CMS Releases Final Rule on the FY 2017 Inpatient Prospective Payment System

Late this afternoon, the Centers for Medicare and Medicaid Services (CMS) released its FY 2017 Inpatient Prospective Payment System (IPPS) Proposed Rule. CMS estimates that the final rule will increase the average FY 2017 IPPS operating payment rate by 0.95 percent for hospitals that successfully participate in the Hospital Inpatient Quality Reporting Program (IQR) and are meaningful electronic health record (EHR) users. CMS also projects that total IPPS payments for operating and capital costs will increase by approximately $746 million in FY 2017, compared to payments made in FY 2016, when all payment changes in the final rule are taken into account. Key items of interest in the final rule are summarized below:

CMS’ Final IPPS Rule for FY 2017 will result in an increase in the average payment per discharge for all hospitals by approximately 0.95 percent. The update includes the following specific adjustments:

- a projected +2.7 percent reflecting changes in the hospital market basket
- an adjustment of -0.3 percentage point for productivity increases
- an adjustment of -0.75 percentage point to the market basket as required by the Affordable Care Act of 2010 (ACA)
- a -1.5 percentage point adjustment for documentation and coding changes required by the American Taxpayer Relief Act of 2013
- a +0.8 percentage point adjustment to remove the impact of CMS’ FY 2014 prospective adjustment of -0.2 percent when it implemented the 2-Midnight policy.

CMS will apply additional reductions for Medicare disproportionate share spending, excess readmissions, a continued 1 percent reduction for hospitals in the highest quartile of hospital acquired conditions, and bonuses and penalties for value-based purchasing.

2-Midnight Rule/Short Inpatient Stays:

CMS finalizes its proposal to reverse course on CMS’ previous policy to apply a -0.2 percent reduction to inpatient rates for anticipated increases in spending due to the implementation of the 2-Midnight policy. CMS first implemented the prospective adjustment in FY 2014. CMS is applying an adjustment of 0.6 percent to pay back the reductions in FY 2014, 2015 and 2016 and a 0.2 percent adjustment to reverse the policy permanently.
New Technology Add-on Payments:

CMS finalizes its proposal to continue new technology add-on payments in FY 2017 for:

- **CardioMEMS™ HF (Heart Failure) Monitoring System.** The maximum new technology add-on payment for a case involving the CardioMEMS HF Monitoirng System will remain at $8,875 for FY 2017.
- **Blinatumomab (BLINCYTO™).** The maximum new technology add-on payment for a case involving BLINCYTO will remain at $27,017.85 for FY 2017.
- **LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter.** The maximum add-on payment for a case involving LUTONIX® and IN.PACT™ Admiral™ remains at $1,035.72 for FY 2017.

CMS also finalizes its proposal to discontinue new technology add-on payments in FY 2017 for:

- **Kcentra™**
- **Argus® II System**
- **MitraClip® System**
- **Responsive Neurostimulator (RNS®) System**

CMS considered nine applications (five of which are for medical device technologies and four for drugs) for new-technology add-on payments in FY 2017. CMS approved five applications, rejected two applications, and one application was withdrawn and another not receive FDA approval. Details for the nine new applications are below:

- **MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine)** – developed for use in the treatment of children diagnosed with severe spinal deformities, such as scoliosis. CMS determined that the MAGEC® Spinal Bracing Distraction system meets all of the criteria for approval of new technology add-on payments for FY 2017. Cases involving the MAGEC® Spinal Bracing Distraction system that are eligible for new technology add-on payments will be identified by the ICD-10-PCS procedure codes XNS0032, XNS0432, XNS3032, XNS3432, XNS4032, and XNS4432. The maximum new technology add-on payment for a case involving the use of the MAGEC® Spinal Bracing Distraction system is $15,750 for FY 2017.
- **Idarucizumab** – a product developed as an antidote to reverse the effects of PRADAXA® (Dabigatran). CMS determined that Idarucizumab meets all of the criteria for approval of new technology add-on payments. Cases involving Idarucizumab that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure code XW03331. The maximum new technology add-on payment amount for a case involving the use of Idarucizumab is $1,750 for FY 2017.
- **Defitelio® (Defibrotide)** – a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. CMS determined that the Defitelio® meets all of the criteria for approval of new technology add-on payments. Cases involving Defitelio® that are eligible for new technology add-on
payments will be identifiable by ICD-10-PCS procedure codes XW03392 and XW04392. The maximum new technology add-on payment amount for a case involving the use of Defitelio® is $75,900 for FY 2017.

- **GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)** – a device that consists of both the Iliac Branch Component (IBC) and the Internal Iliac Component (IIC) and each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. CMS has determined that the GORE IBE device system meets all of the criteria for approval of new technology add-on payments for FY 2017. Cases involving the GORE IBE device that are eligible for new technology add-on payments will be identified by ICD-10-PCS procedure codes: 04VC0EZ; 04VC0FZ; 04VC3EZ; 04VC3FZ; 04VC4EZ; 04VC4FZ; 04VD0EZ; 04VD0FZ; 04VD3EZ; 04VD3FZ; 04VD4EZ; and 04VD4FZ. The maximum new technology add-on payment for a case involving the use of the GORE IBE device is $5,250 for FY 2017.

- **Vistogard™ (Uridine Triacetate)** – developed as an antidote to Fluorouracil toxicity. CMS determined that Vistogard™ meets all of the criteria for approval of new technology add-on payments for FY 2017. Cases involving Vistogard™ that are eligible for new technology add-on payments will be identified by any one of ICD-10-PCS diagnosis codes T45.1X1A, T45.1X1D, T45.1X1S, T45.1X5A, T45.1X5D, and T45.1X5S in combination with ICD-10-PCS procedure code XW0DX82. The maximum new technology add-on payment amount for a case involving the use of Vistogard™ is $37,500 for FY 2017.

