KEY CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) PROPOSED RULE FOR FY 2017

This Quorum IPPS Compass memo highlights the key payment policy changes proposed in the rule, which can be found at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-09120.pdf. It focuses on proposed changes that will be important to medical device and drug companies.

CONTENTS AND EXECUTIVE SUMMARY

On April 18, 2016, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that updates fiscal year (FY) 2017 Medicare payment policies and rates for inpatient stays at general acute care and long-term care hospitals (LTCHs), and implements statutory provisions from the Affordable Care Act (ACA), American Taxpayer Relief Act of 2012, and other legislation.

How to Comment

Please note that all payment policies discussed below are tentative and that CMS invites comments from the public. The comment deadline is 5 p.m. EST on June 17, 2016. CMS encourages comments to be submitted electronically at: http://www.regulations.gov/

I. TECHNICAL CHANGES

- Proposed Changes in the Inpatient Hospital Update for FY 2017
  - Payment for hospitals will remain directly impacted by whether they participate in submitting quality data and are meaningful Electronic Health Record (EHR) users.

II. PROPOSED RULE POLICIES THAT ARE NOT TECHNOLOGY SPECIFIC

- ICD-10 Conversion
  - CMS has lifted the “code freeze” and will resume regular annual updates to ICD-10 coding sets. The first set new ICD-10-CM diagnosis and ICD-10-PCS procedure codes are due to be implemented on October 1, 2016.

- Two Midnight Policy
  - CMS is proposing to remove the -0.2% payment adjustment under the Two Midnight Policy and to implement a “-0.8% increase in FY 2017 to make up for the 0.2% reduction in hospital payment rates from FY 2014-2016.
Disproportionate Share Hospital (DSH) Payment
   - CMS projects that Medicare DSH payments and additional payments for uncompensated care made for FY 2017 would reduce payments overall by approximately 0.3% compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2016.

Proposals to Improve Quality of Care during Hospital Inpatient Stays
   - The proposed rule will update the measures and financial incentives in programs such as the Hospital Acquired Condition (HAC) Reduction Program, Hospital Value-Based Purchasing (VBP) Program, and Hospital Inpatient Quality Reporting (IQR) Program.

III. MEDICAL TECHNOLOGY RELATED ISSUES AND OTHER CMS RECOMMENDATIONS THAT HELP INFORM ON RATIONALE FOR PAYMENT POLICY

New Technology Add-On Payment (NTAP) Applications

The majority of the nine applications submitted for NTAP were not supported by CMS based on the following concerns:
   - Substantial similarity to other currently available treatment options
   - Trial design and outcomes data
   - Insufficient clinical improvement over existing technology

MS-DRG Classifications: Payment Updates

Requests made to establish entirely new Medicare Severity Diagnosis Related Groups (MS-DRGs) were generally not supported by CMS. However, CMS is supporting multiple requests for reassignments of ICD-10-PCS procedure codes to different MS-DRGs under more clinically appropriate MDCs and in general, MS-DRG reassignments that would more accurately replicate and be more consistent with ICD-9-CM MS-DRG logic. Some of the significant changes supported by CMS include, but are not limited to:
   - Deleting MS-DRG 30 and modifying MS-DRG 228-229 for transcatheter mitral valve repair with implant procedures:
     - Proposed MS-DRG 228: Other Cardiothoracic Procedures with MCC
     - Proposed MS-DRG 229: Other Cardiothoracic Procedures without MCC
   - Revising ICD-10 MS-DRG logic behind assignments to MS-DRGs 242-243, 258-259, and 260-261 for certain pacemaker insertion and removal procedures.
   - Adding 58 new ICD-10-PCS procedure code combinations describing knee joint procedures to MS-DRGs 466-468.
   - Re-assigning certain ICD-10-PCS codes describing endovascular thrombectomy of the lower and upper limbs to MS-DRGs 270-272.
   - Designating certain ICD-10-PCS procedure codes describing implantation or revision of a loop recorder as O.R. procedures and assignment of those codes to MS-DRGs 40-42, 260-262, 579-581, 907-909, 957-959.
I. TECHNICAL CHANGES

❖ Proposed Changes in the Inpatient Hospital Update for FY 2017

In FY 2015, CMS implemented major changes that affected hospital-specific MS-DRG payment rates. This year, payment for hospitals will continue to be directly impacted by whether they participate in submitting quality data and are meaningful Electronic Health Record (EHR) users.

For FY 2017, there are four possible scenarios for payment:

1. For hospitals that do not submit quality data and are not meaningful EHR users, the applicable percentage adjustment is -1.25% to the operating standardized amount.
2. For hospitals that submit quality data but are not meaningful EHR users, the applicable percentage adjustment is -0.55% to the operating standardized amount.
3. For hospitals that do not submit quality data but are meaningful EHR users, the applicable percentage adjustment is 0.85% to the operating standardized amount.
4. For hospitals that submit quality data and are meaningful EHR users, the applicable percentage adjustment is 1.55% to the operating standardized amount.

The annual rate update includes a -1.5% adjustment based on the American Taxpayer Relief Act of 2012, which requires CMS to recover $11 billion by FY 2017 to fully recoup documentation and coding overpayments related to the transition to the MS-DRG payment system, which began in FY 2008.

