diagnosis codes considered for MS-DRG assignment. The differences in the average lengths of stay and the average costs represented in the above table are too small to warrant an assignment to the higher weighted MS-DRGs, and the differences in the length of stay and costs are not substantial enough to justify the creation of additional MS-DRGs. Therefore, for FY 2011, we are not making any changes to MS-DRGs 061, 062, 063, 064, 065, 066, 067, and 068; nor are we making changes to the MS-DRG assignment of diagnosis code V45.88.

We will continue to monitor these MS-DRGs and diagnosis code V45.88 in upcoming annual reviews of the IPPS.

3. MDC 5 (Diseases and Disorders of the Circulatory System): Intraoperative Fluorescence Vascular Angiography (IFVA) and X-Ray Coronary Angiography in Coronary Artery Bypass Graft Surgery

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR43785 through 43787), we discussed a request we received to reassign cases reporting the use of intraoperative fluorescence vascular angiography (IFVA) with coronary artery bypass graft (CABG) procedures from MS-DRGs 235 and 236 (Coronary Bypass without Cardiac Catheterization with and without MCC, respectively) to MS-DRG 233 (Coronary Bypass with Cardiac Catheterization with MCC) and MS-DRG 234 (Coronary Bypass with Cardiac Catheterization without MCC). Effective October 1, 2007, procedure code 88.59 (Intraoperative fluorescence vascular angiography (IFVA)) was established to describe this technology.

In addition, we also discussed receiving related requests (74 FR 43798 through 43799) that were outside the scope of issues addressed for MDC 5 in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule. There were three components to these requests. The first component involved the creation of new MS-DRGs. One request was to create four new MS-DRGs that would differentiate the utilization of resources between intraoperative angiography and IFVA when utilized with CABG. A second request was to create only one new MS-DRG to separately identify the use of intraoperative angiography, by any method, in CABG surgery. The second component involved reviewing the ICD-9-CM procedure codes. Currently, the ICD-9-CM procedure codes do not distinguish between preoperative, intraoperative, and postoperative angiography. Procedure code 88.59 (Intraoperative fluorescence vascular angiography (IFVA)) is one intraoperative angiography technique that allows visualization of the coronary vasculature. The third component involved reassigning cases with procedure code 88.59 to the "Other Cardiovascular MS-DRG"s: MS-DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, CC, and without CC/MCC, respectively). We stated our intent to consider these requests during the FY 2011 rulemaking process.

After publication of the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we were contacted by one of the requestors, the manufacturer of the IFVA technology. We met with the requestor in mid-November 2009 to discuss evaluating the data for IFVA (procedure code 88.59) again in consideration of a proposal to create new MS-DRGs and to discuss a request for a new procedure code(s).

IFVA technology consists of a mobile device imaging system with software. It is used to test cardiac graft patency and technical adequacy at the time of coronary artery bypass grafting (CABG). While this system does not involve fluoroscopy or cardiac catheterization, it has been suggested that it yields results that are similar to those achieved with selective coronary arteriography and cardiac catheterization.

Intraoperative coronary angiography provides information about the quality of the anastomosis, blood flow through the graft, distal perfusion, and durability. For additional information regarding IFVA technology, we refer readers to the September 28-29, 2006 ICD-9-CM Coordination and Maintenance Committee meeting handout at the following website:

http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage.

a. New MS-DRGs for Intraoperative Fluorescence Vascular Angiography (IFVA) with CABG

As stated in the FY 2010 IPPS/LTCH PPS proposed rule (75 FR 23900), the manufacturer requested that we create four new MS-DRGs for CABG to distinguish CABG surgeries performed with IFVA and those performed without IFVA. According to the requestor, these four new MS-DRGs would correspond to the existing MS-DRG for CABG but would also include intraoperative angiography. The requestor proposed the following four new MS-DRGs:

MS-DRG XXX (Coronary Bypass with Cardiac Catheterization with MCC with Intraoperative Angiography)

MS-DRG XXX (Coronary Bypass with Cardiac Catheterization without MCC with Intraoperative Angiography)

MS-DRG XXX (Coronary Bypass without Cardiac Catheterization with MCC with Intraoperative Angiography)

MS-DRG XXX (Coronary Bypass without Cardiac Catheterization without MCC with Intraoperative Angiography)

