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June 07, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1632–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1677-P — Fiscal Year 2018 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals – Proposed Relative Weight for Heart Assist Pumps (MS-DRG 215)

Dear Administrator Verma:

Abiomed, Inc., appreciates the opportunity to comment on the FY 2018 Hospital Inpatient Prospective Payment Systems (IPPS) Proposed Rule, published on April 28, 2017.[1] Abiomed is a leading provider of heart assist devices that provide circulatory support, enabling the heart to rest by improving blood flow and/or performing the pumping functions of the heart after a life-threatening event such as a heart attack or severe heart failure. In the Proposed Rule, the relative weight for Other Heart Assist System Implant (MS-DRG 215) was significantly decreased by 34.8% relative to FY 2017. This is the single largest decrease of any MS-DRG this year, and it was not as a result of a new policy proposal in the Proposed Rule. Instead the decrease appears to be a result of the shift from ICD-9 to ICD-10 coding in claims data used to set relative weights. This substantial decrease in relative weight is also in direct conflict with the recent American Hospital Association (AHA) coding guidance that will direct higher-cost patients into MS-DRG 215 for FY 2018 and years beyond. It is also at odds with the recent Premarket Approvals by the Food and Drug Administration (FDA) for specific heart pumps which are allowing providers to treat these severely ill patients. We are concerned that this significant payment cut, if finalized, would drastically underpay hospitals for these life-saving and resource-intensive procedures.

In this comment letter, we recommend two policy options for CMS to revise the proposed FY 2018 relative weight for MS-DRG 215 to more appropriately reflect hospitals' costs for performing these procedures:

(1) Revise the assignment of ICD-10 codes to MS-DRG 215 to more accurately replicate the assignment of ICD-9 codes in FY 2017 for the purpose of calculating FY 2018 relative weights; or

(2) Implement a multi-year transition period for any one-year decrease in MS-DRG relative weight that exceeds 10% where CMS does not specifically propose and explain the reduction in the preamble to the proposed rule and provide the public with the opportunity to submit comments on the proposed decrease and rationale.

[1] CMS, Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates, etc., Proposed Rule, 82 Fed. Reg. 19796 (April 28, 2017).

A re-assignment of codes to MS-DRG 215 to better replicate the logic of ICD-9 MS-DRGs and approximate the resources required for these heart assist device-related procedures in FY 2018 would be consistent with other DRG refinements in the Proposed Rule and previous rulemakings. Alternately, CMS has broad authority to implement a multi-year transition to significant MS-DRG relative weight reductions pursuant to the its "exceptions and adjustments" authority under Section 1886(d)(5)(I)(i) of the Social Security Act.

I. Background on Heart Assist Devices

A. Clinical Overview of Heart Assist Devices

Heart assist devices are utilized in a variety of clinical scenarios. These include use by patients waiting for replacement hearts and patients recovering from heart attacks, and to maintain heart function during percutaneous coronary intervention procedures, commonly known as angioplasties, which remove coronary artery blockages.

Heart assist devices include Left Ventricular Assist Devices (LVADs), which assist the heart's left ventricle (the major blood pumping chamber of the heart) in pumping blood to other parts of the body. These devices are generally placed through a sternotomy or "open chest" approach and can either be implanted or extracorporeal. Another type of heart assist device is the Percutaneous Ventricular Assist Device (pVAD), a category that includes Abiomed's Impella products. These devices are placed percutaneously into the leg and are used for in-hospital care in the catheterization lab and the ICU. PVADs have been FDA-approved for the treatment of heart attacks that deteriorate into cardiogenic shock with the goal of promoting heart recovery, and for stabilization during high risk coronary procedures for patients who are often refused for surgical procedures.[2]

The use of heart assist devices for the treatment of critically ill cardiovascular patients is supported by extensive clinical society guidelines and publications, clinical studies specifically in the Medicare population, and cost effectiveness studies demonstrating improved long term costs of heart recovery. Patients receiving heart assist devices generally require intensive care and longer hospital stays.

B. MS-DRG Assignment of Patients Receiving Heart Assist Devices

CMS and the AHA have developed a system of care surrounding the utilization of heart assist devices in the catheterization lab, along with ICU support and the transfer of patients to specialized centers. Cases involving patients receiving heart assist devices are most commonly reimbursed under four MS-DRG categories, one of which consists of MS-DRG 215 and another of which consists of MS-DRGs 001 and 002.

The move from using ICD-9 to ICD-10 diagnosis and procedure codes as the basis for assignment to MS-DRGs has significantly increased the number of codes relevant to the assignment of procedures to an MS-DRG (because ICD-10 is a more granular coding system) and appears to have impacted these assignments. For instance, as relevant to MS-DRG 215, generally ICD-10 codes for the "insertion" and "revision" of external or implantable heart assist systems are assigned to MS-DRG 215. However, when billed with a code for the "removal" of a heart assist system, these procedures are usually reassigned from MS-DRG 215 to MS-DRGs 001 and 002.[3] In addition, certain ICD-10 codes for the insertion of implantable heart assist systems have been assigned to MS DRGs 001 and 002, where they were historically assigned to MS-DRG 215 when billed with the repair ICD-9 code 37.63. Some of these factors, which are illustrated in the table attached as Appendix B,

[2] Recent FDA approvals for Abiomed's Impella products are enclosed as Appendix A.
[3] MS-DRG Definitions Manual, v. 34, available at https://www.cms.gov/ICD10Manual/version34-fullcode-cms/fullcode_cms/P0039.html.

may have resulted in significant changes in the procedures assigned to MS-DRG 215, contributing to the steep reduction in relative weight for FY 2018.