II. PROPOSED RULE POLICIES THAT ARE NOT TECHNOLOGY-SPECIFIC

❖ ICD-10 Conversion

The ICD-9 to ICD-10-CM/PCS transition was officially implemented October 1, 2015. The FY 2017 Proposed Rule release includes a table of 1900 new ICD-10-CM diagnosis codes and nearly 3650 new ICD-10-PCS procedure codes.

The ICD-10-PCS codes provide a heightened level of detail in the procedures and the recognition of medical devices. However, even with this additional granularity, the class of procedures with multiple devices classify into the same array of MS-DRGs. For example, ICD-10-PCS code 047Y446 (Dilation of Lower Artery, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach) and 047Y47Z (Dilation of Lower Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach) both map to MS-DRGs 252-254 and 981-983.

From October 1, 2012 to October 1, 2015, CMS put in place a “code freeze” that limited updates to ICD-9-CM and ICD-10 code sets. During this time, the ICD-10 (previously ICD-9-CM) Coordination and Maintenance Committee continued to meet twice a year. Requests for new ICD-10-CM diagnosis and ICD-10-PCS procedure codes were discussed at the most recent September 22-23, 2015 and March 9-10, 2016 Committee meetings for implementation on October 1, 2016.

In the FY 2017 Proposed Rule, CMS has lifted this freeze and on October 1, 2016, one year after ICD-10 implementation, CMS will release its first annual update to ICD-10.
Key Proposed Changes to IPPS for FY 2017

- **Two Midnight Policy**

  CMS is proposing to remove the -0.2% payment adjustment under the Two Midnight Policy. Medicare initially imposed this cut because they anticipated a $220 million spending increase due to an expected increase in inpatient admissions. Due to industry backlash and legal troubles, CMS is permanently removing this adjustment and for FY 2017, hospitals will see an increase of ~0.8% to make up for the 0.2% reduction in payment rates from FY 2014-2016.

- **Disproportionate Share Hospital (DSH) Payment**

  Disproportionate Share Hospitals serve a high number of low-income patients and as such, qualify for additional Medicare payments.

  CMS continues to implement the changes to DSH hospital payment as mandated by the ACA. Hospitals that receive Medicare DSH payments receive 25% of the amount they previously would have received prior to ACA. The remainder, equal to 75% of what otherwise would have been paid as Medicare DSH payments, will be the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments.

  For FY 2017, hospitals will still receive the initial 25% payment. CMS is proposing to provide approximately 42.56% (56.74% of the remaining 75%) of the estimated Medicare DSH payments prior to the ACA as additional payment to hospitals for their relative share of the total amount of uncompensated care. This proposal would cut total uncompensated care payments (approximately $6.4 billion) by 5.49% in FY 2017 compared to uncompensated care payments in FY 2016 (approximately $6 billion).

  For FY 2017, CMS continues to base uncompensated care payment distribution on insured low-income days, but is changing its cost reporting requirements for DSH eligible hospitals. In contrast to its FY 2016 methodology, CMS is proposing to utilize data on low-income insured days from three years of cost reporting periods (data from FY 2011, FY 2012, FY 2013 cost reports) instead of one. Additionally, CMS is also proposing to create proxy Medicare SSI values for Puerto Rico hospitals.

  For FY 2017, CMS conducted an impact analysis of the above changes that estimates total Medicare DSH payments across all eligible DSH hospitals for FY 2017 to be $9.598 billion, a reduction of approximately 1.4% (or approximately $134 million) compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2016 ($9.732 billion). DSH payment reductions in FY 2017 are to estimated be $114 million for urban hospitals and $20 million for rural hospitals. CMS projects that rural hospitals will face a greater impact from reduction in DSH payments (-4.3%) than urban hospitals (-1.2%). Among rural hospitals, smaller hospitals are projected to have greater reductions (-6.3%) than larger hospitals (reductions of less than -3.5%). By contrast, among urban hospitals, smaller hospitals are estimated to have an increase in DSH payments (+0.9%) compared to payment reductions for larger hospitals (-1.3%).

  For FY 2018 and subsequent years, CMS is proposing the following updates to its uncompensated care payment methodology:
Key Proposed Changes to IPPS for FY 2017

- **Utilization of Worksheet S-10 data in addition to low-income insured days data**: The use of Worksheet S-10 as a data source was originally proposed in FY2014 IPPS rulemaking and has since been validated by CMS’ benchmark analysis, which showed strong correlation between data pulled from Worksheet S-10 and from IRS Form 990 as used by non-profit hospitals. Starting with FY 2014 Worksheet S-10 data in the Medicare Cost report, CMS is proposing to incorporate cost data from Worksheet S-10 data over a three-year period in its calculation of uncompensated cost care payments along with insured low income day data. However, CMS intends to move towards exclusive reliance on Worksheet S-10 data in distributing uncompensated care payments by FY 2020.

