

FY2016 Hospital Inpatient Proposed Rule (IPPS)

Interventional Cardiology Peripheral Interventions Rhythm Management

On April 17, 2015 the Centers for Medicare and Medicaid Services (CMS) released the Proposed Hospital Inpatient Payment System (IPPS) rates for FY2016 which apply to approximately 3,400 acute care hospitals. CMS' final payment and policy changes are issued around August 1st and will go into effect October 1, 2015.

Overall payment rates will increase slightly, with a 1.1% increase for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program. See Table 1 on pages 5 and 6 for payment rates for procedures of interest to Interventional Cardiology (IC), Peripheral Interventions (PI) and Rhythm Management (RM).

IPPS RULE HIGHLIGHTS

CMS will increase FY2016 payment rates by 1.1% for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) and Meaningful Electronic Health Record (EHR) programs. CMS projects total payments will increase by about \$120 million in FY2016. (Medicare spends about \$120-125 billion on inpatient services each year.)

The proposed FY2016 inpatient prospective payment rule policies that impact payment include four quality pay for performance programs (Inpatient Quality Reporting, Value Based Purchasing, Readmission Reduction Program, Hospital Acquired Conditions Program) discussed below. CMS also changed the Disproportionate Share (DSH) payment methodology so hospitals now receive 25% of the previous formula amount. CMS believes since the implementation of the Affordable Care Act the number of uninsured patients will decrease, thus the estimate for uncompensated care payments for FY2016 will be updated in the final rule based on more recent data.

QUALITY PAY FOR PERFORMANCE PROGRAMS

CMS continues to refine various “pay-for-performance” programs to drive improvements in quality and patient outcomes. Change highlights for each program include:

Inpatient Quality Reporting (IQR)

CMS proposes to add a total of eight new measures in FY2018. Five would be clinical episode-based payment measures, one patient safety measure, and two coordination-of-care measures. The two

cardiovascular claim based measures are:

- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction
- Excess Days in Acute Care after Hospitalization for Heart Failure

CMS proposes removing nine measures, two of which are suspended, as well as refining two previously adopted measures to expand measure cohorts. The measures include Venous Thromboembolism (VTE) Prophylaxis: Discharged on Statin Medication, Stroke Education, Venous Thromboembolism Prophylaxis, Intensive Care Unit Venous Thromboembolism Prophylaxis, Venous Thromboembolism Patients with Anticoagulation Overlap Therapy, Pneumococcal Immunization, AMI-7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival, and Cardiac Surgery Patients with Controlled Postoperative Blood Glucose.

Value-Based Purchasing (VBP) Program

The VBP program builds upon the current Inpatient Quality Reporting Program, using performance data to adjust payments. In FY2016, the VBP will redistribute 1.5% of hospital payments, which CMS estimates will allow for \$1.5 billion in incentive payments. The incentive payments will be based on a hospital's reported quality and efficiency measures during a defined performance period. Notably, CMS expanded the program to include Medicare spending per beneficiary for FY2015. For FY2016 reporting impacting FY2018 payments, CMS is proposing to add a care coordination measure. For FY2021 reporting CMS is proposing to add a 30-day mortality measure for chronic obstructive pulmonary disease.

Readmission Reduction Program (RRP)

The Hospital Readmissions Reduction Program will continue to assess hospitals' readmission penalties using five readmissions measures endorsed by the National Quality Forum (NQF): heart attack, heart failure, pneumonia, chronic obstructive pulmonary disease, and hip/knee arthroplasty. For FY2016, the maximum reduction will be 3%. CMS continues to work on the issue of risk adjustment for this program. CMS still plans to add the readmission measure for coronary artery bypass graft (CABG) surgical procedures in FY2017.

Hospital Acquired Conditions (HAC) Program

The HACs payment policy currently prohibits hospitals from being paid at a higher MS-DRG rate for patients with major complications if the sole reason for the higher payment is the occurrence of one of the conditions on the HACs list during the beneficiary's hospital stay. CMS is proposing to expand the reach of the CLASBI and the CAUTI measures to those patients that are not in the ICU. CMS will implement a 1% payment reduction for the lowest-performing hospitals.

TWO-MIDNIGHT RULE

CMS notes that hospitals and physicians continue to voice concern over the two midnight rule. CMS is considering this feedback and MedPAC recommendations, stating further discussion related to short inpatient hospital stays and long outpatient stays will be included with the CY2016 Hospital Outpatient rule that will be released this summer.

NEW TECHNOLOGY ADD-ON PAYMENT (NTAP) APPLICATIONS

For FY2016, CMS received a total of nine NTAP applications with five applications specific to medical devices including the WATCHMAN™ Left Atrial Appendage Closure System as FDA approval was obtained on March 16, 2015. WATCHMAN is an implant that acts as a physical barrier, sealing the LAA

to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for Warfarin therapy in those patients diagnosed with non-valvular AF and who are eligible for Warfarin therapy. In addition to WATCHMAN, other technologies applying for NTAP include the following: an ischemic monitoring device, coronary orbital atherectomy system, and a knee balancer system to facilitate total knee arthroplasty surgery. CMS is also requesting public comments as outlined by their concerns on newness, cost, and substantial clinical improvement.