II. Large Reductions in MS-DRG 215 Relative Weight Not Explained in Proposed Rule

A. Proposed Rule Summary

Under the FY 2018 IPPS Proposed Rule, the relative weight for MS-DRG 215 would be reduced from 16.1076 in FY 2017 to 10.4983, an approximately 35% cut. Importantly, this drastic cut is not addressed in the preamble to the Proposed Rule, and the Proposed Rule does not include any policy proposals indicating a decrease in the relative weight for MS-DRG 215 or in reimbursement for heart assist devices more broadly. In fact, there is no discussion whatsoever of MS-DRG 215 in the preamble to the Proposed Rule. The only reference in the Proposed Rule to a relative weight for MS-DRG 215 of 10.4983 is found in Table 5.

The proposed 35% decrease in relative weight for MS-DRG 215 represents the largest cut in relative weight proposed for any MS-DRG for FY 2018, and the only cut in excess of 30%. No other MS-DRG in Major Diagnostic Category (MDC) 05, which comprises diseases and disorders of the circulatory system, received a cut in excess of 13%. No other surgical MS-DRG in MDC 05 received a reduction in excess of 10%. This proposed relative weight is not reflective of the resources expended by providers to treat the seriously ill patient population who require the complex heart assist device implantation and revision procedures assigned to MS-DRG 215.

B. Claims Analysis Indicates Possible Discrepancies Between ICD-10 Based MS-DRG 215 and ICD-9 Based MS-DRG 215

Abiomed has analyzed claims data used as the basis for the proposed relative weight of MS-DRG 215 in FY 2018. This analysis of the proposed 35% cut in the relative weight of MS-DRG 215 is set out in greater detail in Appendix C. According to this claims analysis, even as the overall number of cases assigned to MS-DRG 215 has remained approximately the same compared to the data used to set FY 2017 relative weights, the charges for claims in MS-DRG 215 were down by approximately 32%, from $426,535 to $289,772. Because MS-DRG 215 is a low volume DRG with fewer than 300 cases per year, movements of small numbers of cases into and out of the DRG can have substantial effects. This appears to have taken place in the move from FY 2015 claims data used to set the relative weight for FY 2017 to the FY 2016 claims data used for FY 2018. Notably, the FY 2015 data consisted predominantly of repair cases, with more than twice as many repair cases as implant cases. In the FY 2016 data this was reversed, as there were almost four times as many implant cases as repair cases. Clinical and usage changes do not account for this dramatic one-year reversal

III. Relative Weight Reductions Inconsistent with CMS Policy on Coding Shift and Likely Patient Mix Change

A. Significant Payment Redistributions Caused by Coding Shift Inconsistent with CMS Policy

Instead, this drastic one-year swing in the MS-DRG 215 claims data and the resulting 35% reduction to the relative weight for MS-DRG 215 can best be explained as an unintended consequence of the shift from ICD-9 to ICD-10 coding in the claims data used to determine relative weights. The FY 2018 IPPS Proposed Rule is the first year that MS-DRG relative weights have been based entirely on claims data using ICD-10 codes,[4] and the shift may have caused the assignment of procedures to MS-DRG 215 based on ICD-10 codes to inaccurately replicate the assignment of procedures to MS-DRG 215 based on ICD-9 codes.

[4] *See* 82 Fed. Reg. 19817 (Apr. 28, 2017).

CMS did not intend for ICD-10 coding implementation to cause such significant one-year shifts in hospital payment rates, and has articulated the exact opposite policy. In the FY 2017 IPPS Final Rule, the agency discussed the importance of ensuring that ICD-10-based MS-DRGs accurately replicate those based on ICD-9 coding. CMS stated:

> If the ICD-9 and ICD-10 versions of the MS-DRGs cease to be replications of each other, the relative payment rates computed using ICD-9 claims data and MS-DRGs would be inconsistent with the relative payment weights assigned for the ICD-10 MS-DRGs, **causing unintended payment redistributions**.[5]

The FY 2018 Proposed Rule refers back to this discussion in the FY 2017 Final Rule on the subject of the "need to accurately replicate the ICD-9-CM based MS-DRGs."[6] Abiomed is concerned that the proposed 35% cut to the relative weight of MS-DRG 215 represents exactly this sort of unwanted payment redistribution based on replication issues between ICD-9 and ICD-10 based MS-DRGs.

B. Decrease in MS-DRG 215 Conflicts with Patient Mix Change

Abiomed is also concerned that the proposed cut in the MS-DRG 215 relative weight will have particularly negative effect in FY 2018 as a result of new AHA Coding Clinic released in October 2016 and again in March 2017, effective March 13, 2017. This guidance confirmed assignment to MS-DRG 215 of the implantation of certain heart assist devices and ICU care. This coding change will result in the assignment to MS-DRG 215 of complex heart assist devices utilized by higher-acuity patients who are likely to spend more time in the hospital, and in the ICU in particular, and who are also more likely to experience Major Complications and Comorbidities. Claims data since this detailed coding guidance is not yet available and was not used for the proposed rule relative weight calculations.

Cases involving these more complex heart assist devices and higher-acuity patients were underrepresented in the data used to set the proposed FY 2018 relative weight for MS-DRG 215. If finalized, the proposed cuts to the relative weight of MS-DRG 215 will result in major underpayments to hospitals treating the highest-acuity Medicare heart failure patients, such as those suffering from heart attacks leading to cardiogenic shock and heart failure patients being treated with percutaneous coronary intervention. This will both upset provider expectations of reimbursement predictability and could potentially give rise to problems of access to treatment for critically ill cardiovascular patients. In order to avoid these underpayments, we respectfully recommend either the reassignment of certain ICD-10 codes to MS-DRG 215 to more accurately replicate the assignment of procedures to this DRG based on ICD-9 codes, or a multi-year transition in the implementation of unexplained cuts in relative weight in excess of 10%. Our recommendations are set out in greater detail below.