- **Formal definition of “uncompensated care”**: Along with incorporating the utilization of Worksheet S-10, CMS is proposing to codify a definition of “uncompensated care” based on line 30 in Worksheet S-10, which calculates uncompensated care by summing the cost of charity care and the cost of non-Medicare bad debt. The proposed definition excludes the cost of Medicaid shortfalls. CMS is proposing to codify this definition of “uncompensated care” in the regulation at § 412.106(g)(1)(iii)(C).

Overall, CMS projects that Medicare DSH payments and additional payments for uncompensated care made for FY 2017 would reduce payments overall by approximately 0.3% as compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2016.

- **Proposals to Improve Quality of Care during Hospital Inpatient Stays**

The FY 2017 IPPS Proposed Rule will update the measures and financial incentives in the Hospital Acquired Condition Reduction, Hospital Value-Based Purchasing and Hospital Readmissions Reduction programs. It also addresses the Hospital Inpatient Quality Reporting Program and Electronic Health Records Incentive Program. The information below summarizes the major quality-related provisions of the proposed rule.

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

Section 1886(p) of the Social Security Act, as added by Section 3008 of the Affordable Care Act, requires CMS to establish an incentive program for hospitals to reduce the incidence of HACs by applying a one percent payment reduction to hospitals that rank in the lowest performing quartile of all subsection (d) hospitals relative to a national average of HACs acquired during an applicable hospital stay. Under the scoring methodology to calculate a Total HAC Score for each hospital, hospitals are given a score for each measure within two domains:

- **Domain 1**: Comprises the Patient Safety Indicator (PSI) 90 measure, a composite of 8 measures
- **Domain 2**: Measures include Centers for Disease Control and Prevention Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia, and *Clostridium difficile* Infection (CDI).

A score is calculated for each domain and the two domains are weighted to determine a Total HAC Score. For FY 2017, the weight of Domain 1 is 15% and the weight of Domain 2 to 85%. Hospitals with a Total HAC Score in the lowest performing quartile are subject to a 1% payment penalty.
In the FY 2017 IPPS Proposed Rule, CMS has proposed the following key changes:

1. Clarify the data submission requirements for Domain 1

Starting in FY 2017, CMS proposes to define “complete data” for the PS1 90 measure within Domain 1 as three or more eligible discharges for at least one component indicator of the composite measure and 12 months or more of data to receive a Domain 1 score. As previously established in the FY 2014 final rule, if a hospital does not have “complete data” to calculate the PSI 90 measure score for Domain 1 but does have “complete data” for at least one measure in Domain 2, the total HAC score would depend entirely on the Domain 2 score.

2. Adopt a Modified PSI 90 Patient Safety and Adverse Events Composite for FY 2018 and beyond

CMS proposes adopting the NQF’s changes to the PSI 90 composite measure, which include:
- Renaming the measure to “Patient Safety and Adverse Events Composite” (NQF #0531)
- Addition of three new indicators: PSI 09 Perioperative Hemorrhage or Hematoma Rate, PSI 10Physiologic and Metabolic Derangement Rate, PSI 11 Postoperative Respiratory Failure Rate
- Removal of PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate
- Revision of the weighting system of each component to account for the volume of occurrence of each event as well as the harms associated with the event

3. Change the scoring methodology from a decile-based scoring system to a continuous scoring methodology

At present, a Total HAC score is calculated for each hospital by assigning a score of 1 to 10 to each measure, then weighting the scores by domain weight. The Total HAC score is used to identify the bottom quartile of subsection (d) hospitals that would be subject to payment adjustments. Instead, CMS is proposing to use a Winsorized z-score system to rank hospital HAC scores, which is a continual measure system to determine a hospital’s score distance from the national mean starting in FY 2018 and beyond.

- **Hospital Readmissions Reduction Program (HRRP)**

The HRRP began on October 1, 2012 and adjusts payments based on each hospital’s ratio of actual versus expected readmissions. For FY 2017, CMS estimates that the HRRP will save approximately $532 million, an increase of approximately $100 million over estimated FY 2016 savings.

The HRRP includes the following five conditions: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), total hip arthroplasty/total knee arthroplasty (THA/TKA), and chronic obstructive pulmonary disease (COPD). Beginning FY 2017, HRRP will include a new sixth condition: Coronary Artery Bypass Graft (CABG) Surgery.

In order to avoid payment reductions, hospitals must have an Excess Readmissions Ratio less than or equal to one for each of the six measures. Similar to the methodology of previous years, CMS proposes
to calculate HRRP payment adjustments for FY 2017 retrospectively, based on data from the 3-year period from July 1, 2012 through June 30, 2015.

- **Hospital Inpatient Quality Reporting (IQR) Program and the Electronic Health Record (HER) Incentive Program**

The Hospital IQR Program grew out of the Hospital Quality Initiative developed by CMS in consultation with hospital groups. Measures reported under the Hospital IQR Program are published on the Hospital Compare Web site (http://www.medicare.gov/hospitalcompare/search.html), and may later be adopted for use in the Hospital VBP Program.

CMS is proposing to remove 15 measures for the FY 2017 Reporting/FY 2019 Payment Determination. The 13 Electronic Clinical Quality Measures (eCQMs) listed in the table below are also proposed to be removed from the EHR Incentive Program.

