurosurgery, other trauma, vascular services, neurology, and orthopedics are expected to receive updates greater than 3%, while general surgery, cardiac services, and medical oncology/hematology are proposed to see payment updates falling short of 3%.

Additionally, CMS is proposing to calculate the rural floor without hospitals that have been newly reclassified as "rural" (vs. "urban") to discourage state reclassification from taking advantage of Medicare payment policies.

Proposed DSH Payment Changes, Seeking Comment on Inclusion of FY 2017 Data

In addition to proposing updates to methodologies for the calculation of DSH payments in 2019, CMS estimates that eligible Disproportionate Share Hospitals (DSH) will receive an overall increase of approximately $8.489 billion in 2020, which reflects an average increase of 2.61%. DSH payments in 2019 were approximately $8.273 billion. These changes are due to methodological changes in Factors 1 and 2, which are used to calculate payment rates.

CMS is also proposing to use a single year of data on uncompensated care costs from Worksheet S-10 for FY 2015 to determine Factor 3 for FY 2020. They are also seeking public comments on whether they should, due to changes in the reporting instructions that became effective for FY 2017, alternatively use a single year of Worksheet S-10 data from the FY 2017 cost reports, instead of the FY 2015 Worksheet S-10 data, to calculate Factor 3 for FY 2020.

Proposed Direct Graduate Medical Education (DGME) Changes

CMS proposes to modify the definition of "non-provider sites" to include critical access hospitals (CAHs). Hospitals may include residents training in a non-provider setting in its full-time equivalent (FTE) count if the hospital incurs the residents' salaries and fringe benefits while the residents are training at that site. CAHs are not considered non-provider sites under CMS's current policy. The proposed modification would allow hospitals to claim residents training in a CAH in its FTE count as long as the nonprovider setting requirements are met.

Proposed Changes to the Hospital Readmissions Reduction Program (HRRP)

CMS is proposing to adopt eight factors CMS would use when deciding whether a measure should be removed from HRRP; update the definition of "dual eligible"; and, adopt a sub-regulatory process to address potential non-substantive changes to the payment adjustment factor components.

Proposed Changes to the Hospital Value-Based Purchasing (VBP) Program

CMS is proposing the VBP would use the same data as the HAC Reduction Program to calculate the National Health Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures beginning with CY 2020 data collection, which is when the Hospital IQR Program will cease collecting data on those measures. CMS is also proposing that the VBP would rely on the process used by the HAC Reduction Program to validate the NHSN HAI measures to ensure that the measure rates are accurate for use in the Hospital VBP Program.

Proposed Changes to the Hospital-Acquired Conditions (HAC) Reduction Program

CMS is proposing to specify the dates to collect data used to calculate hospital performance for the FY 2022 HAC Reduction Program; adopt eight factors CMS would use when deciding whether a measure should be removed from the HAC Reduction Program; and, clarify administrative processes for validating National Healthcare Safety Network (NHSN) Healthcare-associated Infection (HAI) data submitted by hospitals to the Center for Disease Control (CDC).

Proposed Changes to the Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes to remove the Claims-Based Hospital-Wide All-Cause Readmission measure and replace it with the proposed Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure with Claims and Electronic Health Record Data measure and require reporting beginning with the FY 2026 payment determination after 2 years of voluntary reporting of the Hybrid HWR measure and establish reporting and submission requirements for the hybrid measures.

CMS also proposes to adopt two new opioid-related electronic clinical quality measures (eCQMs) beginning with the CY 2021 reporting period/FY 2023 payment determination: Safe Use of Opioids – Concurrent Prescribing eCQM; and, Hospital Harm – Opioid-Related Adverse Events eCQM. CMS is also proposing three changes for reporting eCQMs. These proposals align with the Promoting Interoperability Program's Clinical Quality Measure proposals. CMS also invites public comment on three potential new measures for the Hospital IQR Program: Hospital Harm—Severe Hypoglycemia eCQM; Hospital Harm—Pressure Injury eCQM; and, Cesarean Birth eCQM.

Proposed Changes to the Medicare and Medicaid Interoperability Programs

CMS proposes several policies related to these programs:

- An EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and critical access hospitals);

- To continue for CY 2020 the Query of Prescription Drug Monitoring Program measure as optional and available for bonus points, instead of being required as finalized last year, because of unforeseen implementation challenges; and
- To remove the Verify Opioid Treatment Agreement measure beginning in CY 2020 because of feedback from stakeholders that this measure presents significant implementation challenges leads to an increase in burden and does not further interoperability.