IV. Recommendations

A. Revise Assignment of ICD-10 Codes to MS-DRG 215 to Replicate ICD-9 Assignments

As discussed above, the proposed relative weight for MS-DRG 215 for FY 2018 represents the largest one-year decrease of all MS-DRGs, and is driven by the shift to ICD-10 claims data rather than a new policy proposal. Abiomed recommends that CMS revise the assignment of ICD-10 codes to MS-DRG 215 for the calculation of FY 2018 relative weights to replicate the MS-DRG assignments based on ICD-9 codes and more accurately reflect the resources required for cases that will be assigned to this DRG in FY 2018.

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[5] 81 Fed. Reg. 56790 (Aug. 22, 2016).
[6] 82 Fed. Reg. 19828 (Apr. 28, 2017).

In prior years, the agency has used the IPPS rulemaking to ensure accurate replication between ICD-9 and ICD-10 based MS-DRGs. In the FY 2016 IPPS Final Rule, for example, CMS re-designated six ICD-10 codes for the insertion of artery pressure sensor monitoring devices as operating room procedures and assigned them to MS-DRG 264 in response to stakeholder comments that these codes represented translations of an ICD-9 code that was designated an operating room procedure and assigned to MS-DRG 264. CMS stated that the purpose of this change was to "accurately replicate the ICD-9-CM . . . logic."[7]

CMS has also implemented DRG refinements to reflect the resources required for a procedure. For example, in this FY 2018 Proposed Rule, CMS proposes to move six ICD-10 codes for total ankle replacement (TAR) procedures from MS-DRG 470 to MS-DRG 469. CMS is proposing this change on the grounds that TAR procedures are more complex and require more resources than the total knee and hip replacements assigned to MS-DRG 470 and on the basis of claims data that demonstrates that TAR procedures assigned to MS-DRG 470 have average costs more similar to procedures assigned to MS-DRG 469.[8] Similarly here, assignment of ICD-10 codes to MS-DRG 215 in a manner that better replicates the ICD-9 based MS-DRG assignments would more accurately reflect the resources required for the procedures included in MS-DRG 215 in FY 2018 in light of the above-referenced FDA approvals and AHA coding change.

We recommend that CMS revise the ICD-10 assignments to MS-DRG 215 to accurately replicate the logic used to assign ICD-9 codes to MS-DRG 215. For example, for the purpose of FY 2018 relative weight calculations CMS could reassign to MS-DRG 215 all claims billed with ICD-10 code 02HA0RZ (insertion of external heart assist system into heart, open approach) and removal code 02PA0RZ (removal of external heart assist system from heart, open approach), which were assigned to MS-DRG 215 when billed under ICD-9 code 37.62. Additionally, CMS could reassign to MS-DRG 215 all claims for the insertion and removal of implantable heart assist systems billed under ICD-10 codes 02HA0QZ + 02PA0QZ, which were assigned to MS-DRG 215 when billed under ICD-9 code 37.63.

B. Implement Transition Period for Significant Cuts to MS-DRG Relative Weight

In the alternative, the agency could also address large one-year cuts in relative weight as a broader policy matter, reflecting the importance of maintaining predictability in provider reimbursement expectations. This could take the form of a transition period for large cuts in relative weight or a cap on the percentage by which the relative weight for an MS-DRG can decrease in a single year. This transition or cap would preserve CMS' policy flexibility by applying only to relative weight reductions that do not arise from specific CMS policy proposals – that is, to reductions that CMS does not propose and explain in the preamble to the proposed rule, allowing the public to comment on the proposed decrease and rationale.

In Appendix D, our outside counsel, Foley Hoag LLP, sets out CMS' authority to implement such changes under Section 1886(d)(5)(I)(i) of the Social Security Act, which allows CMS to "provide by regulation for such other exceptions and adjustments to such payment amounts under [IPPS] as the Secretary deems appropriate." CMS has used this "exceptions and adjustments" authority frequently in the past to provide for transition periods "when adopting changes that have significant payment implications, particularly large negative impacts."[9]

As a broader policy approach, we recommend that CMS use its authority under § 1886(d)(5)(I)(i) to provide for a multi-year transition period for any one-year cut to the relative weight of an MS-DRG in excess of 10% that CMS did not specifically propose and explain in the proposed rule.

[7] 80 Fed. Reg. 49356 – 57 (Aug. 17, 2015).
[8] 82 Fed. Reg. 19829 – 30 (Apr. 28, 2017).
[9] 81 Fed. Reg. 57280 (Aug. 22, 2016).

V. Conclusion

We appreciate CMS's consideration of our comments on the proposed cuts in relative weight for MS-DRG 215, and respectfully request that CMS revise these cuts as set out above to avoid substantial payment redistributions that are not the result of CMS policy. To discuss any of the issues raised in this comment letter, please contact me at sbunk@abiomed.com or (978)882-8042.