**Table 1: Measures Proposed for Removal for FY 2019 Payment Determination and Subsequent Years**

<table>
<thead>
<tr>
<th>Electronic Clinical Quality Measures</th>
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<tbody>
<tr>
<td>• AMI-2: Aspirin Prescribed at Discharge for AMI (NQF #0142)</td>
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<td>• AMI-7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival</td>
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<td>• AMI-10: Statin Prescribed at Discharge</td>
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<td>• HTN: Healthy Term Newborn (NQF #0716)</td>
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<td>• PN-6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147)</td>
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<td>• SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527)</td>
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<td>• SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)</td>
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<tr>
<td>• SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero</td>
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<tr>
<td>• STK-4: Thrombolytic Therapy (NQF #0437)</td>
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<tr>
<td>• VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373)</td>
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<tr>
<td>• VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram)</td>
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<td>• VTE-5: Venous Thromboembolism Discharge Instructions</td>
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<tr>
<td>• VTE-6: Incidence of Potentially Preventable VTE*</td>
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<th>Structural Measures</th>
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<tr>
<td>• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care</td>
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<td>• Participation in a Systematic Clinical Database Registry for General Surgery</td>
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<tr>
<th>Chart-abstracted Measures</th>
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<tr>
<td>• STK-4: Thrombolytic Therapy (NQF #0437)</td>
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<td>• VTE-5: VTE Discharge Instructions</td>
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* Retained in chart-abstracted form.

CMS is seeking to refine two previously adopted measures beginning with the FY 2018 payment determination:

- Hospital-level, Risk-standardized Payment Associated with a 30-day Episode-of-Care for Pneumonia (NQF # 2579); and
- Patient Safety and Adverse Events Composite (NQF #0531)
CMS is proposing to add four new claims-based measures for the FY 2019 payment determination and subsequent years:

- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure
- Spinal Fusion Clinical Episode-Based Payment Measure
- Excess Days in Acute Care after Hospitalization for Pneumonia

In addition, CMS is proposing to increase the frequency of reporting of eCQMs by hospitals. Beginning with the FY 2017 reporting period/FY 2019 payment determination, hospitals would be required to submit a full calendar year of data on all eCQMs in the Hospital IQR Program measure set, on an annual basis.

- **Value Based Purchasing (VBP) Program**

Section 1886(o) of the Social Security Act, as added by Section 3008 of the Affordable Care Act, requires CMS to establish the VBP Program, which funds incentive payments to high performing hospitals through a coefficient reduction in base operating DRG payments for all hospital discharges.

- In FY 2014, the coefficient for the reduction was set at 1.25%
- In FY 2015, the coefficient for the reduction was set at 1.5%
- In FY 2016, the coefficient for the reduction was set at 1.75%
- **In FY 2017 and beyond, the coefficient will be 2%**

All the base payment reductions will be reallocated within the IPPS system in order to fund an equivalent amount of value-based incentive payments. For FY 2017, CMS estimates that the total amount available for value-based incentive payments will be $1.7 billion.

The proposed rule outlines the adoption of three new measures:

- 2021 Program Year:
  - Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) (NQF #2431)
  - Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) (NQF #2436)

- 2022 Program Year:
  - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)

CMS is proposing to change the performance period for the PSI 90: Patient Safety for Selected Indicators measure for the FY 2018 program year from July 1, 2014 – June 30, 2016 to a 15-month performance period from July 1, 2014 – September 30, 2015. Due to the complexities of converting ICD-9 to ICD-10, CMS made the preliminary decision to shorten the performance period and only use ICD-9 data to calculate performance standards for the PSI 90 measure.

CMS is also proposing to shorten the name of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to the Person and Community Engagement domain beginning with the FY 2019 program year.
Finally, CMS is recommending changes in how it defines a hospital that is, “cited for deficiencies that pose immediate jeopardy” to the health or safety of their patients and would thus be excluded from the Hospital VBP Program for that year. Currently it is defined as when, “the Secretary cited the hospital for immediate jeopardy on at least two surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction.” CMS is proposing to increase the number of surveys from two to three to be more inclusive of hospitals while maintaining high quality care for patients. Thus, hospitals, as of October 1, 2016, cited for immediate jeopardy of two surveys during the performance period that applies to FY 2017 program year would still have the opportunity to participate in the Hospital VBP Program for FY 2017.

III. MEDICAL TECHNOLOGY RELATED ISSUES AND OTHER CMS RECOMMENDATIONS THAT HELP INFORM ON RATIONALE FOR PAYMENT POLICY

❖ New Technology Add-On Payment (NTAP) Applications

For FY 2017, CMS received nine New Technology Add-On Payment (NTAP) applications. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. Applicants for new technology add-on payments must have FDA approval by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The nine applications reviewed by CMS include:

a) MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine) (Ellipse Technologies, Inc.)
b) MIRODERM Biologic Wound Matrix (MIRODERM) (Miromatrix Medical, Inc.)
c) Idarucizumab (Boehringer Ingelheim Pharmaceuticals, Inc.)
d) Titan Spine (Titan Spine Endoskeleton® nanoLOCK™ Interbody Device) (Titan Spine)
e) Andexanet Alfa (Portola Pharmaceuticals, Inc.)
f) Defitelio® (Defibrotide) (Jazz Pharmaceuticals)
g) EDWARDS INTUITY Elite™ Valve System (Edwards Lifesciences)
h) GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) (W. L. Gore and Associates, Inc.)
i) Vistogard™ (Uridine Triacetate) (BTG International Inc.)