CMS proposed to discontinue NTAP payment for FY2016 for Zilver PTX. CMS proposed to continue NTAP payment for FY2016 MitraClip® System and Responsive Neurostimulator (RNS® System): Medical Device Specific NTAP new applications: In addition to WATCHMAN™, the cardiovascular-related applications are:

- Angel Medical Guardian® Ischemic Monitoring Device.
- DIAMONDBACK 360® Coronary Orbital Atherectomy System
- LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter
- IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

TRANSPARENCY OF HOSPITAL CHARGES

CMS reminds hospitals that the Affordable Care Act requires them to provide a list of standard charges to the public and indicated that it will continue disclosing charges itself (as it did with hospital charges and payments to individual physicians) and discussed how the charges of those hospitals participating in the Bundled Payment Care Initiative would still be used in the rate setting process.

BUNDLED PAYMENT CARE INITIATIVE

In 2011, CMS launched the Bundled Payment Care Initiative (BPCI) linking payment for multiple services during an episode of care into a bundled payment. In this rule, CMS is seeking comment on policy and operational issues surrounding the potential future expansion of this initiative, including scope, definition of episodes, models for expansion, accuracy of payment amounts, mitigating risk of high cost cases, and issues regarding implementation.

SPECIFIC PROPOSED PAYMENT CHANGES

Interventional Cardiology (% weighted averages shown)

- Drug-eluting stent payment rates proposed to increase by 3.83%
- Bare metal stent payment rates proposed to increase by 2.76%

IC Structural Heart—Aortic Valves (% weighted average shown)

- TAVR payment rates proposed to slightly decrease by 1.83%

Peripheral Interventions (% weighted averages shown)

- Peripheral PTA, Stenting, Atherectomy & Embolization payment rates proposed to increase 2.33%
- Carotid artery stent payment rates proposed to increase 2.43%
- Thrombectomy payment rates proposed to decrease by 4.58% (*Thrombectomy proposed to map to 3 newly created MS-DRGs*)

Rhythm Management (% weighted averages shown)

- ICD and CRT-D system implant payment rates are proposed to increase 2.01%
- ICD and CRT-D system replacement payment rates are proposed to increase 2.97%
- Pacemaker and CRT-P system implant payment rates are proposed to increase 1.67%
- Pacemaker and CRT-P system replacement payment rates are proposed to increase 1.91%
- Overall, Intracardiac Ablation and WATCHMAN payment rates are proposed to increase by 19.45%
 - CMS proposes to reassign WATCHMAN and Intracardiac Ablation procedures from MS-DRGs 250 and 251 to new MS-DRGs 273 and 274 to better reflect higher resource costs and the new alignment to the ICD-10 procedure coding.

COMMENTS / QUESTIONS

If you have questions or would like additional information contact:

Interventional Cardiology (IC)

Deb Lorenz – IC

763-494-2112

Deb.lorenz@bsci.com

Peripheral Interventions (PI)

Brent Hale – PI

763-494-1448

Brent.Hale@bsci.com

Rhythm Management (RM)

Call 1-800-CARDIAC (request Reimbursement Support)

CRM.Reimbursement@bsci.com

ADDITIONAL INFORMATION

Read the full FY2016 Proposed IPPS Rule (CMS-1621-P) at the following link:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Proposed-Rule-Home-Page-Items/FY2016-IPPS-Proposed-Rule-Regulations.html?DLPage=1&DLSort=0&DLSortDir=ascending>