Respectfully submitted,

Stacey A. Bunk, MS, CPC, CCC, FABC
Associate Director, Reimbursement
ABIOMED, Inc

Appendix A: FDA Indications for Use

INDICATIONS FOR USE

Protected PCI
The Impella 2.5® and Impella CP® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and Impella CP Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Cardiogenic Shock
The Impella 2.5®, Impella CP®, Impella 5.0®, and Impella LD® Catheters, in conjunction with the Automated Impella Controller (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5 and Impella CP, and ≤ 6 days for the Impella 5.0, and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

INDICATIONS FOR USE

The Impella RP® is indicated for providing circulatory assistance for up to 14 days in pediatric or adult patients with a body surface area ≥ 1.5 m2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Appendix B: Insertion, Revision, and Removal ICD-9 and ICD-10 Codes Assigned to MS-DRGs 215, 001, and 002

	DRG 215	**DRGs 001/002**
ICD-9	*37.53 - Replacement or repair of thoracic unit of (total) replacement heart system* *37.54 - Replacement or repair of other implantable component of (total) replacement heart system* *37.60 – Implantation or insertion of biventricular external heart assist system* *37.62 – Insertion of temporary non-implantable extracorporeal circulatory assist device* *37.63 – Repair of heart assist system* *37.65 – Implant of single ventricular (extracorporeal) external heart assist system*	*33.6 – Combined heart-lung transplantation* *37.51 – Heart transplantation* *37.52 – Implantation of total internal biventricular heart replacement system* *37.66- Insertion of implantable heart assist system* *37.60 – Implantation or insertion of biventricular external heart assist system* *37.63 – Repair of heart assist system* *37.65 – Implant of single ventricular (extracorporeal) external heart assist system* ***AND*** *37.64 - Removal of external heart assist system(s) or device(s)*
ICD-10	*02HA[0,3,4]R[S,Z] – Insert [Bivent, Ext Heart Assist] into heart, [opn, perc, perc endo] appr* *02WA[0,3,4][J,Q,R]Z – Rev [Synth Sub, Implant Heart Assist, Ext Heart Assist] in heart, [opn, perc, perc endo] appr*	*02YA0Z[0,1,2] Transplantation/Heart, Opn, No Dev, [Allogeneic, Syngeneic, Zooplastic]* ***OR*** *02RK0JZ – Replace R Ventricle w/ Synth Sub, Opn Appr* ***AND*** *02RL0JZ – Replace L Ventricle w/ Synth Sub, Opn Appr* ***OR*** *02HA[0,3,4]QZ – Insert heart, [Opn, Perc, Perc Endo], Implantable Heart Assist Sys, NQ* ***OR*** *02HA0RS – Insert Bivent Ext Heart Assist into Heart, Opn Appr* *02HA0RZ – Insert Ext Heart Assist into Heart, Opn Appr* *02HA3RS – Insert Bivent Ext Heart Assist into Heart, Perc Appr* *02HA4RS – Insert Bivent Ext Heart Assist into Heart, Perc Endo Appr* *02WA[0,3,4][Q,R]Z – Rev Heart, [Opn, Perc, Perc Endo],[Implantable Heart Assist Sys, Ext Heart Assist Sys], NQ* ***AND*** *02PA[0,3,4]RZ – Removal Heart, [Opn, Perc, Perc Endo],Ext Heart Assist Sys, NQ*

Braid-Forbes Health Research

Data analysis informing sound policy

TO: Stacey Bunk and Andrew Greenfield, Abiomed

FROM: Mary Jo Braid-Forbes

DATE: June 6, 2017

RE: Summary of Findings

This memo summarizes the key findings from several of the data analyses undertaken in support of your investigation into the decrease in charges in DRG 215. I used the first release of the FY 2016 MedPAR file which is known to be missing claims that contain substance abuse diagnosis codes. Comparisons were made to the FY 2015 MedPAR file (proposed rule version).

The weights for MS-DRG 215 showed the largest decrease in the FY 2018 proposed rule compared FY 2017. MS-DRG 215 weights decreased 35%. Table 1 shows the MS-DRGs with decreases greater than 10%.

Table 1: Change in weights, FY 2017 to FY 2018

MS-DRG	MS-DRG Title	FY 2017	FY 2018	FY 2018 proposed weights compared to FY 2017 weights (%
215	***OTHER HEART ASSIST SYSTEM IMPLANT***	***16.1076***	***10.4983***	***-35%***
780	FALSE LABOR	0.6099	0.4401	-28%
332	RECTAL RESECTION W MCC	4.7767	3.6476	-24%
517	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC/MCC	1.7951	1.3716	-24%
333	RECTAL RESECTION W CC	2.4906	1.9645	-21%
454	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W CC	8.121	6.4297	-21%
734	PELVIC EVISCERATION, RAD HYSTERECTOMY & RAD VULVECTOMY W CC/MCC	2.7192	2.1648	-20%
770	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	0.9707	0.7741	-20%
455	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W/O CC/MCC	6.3467	5.0622	-20%
768	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C	1.2712	1.0173	-20%
334	RECTAL RESECTION W/O CC/MCC	1.5954	1.2915	-19%
423	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES W MCC	4.4817	3.6347	-19%
867	OTHER INFECTIOUS & PARASITIC DISEASES DIAGNOSES W MCC	2.6467	2.1586	-18%
327	STOMACH, ESOPHAGEAL & DUODENAL PROC W CC	2.5899	2.1177	-18%
830	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R. PROC W/O CC/MCC	1.5046	1.2757	-15%
326	STOMACH, ESOPHAGEAL & DUODENAL PROC W MCC	5.367	4.5588	-15%
951	OTHER FACTORS INFLUENCING HEALTH STATUS	0.9244	0.787	-15%
712	TESTES PROCEDURES W/O CC/MCC	1.0714	0.9232	-14%
769	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	2.0576	1.7736	-14%
290	ACUTE & SUBACUTE ENDOCARDITIS W/O CC/MCC	1.2605	1.0907	-13%
344	MINOR SMALL & LARGE BOWEL PROCEDURES W MCC	3.1626	2.7467	-13%
981	EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS W MCC	4.9451	4.3369	-12%
777	ECTOPIC PREGNANCY	0.9897	0.872	-12%
148	EAR, NOSE, MOUTH & THROAT MALIGNANCY W/O CC/MCC	0.9122	0.8064	-12%
713	TRANSURETHRAL PROSTATECTOMY W CC/MCC	1.5948	1.4197	-11%
346	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC/MCC	1.2303	1.0984	-11%
453	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION W MCC	10.8459	9.7066	-11%