As described in greater detail below, CMS expressed concerns that at least seven of the applications did not meet the criteria for NTAP. In the Proposed Rule, CMS considered the application along with public comments and analyzed whether the technology met the criteria for NTAP. The three criteria for evaluating whether a new technology is eligible for NTAP status are:

1. **Newness:** the medical service or technology must be new and not be considered substantially similar to existing technologies in terms of its mechanism of action, therapeutic outcomes, MS-DRG assignment, or the intended patient population or disease;
2. **Cost:** the charges for the medical service or technology must exceed certain cost thresholds; and
3. **Substantial clinical improvement:** the medical service or technology must demonstrate a substantial clinical improvement in the diagnosis or treatment of Medicare beneficiaries
compared to existing services or technologies such as decreased mortality or reduced hospitalizations.

If a technology meets all three of the criteria above, it is eligible for new technology add-on payments, which can last two to three years. The amount of the additional payment is typically calculated to be 50% of the estimated costs of the new technology.

Table 2: FY 2017 NTAP Applications and CMS’ Responses

<table>
<thead>
<tr>
<th>Technology (Manufacturer)</th>
<th>Description</th>
<th>CMS’ Response</th>
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<tr>
<td>MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine) (Ellipse Technologies, Inc.)</td>
<td>MAGEC® Spine is intended to children diagnosed with severe spinal deformities, such as scoliosis. The system can be used in the treatment of skeletally immature patients less than 10 years of age who have been diagnosed with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS). The MAGEC® Spine consists of a (spinal growth) rod that can be lengthened through the use of magnets that are controlled by an external remote controller (ERC). The rod(s) can be implanted into children as young as 2 years of age.</td>
<td>With regards to the newness criterion, CMS expressed multiple concerns that the MAGEC® Spine was substantially similar to other currently available technologies with regards to mechanism of action, therapeutic outcome, MS-DRG assignment, and intended patient population. CMS drew comparisons between the MAGEC® Spine and other technologies, including traditional growth rods (TGRs) and the Shilla growth guidance system. With regards to the cost criterion, CMS expressed concerns that the applicant did not specify certain details of their cost analysis and methodology, including the numerical breakdown of Medicare vs non-Medicare cases that were examined, the use of a 10-percent inflation factor when making FY 2017 projections, and the use of an average overall CCR for hospitals rather than each individual hospital’s CCR. With regards to the substantial clinical improvement criterion, CMS expressed doubt regarding study evidence of improved clinical outcomes (specifically, regarding decreased infection rates) and reiterated concern that MAGEC® Spine may not represent an improvement over technologies that achieve the same therapeutic outcome and that do not require additional surgery.</td>
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<tr>
<td>MIRODERM Biologic Wound Matrix (MIRODERM) (Miromatrix Medical, Inc.)</td>
<td>MIRODERM is a non-crosslinked acellular wound matrix that is derived from the porcine liver and is processed and stored in a phosphate buffered aqueous solution. MIRODERM is clinically indicated for the management of wounds, including: partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, drainage wounds, and surgical wounds</td>
<td>With regards to the newness criterion, CMS expressed concern that the MIRODERM was substantially similar to other wound matrix treatments in terms of mechanism of action (citing similar usage of a collagen matrix for tissue repair and regeneration), MS-DRG assignment, and intended patient population. With regards to the cost criterion, CMS did not express any concerns and as with all the applications and criteria, invited public comment.</td>
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<tr>
<td>Technology (Manufacturer)</td>
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<tr>
<td>Idarucizumab (Boehringer Ingelheim Pharmaceuticals, Inc.)</td>
<td>Idarucizumab is a humanized fragment antigen binding (Fab) molecule, intended to reverse the effects of Dabigatran, an oral anticoagulant that treats stroke and systemic embolism in patients. In the event of a major bleeding episode, Idarucizumab deactivates Dabigatran, thereby allowing thrombin to act in blood clot formation. Both drugs are manufactured by Boehringer Ingelheim Pharmaceuticals, Inc.</td>
<td>With regards to the newness criterion, CMS did not express any concerns and invited public comment. With regards to the cost criterion, CMS did not express any concerns and invited public comment. With regards to the substantial clinical improvement criterion, CMS did not express any concerns and invited public comment.</td>
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<tr>
<td>Titan Spine Endoskeleton® nanoLOCK™ Interbody Device (Titan Spine)</td>