CMS also requests information on including more meaningful measures to combat the opioid epidemic, engaging vendors and providers in improving the efficiency of EHRs, and integrating data into the Hospital Compare website, among other topics.

Proposed Long-Term Care Hospital (LTCH) Payment Updates

CMS estimates that LTCH Prospective Payment System (PPS) payments would increase by approximately 0.9%, or $37 million, in FY 2020. LTCH PPS cases paid the standard federal payment rate (i.e., cases that meet clinical criteria) are expected to increase by 2.3%, or approximately $79 million, while cases continuing to transition to the site-neutral payment rate (i.e., cases that do not meet clinical criteria) are expected to decrease by approximately 4.9%, or roughly $41 million. The site-neutral estimate includes cases that will no longer be paid a blended rate as the statutory transitional period ends for LTCH discharges occurring in cost reporting periods beginning in FY2020. CMS estimates that approximately 29% of LTCH PPS cases will be paid the site-neutral payment rate in FY 2020.

Proposed LTCH Quality Reporting Program (QRP) Changes

CMS is proposing to adopt 2 new quality measures related to transferring health information including 1) Transfer of Health Information to the Provider- Post-Acute Care (PAC), and 2) Transfer of Health Information to the Patient- Post-Acute Care (PAC), to align with the Meaningful Measures Initiative and satisfy the quality measure domain of the IMPACT Act. CMS also proposes to update the specifications to the LTCH QRP measure, Discharge to Community Post-Acute Care, by excluding nursing facility residents who already reside in the nursing home from the measure.

Proposed Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

CMS is proposing to adopt one new measure and remove two existing measures, as well as publicly report performance data on the emergency department, infection, and personnel vaccination measures. CMS is seeking public comment on potential future quality measures that could assess pain management without incentivizing the overprescribing of opioids, as well as those that could assess alternative pain management methodologies for individuals with cancer.

Payment Methodologies for CAR-T Therapies

The proposed rule states that CMS has received a request to create a new Medicare Severity Diagnosis Related Groups (MS-DRG) for procedures involving CAR T-cell therapies. The agency notes its belief that it may be premature to consider this since these therapies are new. For FY 2020, CAR-T therapies will continue to use the current MS-DRG assignment. However, CMS is seeking public comment on payment alternatives for CAR-T therapies and how these alternatives would affect access to care and incentives to lower drug prices.

Proposed Increase to New Technology Add-On Payments (NTAP)

CMS' NTAP allows for an additional payment for medical services or technologies found to be 1) new; 2) disproportionately costly to the existing MS-DRG, and 3) a substantial clinical improvement. This additional payment is equal to the lesser of:

- 50 percent of the cost of the new technology or service, or
- 50 percent of the amount by which the costs of the case exceed the DRG payment.

CMS received feedback from stakeholders that the 50 percent add-on does not adequately reflect the cost of some extremely-high-cost therapies (e.g., CAR-T therapy). Therefore, for FY 2020, CMS proposes to increase this percentage increase threshold to 65 percent in both of the above cases. CMS estimates that this increase in payments will total $110 million in FY 2020.

Request for Comments on NTAP Substantial Clinical Improvement

CMS notes that, over the years, there have been multiple requests for clarification as to what constitutes a substantial clinical improvement for both NTAP and outpatient pass-through payments, and is seeking comments on the type of additional information and guidance that would be helpful. These comments will serve as the basis for future rulemaking.

NTAP Applications for FY 2020

CMS identified 17 new applications for NTAP for FY 2020:

- AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution for obenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma (Progenics Pharmaceuticals)
- CABLIVI® (caplacizumab-yhdp) humanized bivalent nanobody to inhibit microclot formation with acquired thrombotic thrombocytopenic purpura (aTTP) (Sanofi)
- CivaSheet® brachytherapy source for the treatment of selected localized tumors (CivaTech Oncology)
- CONTEPO™ (Fosfomycin for Injection) to treat complicated urinary tract infections (cUTIs) caused by multi-drug resistant (MDR) pathogens in hospitalized patients (Nabriva Therapeutics)
- DuraGraft® Vascular Conduit Solution to protect the endothelium of the vein graft by mitigating ischemic reperfusion injury (Somahlution)
- Eluvia™ Drug-Eluting Vascular Stent System for the treatment of lesions in the femoropopliteal arteries (Boston Scientific)
- ELZONRIS™ (tagraxofusp, SL-401) targeted therapy for the treatment of blastic plasmacytoid dendritic cell neoplasm (Stemline Therapeutics)
- Erdafitinib second-line treatment for locally advanced or metastatic urothelial carcinoma (Johnson & Johnson/Janssen Oncology)
- ERLEADA™ (Apalutamide) androgen receptor inhibitor for non-metastatic castration-resistant prostate cancer (Johnson & Johnson/Janssen Products)
- SPRAVATO (Esketamine) nasal spray for treatment-resistant depression (Johnson & Johnson/Janssen Pharmaceuticals)
- XOSPATA for relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation (Astellas Pharma)

- GammaTile™ brachytherapy technology for brain tumors (GT Medical Technologies, previously submitted for FY 2018 and 2019)
- Imipenem, Cilastatin, and Relebactam (IMI/REL) Injection for complicated intra-abdominal infections and complicated urinary tract infections (Merck & Co.)
- JAKAFI™ (Ruxolitinib) oral kinase inhibitor (Incyte Corporation)
- Supersaturated Oxygen (SSO2) Therapy (DownStream® System) for myocardial infarction (TherOx, Inc.)
- T2Bacteria® Panel (T2 Bacteria Test Panel) to aid in the diagnosis of bacteremia (T2 Biosystems)
- VENCLEXTA® oral anti-cancer drug for chronic lymphocytic leukemia or small lymphocytic lymphoma or acute myeloid leukemia (AbbVie Pharmaceuticals)

Proposed Discontinued and Continued NTAP Payments

CMS is proposing to maintain NTAP for 10 of the 13 technologies that currently receive these payments and discontinue NTAP for the remaining three technologies in FY 2020.

CMS proposes ending NTAP payment for the following:

- Defitelio® treatment for the hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. (Jazz Pharmaceuticals' NTAP application approved for the fiscal year 2017)
- Ustekinumab (Stelara®) intravenous (IV) infusion treatment for moderately to severely active Crohn's disease. (Janssen Biotech FY 2018)
- Bezlotoxumab (ZINPLAVA™) to reduce the recurrence of Clostridium difficile infection. (Merck & Co. FY 2018)

CMS proposes to extend NTAP status for the following:

- KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel) CD-19-directed T-cell immunotherapies for aggressive variants of non-Hodgkin lymphoma. (Novartis Pharmaceuticals & Kite Pharma FY 2019)
- VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection) for newly diagnosed therapy-related acute myeloid leukemia. (Jazz Pharmaceuticals FY 2019)
- VABOMERE™ (meropenem-vaborbactam) for complicated urinary tract infections (cUTIs). (Melinta Therapeutics FY 2019)
- remedē® System transvenous phrenic nerve stimulator for moderate to severe central sleep apnea. (Respicardia FY 2019)
- ZEMDRI™ (Plazomicin) a next-generation aminoglycoside antibiotic. (Achaogen FY 2019)
- GIAPREZA™ synthetic human angiotensin II to raise blood pressure in septic or other distributive shock. (La Jolla Pharmaceutical Company FY 2019)
- Sentinel® Cerebral Protection System. (Claret Medical FY 2019)
- AQUABEAM System (Aquablation) for lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH). (PROCEPT BioRobotics Corporation FY 2019)
- AndexXa™ (Andexanet alfa) for use in the treatment of patients who are receiving treatment with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. (Portola Pharmaceuticals FY 2019).

Proposed NTAP Pathway for Devices

CMS proposed an alternative NTAP pathway for a medical device that receives Food and Drug Administration (FDA) marketing authorization and is part of an FDA expedited program for medical devices, which is currently the Breakthrough Devices Program.

If a medical device subject to one of the FDA's expedited programs has received marketing authorization from the FDA, CMS would consider that product "new" and "not substantially similar" to existing technology for purposes of the NTAP. Under this proposal, the medical device would only need to meet the cost criterion to receive the add-on payment. This change would begin with applications received for new technology add on payments for FY 2021.