There was no methodological change that caused MS-DRG 2015 weights to change. The change was due to a change in the average charge of the cases assigned to this DRG. The charges decreased due to a change in the types of cases that mapped to this DRG. Overall, between the FY 2015 data based on ICD-9 diagnosis and procedure codes and the FY 2016 data based on ICD-10, there was a decrease in repair/revision cases and an increase in implant cases, particularly percutaneous approach, as well as a decrease in the average charge for both types of cases.

- In FY 2015 data (FY2017 rule) there were more than twice as many repair/revision cases as implant cases:
    - Repair or revision of heart assist system: 37.63 (187 discharges).
    - Implant of external heart assist device: 37.62 (69 discharges) and 37.65 (12 discharges). Code 37.60 had fewer than 11 cases.

ICD-9 Code	Descriptor	FY 2015 cases (proposed rule file)
37.63	Repair of heart assist system	187
37.62	Insertion of temporary non-implantable extracorporeal circulatory assist device	69
37.65	Implant of single ventricular (extracorporeal) external heart assist system	12
37.60	Implantation or insertion of biventricular external heart assist system	<11

- In FY 2016 data (FY 2018 rule) there were almost four times as many implant cases as repair cases:
    - Repair or revision of heart assist system: 02WA*** (61 discharges).
    - Implant of external heart assist device: 02HA*** (231 discharges)
    - Percutaneous approach (02HA3RZ) comprised the majority of the implant cases (77%)

ICD-10 code	Descriptor	FY 2016 cases (proposed rule file)
02WA0QZ	Revision of Implant Heart Assist in Heart, Open Approach	43
02WA3RZ	Revision of Implant Heart Assist in Heart, Perc Approach	11
Unduplicated total repair		*61*
02HA3RZ	Insertion of Ext Heart Assist into Heart, Perc Approach	175
02HA0RZ	Insertion of Ext Heart Assist into Heart, Open Approach	43
Unduplicated total implant		*231*

- For both types of cases the average total standardized charge decreased:
    - For revisions the standardized charges decreased 28%
    - For implant cases the standardized charges decreased 20%

Table 2 shows the length of stay, mean standardized charge and mean cost in total and by department.

Table 2: LOS, Charges, and Costs for Implant and Revision Cases in MS-DRG 215

	FY 2015		FY 2016		Change FY 2015 to FY 2016	
	Implant	Revision	Implant	Revision	Implant	Revision
Discharges after statistical outliers removed	88	186	224	60	136	(126)
LOS	13.6	21.7	10.3	18.5	(3)	(3)
ICU LOS	12.0	16.9	8.1	14.2	(4)	(3)
Mean standardized CHARGES	377,916	468,203	302,085	338,192	(75,831)	(130,010)
Mean COST	94,193	124,861	73,612	89,001	(20,581)	(35,860)
Average COST by department						
Routine	991	3,665	1,569	3,412	579	(253)
Intensive Care	22,638	24,353	13,304	18,787	(9,334)	(5,565)
Implants	17,411	43,395	20,728	27,406	3,318	(15,990)
Drugs	9,277	10,012	4,802	5,005	(4,474)	(5,008)
Operating Room	12,144	8,242	5,804	5,390	(6,340)	(2,852)
Supplies	13,632	16,923	13,256	17,226	(376)	303
Therapy	449	763	365	583	(84)	(180)
Lab	4,417	5,502	2,987	3,849	(1,430)	(1,653)
Cardiology	740	1,000	1,138	971	398	(29)
Cath	1,202	715	3,573	1,000	2,371	285
Radiology	746	806	624	659	(121)	(147)
MRI	2	2	22	-	20	(2)
CT	70	161	61	149	(8)	(11)
ER	130	109	188	166	58	58
Blood	5,770	4,334	2,010	1,500	(3,760)	(2,834)
Other	1,485	2,063	1,135	826	(349)	(1,237)
Inhalation Therapy	2,555	2,253	1,746	1,633	(810)	(619)
Anesthesia	537	565	298	438	(239)	(126)

There was also a decrease in the acuity of the patients assigned to this DRG for both types of cases:

- In FY 2015, 95% of implant cases had an MCC as a secondary diagnosis. In FY 2016, this dropped to 84% a 11 percentage point drop, but still very high percent of cases with MCC diagnoses.

- In FY 2015, 73% of revision cases (37.68) had an MCC as a secondary diagnosis. In FY 2016, this dropped to 67%, a 6 percentage point reduction.

- The drop in the percent of cases with an MCC as a secondary diagnosis is consistent with the finding that the ICU length of stay and corresponding costs dropped.

Table 3 shows the percent of cases with MCC as a secondary diagnosis and the average charges with and without the MCC.