- **MIRODERM Biologic Wound Matrix** – a non-crosslinked acellular wound matrix that is derived from the porcine liver and is processed and stored in a phosphate buffered aqueous solution to manage and heal wounds. CMS believes that MIRODERM is substantially similar to other wound treatment matrixes and, therefore, finds that it does not meet the newness criterion, and is not eligible for new technology add-on payments.

- **Titan Spine Endoskeleton® nanoLOCK™ Interbody Device** – a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). Due to the lack of actual clinical data using the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD and Cervical DDD, CMS is unable to determine if Titan Spine Endoskeleton® meets the substantial clinical improvement criterion. Therefore, CMS is not approving new technology add-on payments for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD and Cervical DDD for FY 2017. CMS states that the applicant can reapply in FY 2018 and provide additional clinical data supporting substantial clinical improvement.

- **Andexanet Alfa** – an antidote used to treat patients who are receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Andexanet Alfa withdrew its application prior to the issuance of the final rule.
• **EDWARDS INTUITY Elite™ Valve System** – a device that uses a rapid deployment valve system and serves as a prosthetic aortic valve, which is inserted using surgical aortic valve replacement (AVR). EDWARDS INTUITY Elite Valve System did not receive FDA approval for its technology by July 1, 2016, and therefore was ineligible for consideration for new-technology add-on payments for FY 2017.

CMS proposed to change the annual in-person New Technology Town Hall meeting to be a webcast/conference call meeting but because of the concerns of commenters has decided in the interim to continue to host the new technology town hall meetings in person.

In response to AdvaMed recommendations for changing and broadening criteria used in the approval process for NTAP, CMS states that it is not including changes in the final rule but would take the recommendations into consideration in future rulemaking.

**Hospital-Acquired Condition (HAC) Reduction Program:**

In the final rule, CMS makes several changes to existing HAC Reduction Program policies including:

- Establishing National Healthcare Safety Network (NHSN) CDC Healthcare Associated Infections (HAI) data submission requirements for newly opened hospitals.
- Clarifying data requirements for Domain 1 scoring;
- Establishing performance periods for the FY 2018 and FY 2019 HAC Reduction Program;
- Adopting the refined PSI 90: Patient Safety for Selected Indicators Composite Measure (NQF # 0531); and
- Changing the Program scoring methodology from the current decile-based scoring to a continuous scoring methodology.

**Hospital Readmissions Reduction Program:**

For FY 2017 and subsequent years, the reduction is based on a hospital’s risk-adjusted readmission rate during a three-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and, effective for FY 2017, coronary artery bypass graft (CABG). In order to align with other quality reporting programs and allow the posting of data as soon as possible, in the final rule CMS is updating the public reporting policy so that excess readmission rates will be posted to the *Hospital Compare* website as soon as feasible following the hospitals’ preview period.
Hospital Value-Based Purchasing (VBP):

CMS finalizes their proposal to implement updates to the Hospital VBP Program and to expand the number of measures.

- For FY 2019 CMS finalizes their proposal:
  - To expand the number of hospital units to include two National Healthcare Safety Network (NHSN) measures – CAUTI and CLABSI.

- For FY 2021 CMS finalizes their proposal:
  - To expand the cohort used to calculate the 30-day pneumonia mortality measure beginning with the FY 2021 program year.
  - To add two condition-specific payment measures – one for acute myocardial infarction and one for heart failure – beginning with the FY 2021 program year and a 30-day mortality measure following CABG surgery beginning with the FY 2022 program year.

- The rule also finalizes changes to the policy that governs whether a hospital will be excluded from the program if it is cited for deficiencies that pose immediate jeopardy to the health and safety of patients.

Hospital Inpatient Quality Reporting (IQR) Program:

- CMS finalizes their proposal to add a total of four new claims-based measures for the FY 2019 payment determination and subsequent years.
  - Three clinical episode-based payment measures, and one communication & coordination-of-care measure, including:
    - Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure;
    - Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure; and
    - Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure.

- CMS is also finalizing their proposal to remove 15 measures for the FY 2019 payment determination and subsequent years.
  - 13 of these measures are electronic clinical quality measures (eCQMs), two of which CMS is also removing in their chart-abstracted form because they are “topped-out” and two others are structural measures.

- CMS is also finalizing a number of changes in relation to eCQMs regarding the validation process and submission requirements.
PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program:

In the FY 2017 IPPS/LTCH PPS final rule, CMS is finalizing one new measure for this program, adding a measure of Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy.

CMS is also expanding the patient cohort of the previously finalized “Radiation Dose Limits to Normal Tissues for Patients Receiving 3D Conformal Radiation Therapy” measure (NQF #0382). The new cohort will include breast and rectal cancer patients in addition to the previous cohort of lung and pancreatic cancer patients.

Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP):

In order to satisfy the requirements of the IMPACT Act, CMS is finalizing one new assessment-based quality measure, and three claims-based measures for inclusion in the LTCH QRP:

- Discharge to Community – Post Acute Care (PAC) LTCH QRP (claims-based);
- Medicare Spending Per Beneficiary (MSPB) – PAC LTCH QRP (claims-based);
- Potentially Preventable 30 Day Post-Discharge Readmission Measure for LTCHs (claims-based); and
- Drug Regimen Review Conducted with Follow-Up for Identified Issues (assessment-based).

A copy of the 2,434 page final rule is available [here](#). A more detailed summary of the final rule will follow in the next couple weeks.

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