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MS-DRG	Procedure	FY 2016 Proposed Rate	FY 2015 Final Rate	\$ Change (FY2016 Proposed - FY2015 Final)	% Change (FY2016 Proposed - FY2015 Final)
Interventional Cardiology					
Drug-Eluting Stents					
246	Percutaneous cardiovascular proc w drug-eluting stent w MCC	\$19,356	\$19,009	\$347	1.82%
247	Percutaneous cardiovascular proc w drug-eluting stent w/o MCC	\$12,697	\$12,090	\$607	5.02%
Bare Metal Stents					
248	Percutaneous cardiovasc proc w non-drug-eluting stent w MCC	\$18,267	\$17,860	\$407	2.28%
249	Percutaneous cardiovasc proc w non-drug-eluting stent w/o MCC	\$11,398	\$11,046	\$352	3.19%
Angioplasty or Atherectomy without Stent					
250	Perc cardiovasc proc w/o coronary artery stent w MCC	\$16,016	\$17,551	(\$1,535)	-8.75%
251	Perc cardiovasc proc w/o coronary artery stent w/o MCC	\$10,032	\$11,980	(\$1,948)	-16.26%
Endovascular Cardiac Valve Replacement (TAVR)					
266	Endovascular Cardiac Valve Replacement w MCC	\$51,472	\$52,808	(\$1,336)	-2.53%
267	Endovascular Cardiac Valve Replacement w/o MCC	\$39,265	\$39,652	(\$387)	-0.97%
WATCHMAN™ LAAC Device					
273	Perc cardiovasc proc w/o coronary artery stent w MCC ***	\$21,091	\$17,551	\$3,540	20.17%
274	Perc cardiovasc proc w/o coronary artery stent w/o MCC ***	\$14,376	\$11,980	\$2,396	20.00%
Peripheral Interventions					
Peripheral PTA, Stent, Atherectomy & Embolization					
252	Other vascular procedure w MCC	\$19,506	\$19,172	\$334	1.74%
253	Other vascular procedure w CC	\$15,503	\$14,994	\$509	3.39%
254	Other vascular procedure w/o MCC/CC	\$10,270	\$10,162	\$108	1.06%
Peripheral Thrombectomy (Proposed New) **					
270	Other major cardiovascular procedures w/ MCC	\$28,082	N/A	N/A	N/A
271	Other major cardiovascular procedures w/ CC	\$18,704	N/A	N/A	N/A
272	Other major cardiovascular procedures w/o MCC/CC	\$13,402	N/A	N/A	N/A
Peripheral Thrombectomy (Proposed Deleted) **					
237	Major cardiovascular procedures w MCC/CC	N/A	\$29,859	N/A	N/A
238	Major cardiovascular procedures w/o MCC/CC	N/A	\$20,109	N/A	N/A
Rhythm Management					
ICD Systems					
222	Cardiac defib implant w cardiac cath w AMI/HF/shock w MCC	\$50,928	\$50,841	\$87	0.17%
223	Cardiac defib implant w cardiac cath w AMI/HF/shock w/o MCC	\$38,209	\$36,954	\$1,255	3.40%
224	Cardiac defib implant w cardiac cath w/o AMI/HF/shock w MCC	\$45,475	\$45,064	\$411	0.91%

MS-DRG	Procedure	FY 2016 Proposed Rate	FY 2015 Final Rate	\$ Change (FY2016 Proposed - FY2015 Final)	% Change (FY2016 Proposed - FY2015 Final)
Rhythm Management					
225	Cardiac defib implant w cardiac cath w/o AMI/HF/shock w/o MCC	\$35,110	\$34,421	\$689	2.00%
226	Cardiac defibrillator implant w/o cardiac cath w MCC	\$41,670	\$40,859	\$811	1.98%
227	Cardiac defibrillator implant w/o cardiac cath w/o MCC	\$32,838	\$32,003	\$835	2.61%
ICD Replacements					
245	AICD generator procedures	\$27,971	\$27,300	\$671	2.46%
265	AICD Lead procedures	\$17,681	\$16,820	\$861	5.12%
Pacemaker Systems					
242	Permanent cardiac pacemaker implant w MCC	\$22,581	\$21,872	\$709	3.24%
243	Permanent cardiac pacemaker implant w CC	\$15,791	\$15,677	\$114	0.72%
244	Permanent cardiac pacemaker implant w/o CC/MCC	\$12,783	\$12,659	\$124	0.98%
Pacemaker Revisions and PG Placements					
258	Cardiac pacemaker device replacement w MCC	\$17,022	\$16,217	\$805	4.97%
259	Cardiac pacemaker device replacement w/o MCC	\$11,575	\$11,701	(\$126)	-1.08%
260	Cardiac pacemaker revision except device replacement w MCC	\$22,184	\$21,997	\$187	0.85%
261	Cardiac pacemaker revision except device replacement w CC	\$11,103	\$10,895	\$208	1.91%
262	Cardiac pacemaker revision except device replacement w/o CC/MCC	\$8,999	\$8,209	\$790	9.62%
Cardiac Catheter Ablation					
273	Percutaneous Intracardiac Procedures w MCC ***	\$21,091	\$17,551	\$3,540	20.17%
274	Percutaneous Intracardiac Procedures w/o MCC ***	\$14,376	\$11,980	\$2,396	20.00%

** MS-DRGs 237-238 are proposed to be deleted in FY16 and replaced with new MS-DRGs 268-272.

***CMS proposed to move intra-cardiac ablation procedures and WATCHMAN procedures from MS-DRG 250 to MS-DRG-273. Therefore the FY15 rate is for MS-DRG 250 and the FY16 rate is for new MS-DRG 273.

***CMS proposed to move intra-cardiac ablation procedures and WATCHMAN procedures from MS-DRG 251 to MS-DRG-274. Therefore the FY15 rate is for MS-DRG 251 and the FY16 rate is for new MS-DRG 274.

WATCHMAN is a registered or unregistered trademark of Boston Scientific Corporation

Note: BSC currently has no FDA-approved stents for use in the infrainguinal regions of the lower extremities. BSC currently has no FDA-approved ablation catheter for the treatment of atrial fibrillation.