Table 3: Cases with MCC as a Secondary Diagnosis in MS-DRG 215

		Total cases	Cases with MCC as 2nd Dx	% MCC	Average Total Charges	Cases WITH MCC as 2nd Dx	Cases WITHOUT MCC as 2nd Dx
FY 2015							
	Implant	81	77	95%	$ 453,810	$ 465,547	$ 227,883
	Repair	187	136	73%	$ 543,772	$ 587,759	$ 426,476
FY 2016							
	Implant	231	195	84%	$ 344,968	$ 371,304	$ 202,316
	Repair	61	41	67%	$ 414,776	$ 477,494	$ 286,206

Appendix D: Memorandum from Foley Hoag LLP

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Memo

Date:	June 7, 2017
To:	Centers for Medicare & Medicaid Services
From:	Thomas R. Barker Brian P. Carey
Regarding:	CMS Authority to Adjust Inpatient Prospective Payment System Relative Weights To Ensure Appropriate Payment

At the request of our client Abiomed, Inc., we have reviewed the legal authority of the Centers for Medicare & Medicaid Services (CMS) under the Social Security Act and implementing regulations to make transitional adjustments under the Inpatient Prospective Payment System (IPPS) to ensure appropriate payment to providers. In particular, we have analyzed the authority of the agency to make transitional adjustments to relative weights of particular diagnosis related groups (DRGs) to mitigate the negative impact of the implementation of new payment methodologies such as a new coding system. In general, under Section 1886(d) of the Social Security Act, CMS has broad authority to adjust payment amounts under the IPPS. In prior rulemakings the agency has used this authority to adopt transition periods to mitigate significant fluctuations in provider reimbursement when implementing new payment methodologies.

In the FY2018 IPPS Proposed Rule, the agency for the first time set relative weights for DRGs based on claims data following the shift from ICD-9 to ICD-10. For certain DRGs, this shift in coding would result in significant payment decreases from fiscal year 2017 if the Proposed Rule is finalized. For example, the relative weight for MS-DRG 215 (Other Heart Assist System Implant) would be decreased by approximately 35 percent. Abiomed and other stakeholders proposed in their comment letters a transition for any one-year decrease in an MS-DRG relative weight that exceeds 10 percent and is not the result of a specific policy proposal to refine the MS-DRG relative weight. We conclude that CMS may implement a transition period, either in the form of a cap on the percent by which the relative weight for an MS-DRG can decrease in a single year or a multi-year phase-in period for large cuts.

I. Statutory Framework

As CMS is aware, Section 1886(d) of the Social Security Act creates the IPPS, a payment system for inpatient stays covered by Medicare Part A based on prospectively set rates. Under the IPPS, a beneficiary is categorized into a diagnosis-related group (DRG). The payment amounts for each DRG are based on a weighted factor assigned to it. CMS is required by statute to establish DRGs and assign appropriate weighting factors which reflect the relative resources used with respect to discharges within that group.[1] CMS must annually adjust the relative weights to reflect changes in treatment patterns.[2]

Section 1886(d)(5) authorizes CMS to make additional payments, exceptions, and adjustments to the scheduled payments under the IPPS. Some of these additional payments, exceptions, and adjustments are specifically defined by statute. For example, CMS is authorized to make additional payments to hospitals serving a significantly disproportionate number of low-income patients.[3] Additionally, Congress also included a "catch-all" provision, which delegates to CMS broad authority to make adjustments to payment amounts made under the IPPS.[4] In relevant part, the statute says: "***The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate***."[5]

This provision, which CMS commonly refers to as its "exceptions and adjustments provision," provides CMS with wide-latitude to make suitable adjustments to payment amounts under the IPPS. CMS is not limited in the type of adjustments it may make nor is it restrained as to which IPPS payment amounts may be affected. The only limit contained in the general exceptions and adjustments provision is that the exception or adjustment must be "appropriate."[6]

Federal courts that have reviewed the exceptions and adjustments provision have described its scope as "broad" and "sweeping."[7] In *Adirondack Med. Ctr. v. Sebelius*, the D.C. Circuit Court of Appeals upheld CMS's downward adjustment to hospital-specific rates for rural and sole community hospitals in order to ameliorate an increase in the rate paid to all hospitals due to the revamping of the diagnosis coding system.[8] The Court concluded that Congress did not cabin the Secretary's ability to rectify unintended changes in payment amounts.

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[1] Social Security Act §1886(d)(4)(A)-(B).
[2] Social Security Act §1886(d)(4)(C)(i).
[3] Social Security Act §1886(d)(5)(F)(i).
[4] *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 252 (D.D.C. 2015) (describing Section §1886(d)(5)(I) as a "catch-all" provision).
[5] Social Security Act §1886(d)(5)(I)(i).
[6] *Shands*, 139 F. Supp. 3d at 252.
[7] *See Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014) (describing §1886(d)(5)(I) as a "broad grant of authority"); *Shands*, 139 F. Supp. 3d at 252 ("the plain language of the general exceptions and adjustments provisions is sweeping").
[8] *See generally*, 740 F.3d at 700.

Although there may be some substantial departures from the IPPS that would cease to be an adjustment, changes in payment amounts made pursuant to the exceptions and adjustments provision will be upheld so long as they do not make basic and fundamental changes to the scheme Congress created.[9] Indeed, adjustments that were far more expansive than the transitional period proposed here have been deemed acceptable. For example, in *Shands Jacksonville Medical Center v. Burwell*, a federal district court found that an *across-the-board* reduction in IPPS rates was a reasonable interpretation of the exceptions and adjustments provision.[10] In so concluding, the court rejected the plaintiffs argument that such an expansive adjustment impeded the overall structure of the Medicare Act.