<td>The Titan Spine nanoLOCK™ is a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). The Titan Spine nanoLOCK™ received FDA approval on October 27, 2014 for the use of five lumbar interbody fusion devices and one cervical interbody fusion device. CMS notes that procedures involving lumbar and cervical interbody devices map to different MS-DRGs. Lumbar devices map to MS-DRGs 28-30 and 453-460, while cervical devices map to MS-DRGs 471-473. Hence, CMS concluded that lumbar and cervical devices must separately meet the NTAP criteria. With regards to the newness criterion, CMS expressed concern that the Titan Spine nanoLOCK™ was substantially similar to other devices in terms of mechanism of action (citing similar usage of titanium surfaces), MS-DRG assignment, and intended patient population. With regards to the cost criterion, CMS did not express any concerns. With regards to the substantial clinical improvement criterion, CMS expressed concern that it could not substantiate the applicant’s evidence for improved outcomes as the applicant only conducted in vitro studies without data form live subjects in a clinical trial.</td>
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<tr>
<td>Andexanet Alfa (Portola Pharmaceuticals, Inc.)</td>
<td>Andexanet Alfa is an antidote used to treat patients who are receiving treatment with an oral Factor Xa inhibitor. Andexanet Alfa is a drug intended to treat patients who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation.</td>
<td>If approved by the FDA, Andexanet Alfa would be the first reversal agent that binds to direct Factor Xa inhibitors with high affinity. With regards to the newness criterion, CMS did not express any concerns. With regards to the cost criterion, CMS expressed general concern that sensitivity analysis was not included in the applicant’s methodology.</td>
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<td><strong>Defitelio® (Defibrotide) (Jazz Pharmaceuticals)</strong></td>
<td>Defitelio® is treatment for hepatic veno-occlusive disease (VOD), a life-threatening complication resulting from hematopoietic stem cell transplantation and can be associated with multi-organ dysfunction. Defitelio® stabilizes endothelial cells by reducing endothelial cell activation and by protecting endothelial cells from further damage. Defitelio® is administered as a 2-hour intravenous infusion every 6 hours.</td>
<td>With regards to the substantial clinical improvement criterion, CMS did not express any concerns and said it would take into account two comments from the February 2016 New Technology Townhall meeting. These comments supported Andexanet Alfa as a significant clinical improvement over existing technologies. With regards to the newness criterion, CMS expressed concern that the manufacturer did not fully understand the Defitelio®’s mechanism of action and subsequently, CMS could not determine whether the drug is similar to other existing drugs without a full understanding of the mechanism of action. CMS expressed concern that Defitelio® mapped to the same MS-DRGs as patients treated with supportive care for VOD with multi-organ failure. CMS expressed also expressed concern regarding the lack of data comparing Defitelio® treatment to patients treated with only supportive care. With regards to the cost criterion, CMS did not express any concerns. With regards to the substantial clinical improvement criterion, CMS expressed concern regarding the applicant’s Phase III clinical trial. Specifically, CMS cited the limitations related to the usage of a historical control group (past patients hospitalized between Jan 1995 – Nov 2007) and discrepancies between the sizes of treatment groups. CMS also noted it was difficult to attribute improved outcomes to Defitelio® treatment alone.</td>
</tr>
<tr>
<td><strong>EDWARDS INTUITY Elite™ Valve System (Edwards Lifesciences)</strong></td>
<td>The EDWARDS INTUITY Elite™ Valve System uses a rapid deployment valve system and serves as a prosthetic aortic valve, which is inserted using surgical aortic valve replacement (AVR). The device replaces the diseased native valve in patients with aortic valve disease, including aortic stenosis.</td>
<td>With regards to the newness criterion, CMS expressed concerns that the INTUITY valve was substantially similar to standard aortic valves for AVR with regards to mechanism of action, MS-DRG assignment, and intended patient population. With regards to the cost criterion, CMS expressed concern regarding a discrepancy between the number of cases eligible for treatment with INTUITY (26,520) and the number of cases included in the final sensitivity analysis (15,291). CMS requested more information regarding the applicant’s cost analysis methodology.</td>
</tr>
<tr>
<td>Technology (Manufacturer)</td>
<td>Description</td>
<td>CMS’ Response</td>
</tr>
<tr>
<td>--------------------------</td>
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<tr>
<td>GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) (W. L. Gore and Associates, Inc.)</td>
<td>The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.</td>
<td>With regards to the newness criterion, CMS expressed multiple concerns that the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) was substantially similar to other currently available technologies with regards to mechanism of action, MS-DRG assignment, and intended patient population. CMS drew comparisons between the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) and stent grafts used to treat abdominal aortic aneurysms (AAAs) patients. With regards to the cost criterion, CMS expressed concern regarding the applicant’s methodology – it could not determine how cases were mapped to certain MS-DRGs nor how many total cases were initially found in the claims data prior to filtering by ICD-9-CM codes. With regards to the substantial clinical improvement criterion, CMS noted the there was a lack of data or insufficient data to support some of the applicant’s statements that the GORE IBE device was associated with reducing certain procedure times and decreased incidence of aneurysm enlargement. CMS also expressed concern regarding the lack of evidence comparing...</td>
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</tbody>
</table>
Vistogard™ (Uridine Triacetate) (BTG International Inc.)