II. Past Examples Support CMS's Authority to Implement Transitionary Periods

As part of the annual IPPS rulemakings CMS regularly implements the exceptions and adjustments authority to revise payment amounts under the IPPS to prevent significant fluctuations in payment rates. As CMS explained in the FY2017 IPPS Final Rule, it is often the agency's practice to "delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year."[11] In prior rulemakings, CMS has transitioned payments both by implementing multi-year phase-ins and capping the maximum amount of any year-to-year decrease.

a. CMS Uses Multi-Year Phase-In Periods to Moderate Fluctuations in Payment

CMS provides for "transition periods when adopting changes that have significant payment implications, particularly large negative impacts."[12] In the FY2015 IPPS Final Rule, for example, a number of hospitals faced the prospect of a sudden and significant decrease in payment rates as a result of the effect that new OMB labor market delineations had on the area wage index. CMS phased in changes in payment rates for hospitals that were located in an urban county that became rural under new OMB delineations.[13] CMS was concerned that hospitals that were originally considered urban, but would now be considered rural under the new labor market area definitions, would face a "steep[] and abrupt" cut in reimbursements. To "alleviate the decreased payments," CMS finalized a policy to assign hospitals in these counties the urban wage index value of the CBSA where they were located in FY2014 for three years from FY2015 through FY2017.[14] CMS also adopted a 1-year blended wage index transitional policy for all hospitals that were going experience *any decrease* in their wage index value as a result of the OMB delineations.

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[9] *Id.*, 139 F. Supp. 3d at 260 citing *Amgen, Inc. v. Smith*, 357 F.3d 103, 118 (D.C. Cir. 2004) (discussing a similar provision in the outpatient prospective payment system).
[10] *Id.*
[11] *See* 81 Fed. Reg. 57281.
[12] *See* 81 Fed. Reg. 57280.
[13] *See* 79 Fed. Reg. 50372.
[14] CMS also adopted a similar transitional period for hospitals that became rural as a result of new OMB delineations in the FY2005 IPPS. *See* 69 Fed. Reg. 48916, 49196.

CMS instituted a similar transitionary period in addressing rural wage floors as part of the FY2009 IPPS Final Rule. The Balanced Budget Act of 1997 both required CMS to establish a rural wage floor such that the wage index for a hospital in an urban area could not be less than the wage index of rural hospitals in the same state and included a budget neutrality requirement. In the FY2009 Final Rule, CMS adjusted the budget neutrality requirement to make budget neutrality adjustments specific to the State rather than on a nationwide basis. Taking into account "the potentially drastic payment cuts that may occur to hospitals in some states," CMS decided to phase in the transition over the course of a 3-year period.

Furthermore, CMS has concluded in prior rulemakings that it is "prudent" to delay implementation of a proposed rate change when more current data could limit cuts to providers. In the FY2010 IPPS Final Rule, CMS delayed adoption of a documentation and coding adjustment to hospital-specific rates until FY2011.[15] CMS had originally indicated in the FY2009 IPPS rule that CMS would make adjustments to the hospital-specific rate in the FY2010 rulemaking if the FY2008 claims data for hospitals paid based on the hospital-specific rate demonstrated a significant increase in payments resulting from documentation and coding changes that did not reflect real increases in patients' severity of illness. The 2008 data showed such a change unrelated to real changes in case-mix. Although CMS proposed to make a negative 2.5% adjustment in the FY2010 proposed rule, the agency decided to delay implementation of the adjustment in the Final Rule so that it could analyze additional claims data. CMS decided to wait to fully review the FY2009 claims data, to determine if it could potentially lessen the anticipated cumulative adjustments. CMS concluded that "it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY2009 claims data for hospitals receiving hospital-specific rates."

b. CMS Uses Caps to Prevent Abrupt Drops in Payment Rates

As described above, CMS is not limited in the type of adjustments it may make under the exceptions and adjustments provision, so long as those adjustments are appropriate. In other payment systems that include adjustments authority that is nearly identical to the authority that exists in the IPPS, CMS has capped the maximum year-to-year decrease for payment rates in order to limit cuts to hospital reimbursement while transitioning to new claims data. For example, in the CY2005 Hospital Outpatient Prospective Payment System (HOPPS) rulemaking, CMS adopted a 5 percent cap on the maximum year-to-year reduction to median costs for device-dependent Ambulatory Payment Classifications (APC). Under the HOPPS, CMS is authorized to make "other adjustments as determined to be necessary to ensure equitable payments."[16] The agency instituted the cap because the claims data being used to set median costs for these APCs in CY2005 did not reflect only those claims containing device

[15] 74 Fed. Reg. 43775

[16] Social Security Act §1833(t)(2)(e). Notably, CMS's authority to make adjustments under the IPPS is broader than under the HOPPS. The HOPPS limits CMS to adjustments that "ensure equitable payments," whereas adjustments under the IPPS need only be "appropriate." *See* Social Security Act C1886(d)(5)(I).

codes, as the CY2004 data had done.[17] As a result, there were concerns that the CY2005 data underestimated the costs of the services. In that year's HOPPS Final Rule, CMS elected to mitigate cuts based on this new data by setting the median for device-dependent APCs at the greater of the CY2005 median cost from claims data or 95 percent of the CY2004 final adjusted median cost.[18] CMS explained that this 5 percent cap on reductions from the CY2004 median represented "a simple and easily understood methodology for adjusting median costs" that would enable reductions to be "sufficiently modest that providers will be able to accommodate them without ceasing to furnish services that Medicare beneficiaries need."[19]

III. A Transition Period for MS-DRG 215 and Similarly Situated MS-DRGs is Consistent with CMS Authority and Precedent

As noted, the Proposed Rule would decrease the relative weight for MS-DRG 215 (Other Heart Assist System Implant) by 34.8 percent if finalized. This significant cut in the relative weight for MS-DRG 215 is not the result of a new policy in the Proposed Rule, as the Proposed Rule does not detail any policy changes to MS-DRG 215 or the codes that are assigned to MS-DRG 215. Instead, this cut can only be explained as the unintended result of the ICD-10 coding implementation. The ICD-10 coding implementation was not intended to bring about such a significant change in hospital payment levels from year to year. In the FY2017 IPPS Final Rule, CMS made clear the need "for the ICD-10 MS-DRGs to accurately replicate the logic of the ICD-9-CM based version of the MS-DRGs." CMS specified that the failure of the ICD-9 and ICD-10 versions of the MS-DRGs to replicate each other could lead to "unintended payment redistributions."[20]

The potential impact of the decrease in the relative weight for MS-DRG 215 is amplified by the recent, first of a kind, FDA approvals for percutaneous and surgical heart pumps that expand therapeutic options for Medicare patients in MS-DRG 215 in FY2018 and years beyond. Additionally, a recent change in the coding guidance for implanting heart pumps from the American Hospital Association (AHA) will result in higher-cost patients with more ICU days and increased length of stays being assigned to MS-DRG 215 in FY2018. Each of these factors will lead to significant underpayment in FY2018 and increases the need for CMS re-evaluate and adjust the proposed change in the relative weight for MS-DRG 215.

Abiomed and other stakeholders have proposed in their comment letters a transition for any one-year decrease in an MS-DRG relative weight that exceeds 10 percent. This transition period could take the form of a cap on the percent by which the relative weight for an MS-DRG can decrease in a single year, or of a multi-year phase-in.[21] Either of these proposals would be consistent with CMS's authority under the IPPS and agency precedent.

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[17] *See* 69 Fed. Reg. 65749-50.
[18] 69 Fed. Reg. 65752-53.
[19] 69 Fed. Reg. 65753.
[20] *See* 81 Fed. Reg. 56790
[21] Although a transition period was not specifically articulated in the Proposed Rule, CMS may implement a transition period without conducting an additional notice and comment period. Transition periods are mechanisms that an agency uses to implement a policy, and do not

a. CMS may implement a multi-year phase-in for an MS-DRG that is scheduled to have a large cut in its relative weight in any single year

CMS may also consider phasing in significant decreases in the relative weight of an MS-DRG over a multi-year period, using a blended payment amount for each of the intervening years. As described in more detail above, CMS has previously used multi-year phase-in periods to moderate the negative effects of changes in payment systems.

The proposed decrease in the relative weight to MS-DRG 215 is similar to the prior instances in which CMS has used a multi-year phase-in period to moderate abrupt and significant changes in payment rates. Like the changes associated with the rural wage index, the decrease in MS-DRG 215 will result in an abrupt and steep cut in reimbursements. MS-DRG 215 was not deliberately targeted for cuts, but like the hospitals facing a cut in payment rates based on changes in OMB's labor market delineations, payment for MS-DRG 215 will be significantly reduced as a result of outside statistical shifts, specifically changes in coding from the ICD-9 and ICD-10 transition. Because a multi-year phase-in period will help moderate the immediate impact of this drop in payment, it is consistent with past CMS policy.

Transitioning the payment reduction for MS-DRG 215 would also be consistent with prior CMS decisions to delay implementation of payment cuts in order to review additional data. As described above, the recent first of its kind FDA approvals for percutaneous and surgical heart pumps as well as a recent change in coding guidance for implanting heart pumps will result in an influx of cases to MS-DRG 215 in FY2018. As a result, the costs associated with MS-DRG 215 in FY2018 may be significantly higher than those accounted for in the proposed relative weight. It would be prudent for CMS to moderate the effect of the proposed decrease in FY2018 to avoid large swings in payment rates between years. CMS will then be able to set a payment rate in FY2019 that takes into account all of the current variability in MS-DRG 215.

b. CMS may implement a cap on the percent by which the relative weight for an MS-DRG may decrease in a single year

Abiomed, Inc. and other stakeholders have proposed to cap the year-over-year decrease of the relative weight of any MS-DRG at 10 percent of the prior year's relative weight. This proposal is consistent with CMS precedent from other payment systems that contain exceptions and adjustment authority that is virtually identical to the authority that exits in the IPPS.[22] Specifically, as described in more detail above, CMS has capped cuts in payment rates as part of transitions to new claims data. Payment caps provide CMS with a means of transitioning to

require an additional notice and comment period. *Select Specialty Hosp. Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 24 (D. DC 2011).

[22] *Compare* Social Security Act §1886(d)(5)(I) (permitting the Secretary to make "such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate") with §1833(t)(2)(e) (permitting the Secretary to establish "other adjustments as determined to be necessary to ensure equitable payments").

the eventual use of the new methodology without limiting access to critical services that may face an abrupt drop in reimbursement. Some MS-DRGs, including MS-DRG 215, are facing abrupt payment cuts resulting from the ICD-9 to ICD-10 coding transition. This is similar to the change in data collection that resulted in decreased reimbursement for certain device-dependent APCs in the CY2005 HOPPS. At the time, CMS determined that a 5 percent cap on median cost decreases was an easily understood methodology to maintain access to care during the transition. A 10 percent cap on year-to-year cuts on MS-DRGs would provide a similar benefit to patients who rely on the technology.

IV. Conclusion

CMS has broad authority under the IPPS to implement a transition period for significant decreases in the relative weight for an MS-DRG, either by capping decreases in relative weights for MS-DRGs or through a multi-year phase-in period. Making this adjustment would be consistent with prior CMS precedent of using the exceptions and adjustments provision or similar statutory authority to moderate large negative year-to-year impacts. For the reasons discussed above, we believe that CMS has the clear statutory authority to do so, and we concur with those commenters that have recommended that CMS implement a transitionary period, either through a cap or a phase-in period, for any MS-DRG that experiences an annual decrease of 10 percent or more in its relative weight.