Vistogard™ is a drug antidote for Fluorouracil toxicity. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. By causing the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. Patients may suffer from fluorouracil toxicity/death if fluorouracil is delivered in slight excess or at faster infusion rates than prescribed. Vistogard™ competes with FUTP, one of the toxic byproducts of fluorouracil, thus reversing fluorouracil toxicity.

With regards to the newness criterion, CMS did not express any concerns.

With regards to the cost criterion, CMS noted the use of an outdated inflation factor (from the FY 2016 Proposed Rule instead of the FY 2016 Final Rule). But CMS believed that the difference between the factors was marginal and that it remained likely the applicant would still meet the cost criterion.

With regards to the substantial clinical improvement criterion, CMS did not express any concerns.

**MS-DRG Classifications: Proposed Changes**

CMS evaluates MS-DRG re-assignments or creation of new MS-DRGs based on claims data analyses that examine the resource consumption, clinical characteristics of patients with a given set of conditions compared to the remaining patients in the MS-DRG, and total volume of cases. CMS also gives weight to the recommendations of clinical advisors who advise on the clinical coherency of any requested changes. The proposed MS-DRG classification changes, described below, represent an important step in the incremental evolution of Medicare inpatient hospital payment for drugs and devices, especially in the early stages of transition to ICD-10-PCS. Underlying CMS’ analysis is the continued goal to achieve clinical and resource coherence or homogeneity within each MS-DRG.

To decide whether to restructure an existing DRG into MCC/CC or MCC/CC/no MCC or CC subgroups, CMS examines the average costs between each subgroup. The average costs in that exercise must meet the five criteria:

1. A reduction in variance of costs of at least 3 percent.
2. At least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup.
3. At least 500 cases are in the CC or MCC subgroup.
4. There is at least a 20-percent difference in average costs between subgroups.
5. There is a $2,000 difference in average costs between subgroups.

Since the transition from ICD-9 to ICD-10, CMS also emphasizes the replicability between ICD-9 MS-DRG logic and ICD-10 MS-DRG logic. Any requested change should be replicable in the ICD-9 MS-DRGs. If the change is not replicable, CMS examines whether the change in the ICD-10 MS-DRGs was likely to cause a significant number of patient cases to change ICD-10 MS-DRGs.

**Table 3: MS-DRG Classification Proposals and CMS’ Responses**

<table>
<thead>
<tr>
<th>Request</th>
<th>CMS Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS identified an error involving the omission of an ICD-10-PCS “code cluster” comprised of procedure codes 02RK0JZ and 02RL0JZ as a code cluster that would map to:</td>
<td>CMS is proposing to assign 02RK0JZ and 02RL0JZ as a code cluster that would map to:</td>
</tr>
</tbody>
</table>
**Key Proposed Changes to IPPS for FY 2017**

### MDC 1 (Diseases and Disorders of the Nervous System)

CMS received a repeat request to change the MS-DRG assignment for multiple ICD-10-PCS procedure codes representing endovascular embolization procedures and additional intracranial procedures (e.g. 03LG3BZ).

**Request**
- 02RL0JZ describing biventricular heart replacement (artificial heart).

**CMS Response**
- MS-DRG 001: Heart Transplant or Implant of Heart Assist System with MCC
- MS-DRG 002: Heart Transplant or Implant of Heart Assist System without MCC

### MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)

A request was submitted to reassign ICD-10-CM diagnosis code R22.2 (Localized swelling, mass and lump, trunk) from MDC 4 to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

**Request**
- A request was submitted to create a new MS-DRG or to reassign cases with a principal diagnosis of pulmonary embolism (e.g ICD-10-CM diagnosis code I26.xx) where tPA or other thrombolytic therapy was administered (e.g. ICD-10-PCS 3E03017) from MS-DRGs 175 and 176 (Pulmonary Embolism with and without MCC, respectively).

**CMS Response**
- CMS is proposing to maintain the current MS-DRG assignments for pulmonary embolism with tPA or other thrombolytic therapy.

### MDC 5 (Diseases and Disorders of the Circulatory System)

CMS received a request to designate the following six ICD-10-PCS procedure codes for implantation or revision of a loop recorder as O.R. procedures and to assign them to the same MS-DRGs as the former ICD-9-CM procedure code 37.79:
- 0JH602Z
- 0JH632Z
- 0JH802Z
- 0JH832Z
- 0JWT02Z
- 0JWT32Z

CMS received a request to evaluate if some procedure code combinations were excluded from the ICD-10 MS-DRG assignments for MS-DRGs 242-244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC).

**Request**
- CMS received a request to reassign several ICD-10-PCS procedure codes describing endovascular thrombectomy (e.g. 04CK3ZZ) of the lower limbs to MS-DRGs 270-272.

**CMS Response**
- CMS agreed and is proposing to reassign the ICD-10-PCS codes for endovascular thrombectomy of the lower limbs to MS-DRGs 270-272.

**CMS Response**
- CMS agreed that inadvertent omissions had been made and is proposing to simplify ICD-10 MS-DRG/Grouper logic in the following ways for pacemaker procedures:
  - Assignment to MS-DRG 242-243:
    - For combinations of ICD-10-PCS procedure codes involving pacemaker devices reported with certain ICD-10-PCS procedure codes involving pacemaker leads.
  - Assignment to MS-DRG 258-259:
    - For ICD-10-PCS procedure codes involving pacemaker device insertions that are reported
### Key Proposed Changes to IPPS for FY 2017

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>CMS received a request to modify the MS-DRG assignment for transcathe\nal mitral valve repair with implanta\n procedures and create a new MS-DRG.</td>
<td>CMS is proposing to delete MS-DRG 230 and collapse the coding structure for MS-DRGs 228-230 from three severity levels to two.</td>
</tr>
<tr>
<td>In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49369), CMS stated it would continue to monitor MS-DRG 245 (AICD Generator Procedures) to determine if the data supported subdividing the MS-DRG into severity levels.</td>
<td>CMS is proposing to maintain the current base MS-DRG 245 and to not subdivide MS-DRG 245 into severity levels.</td>
</tr>
<tr>
<td>MDC 6 (Diseases and Disorders of the Digestive System)</td>
<td>CMS is proposing to reassign two ICD-10-PCS codes for ileum excision, 0DBB0ZZ and 0DBA0ZZ, from MS-DRGs 347-349 to MS-DRGs 329-331.</td>
</tr>
<tr>
<td>MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas)</td>
<td>CMS agreed and is proposing to assign 06183DY to MS-DRGs 405-407.</td>
</tr>
<tr>
<td>MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)</td>
<td>CMS is proposing to maintain the current assignment to MS-DRGs 469-470 and to not create a new MS-DRG.</td>
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<tr>
<td>CMS received several requests to remove hip replacement procedures with a principal diagnosis of hip fracture from MS-DRGs 469-470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively) and to create a new MS-DRG for the hip replacement procedures.</td>
<td>CMS is proposing to maintain the current assignment to MS-DRGs 469-470 and to not create a new MS-DRG.</td>
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<td>CMS received a request to modify the MS-DRG assignment for revision of total ankle replacement procedures which are currently assigned to MS-DRGs 515-517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC and without CC/MCC, respectively).</td>
<td>CMS is proposing to maintain the current assignment to MS-DRGs 515-517 for revision of total ankle replacement procedures.</td>
</tr>
<tr>
<td>CMS received several requests to examine whether additional combinations of procedure codes for the removal and replacements of knee joints should be added to MS-DRGs 466-</td>
<td>CMS agreed and is proposing 58 new code combinations to capture knee joint revisions for MS-DRGs 466-468 (e.g 0SP4JZ and 0SRU0JZ).</td>
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**Quorum Consulting**

*April 25, 2016 | page 16*
### Request | CMS Response
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468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively). | CMS agreed and is proposing to reassign these ICD-10-PCS procedure codes from MS-DRGs 515-517 to both MS-DRGs 28-30 and MS-DRGs 518-520.
CMS received a suggestion to reassign a subset of codes describing decompression laminectomy, or release of specific peripheral nerve (e.g. 01NB0ZZ), to MS-DRGs 28-30 and MS-DRGs 518-520 for clinical coherence purposes. | CMS is proposing to reassign the four diagnosis codes from the secondary diagnosis list while maintaining the same four codes on the principal diagnosis list under MS-DRGs 456-458.
CMS discovered an ICD-10 replication issue involving four diagnosis codes for lordosis (excessive curvature of the lower spine) which are on both the principal and secondary diagnosis lists under MS-DRGs 456-458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC):
- M40.50
- M40.55
- M40.56
- M40.57 | CMS is proposing to remove the four diagnosis codes from the secondary diagnosis list while maintaining the same four codes on the principal diagnosis list under MS-DRGs 456-458.

**MDC 13 (Diseases and Disorders of the Female Reproductive System)**

CMS examined the logic of retaining ICD-10-PCS procedure code clusters for pelvic evisceration procedures under MDC 6 (Diseases and Disorders of the Digestive System). | CMS is proposing to remove the code clusters for pelvic evisceration procedures from MDC 6 and to retain the code clusters in MDC 13 under MS-DRGs 734-735 only.

**MDC 19 (Mental Diseases and Disorders)**

CMS received a request to change the title of MS-DRG 884 (Organic Disturbances and Mental Retardation) to "MS-DRG 884 (Organic Disturbances and Intellectual Disability)". | CMS agreed and is proposing to change the title of MS-DRG 884 as requested.

**MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)**

CMS received several requests to examine the logic of MS-DRGs 945-946 (Rehabilitation with CC/MCC and without CC/MCC, respectively) as ICD-9-CM codes that clearly identified an encounter for rehabilitation services (such as V57.89, V57.9) were not included in ICD-10-CM.

Specific requests were also submitted to:
- Review diagnosis codes in ICD-10-CM category I69 and other categories for possible addition to MS-DRGs 945-946
- Designate MS-DRGs 945-946 as pre-major diagnostic categories (Pre-MDC)
- Revise ICD-10-PCS Official Guidelines for Coding and Reporting and designate that the ICD-10-PCS rehabilitation codes be used only for admissions for rehabilitation therapy. | CMS is proposing to maintain the current structure of MS-DRGs 945-946 and to reconsider the issue when ICD-10 claims data become available.