For the FY 2011 proposed rule, using claims data from the FY 2009 MedPAR file, we examined cases identified by procedure code 88.59 in MS-DRGs 233, 234, 235, and 236. As shown in the table below, for both MS-DRGs 235 and 236, the cases utilizing IFVA technology (code 88.59) have a shorter length of stay and lower average costs compared to all cases in MS-DRGs 235 and 236. There were a total of 10,281 cases in MS-DRG 235 with an average length of stay of 10.61 days and average costs of \$34,639. There were 114 cases identified by procedure code 88.59 with an average length of stay of 10.38 days with average costs of \$28,238. In MS-DRG 236, there were a total of 22,410 cases with an average length of stay of 6.37 days and average costs of \$23,402; and there were 186 cases identified by procedure code 88.59 with an average length of stay of 6.54 days and average costs of \$19,305. Similar to the data reported last year, the data for FY 2009 clearly demonstrate that the IFVA cases (identified by procedure code 88.59) are assigned appropriately to MS-DRGs 235 and 236. We also examined cases identified by procedure code 88.59 in MS-DRGs 233 and 234. Likewise, in MS-DRGs 233 and 234 cases identified by code 88.59 reflect shorter lengths of stay and lower average costs compared to the remainder of the cases in those MS-DRGs; and

there were a total of 16,475 cases in MS-DRG 233 with an average length of stay of 13.47 days and average costs of \$42,662. There were 58 cases identified by procedure code 88.59 with an average length of stay of 12.12 days and average costs of \$35,940. In MS-DRG 234, there were a total of 23,478 cases with an average length of stay of 8.61 days and average costs of \$29,615; and there were 67 cases identified by procedure code 88.59 with an average length of stay of 8.85 days and average costs of \$25,379. The data clearly demonstrate the IFVA cases (identified by procedure code 88.59) are appropriately assigned to MS-DRGs 233 and 234.

MS-DRG	Number of Cases	Average Length of Stay	Average Cost
235 – All cases	10,281	10.61	\$34,639
235 – Cases with procedure code 88.59	114	10.38	\$28,238
235 – Cases without procedure code 88.59	10,167	10.62	\$34,711
236 – All cases	22,410	6.37	\$23,402
236 – Cases with code procedure 88.59	186	6.54	\$19,305
236 – Cases without procedure code 88.59	22,224	6.37	\$23,436

MS- DRG	Number of Cases	Average Length of Stay	Average Cost
233 – All cases	16,475	13.47	\$42,662
233 – Cases with procedure code 88.59	58	12.12	\$35,940
233 – Cases without procedure code 88.59	16,417	13.47	\$42,686
234 – All cases	23,478	8.61	\$29,615
234 – Cases with procedure code 88.59	67	8.85	\$25,379
234 – Cases without procedure code 88.59	23,411	8.61	\$29,627

We stated in the proposed rule that if the cases identified by procedure code 88.59 were proposed to be reassigned from MS-DRGs 235 and 236 to MS-DRGs 233 and 234, they would be significantly overpaid. In addition, we indicated that because the cases in MS-DRGs 235 and 236 did not actually have a cardiac catheterization performed, a

proposal to reassign cases identified by procedure code 88.59 would result in lowering the relative weights of MS-DRGs 233 and 234 where a cardiac catheterization is truly performed.

In summary, in the proposed rule, we indicated that the data do not support moving IFVA cases (procedure code 88.59) from MS-DRGs 235 and 236 to MS-DRGs 233 and 234. Therefore, we did not propose to make any MS-DRG modifications for cases reporting procedure code 88.59 for FY 2011.

Comment: Several commenters agreed with CMS' proposal to not make any MS-DRG modifications in FY 2011 for cases reporting procedure code 88.59. One commenter, the manufacturer, reported that they worked with a consulting group to conduct an analysis on a subset of MedPAR claims data that reported procedure code 88.59. According to the data presented, the consultant's methodology for the analysis involved examining only cases from the facilities that reported procedure code 88.59, in any procedure code sequencing position, in each one of the four MS-DRGs previously discussed (233, 234, 235, or 236). The manufacturer asserted that results of the consultant's analysis varied significantly from the CMS data and that their data supported reassignment of cases reporting procedure code 88.59 from MS-DRGs 235 and 236 to MS-DRGs 233 and 234.

Response: We acknowledge the commenters who supported our proposal to not make any MS-DRG modifications for cases reporting procedure code 88.59 for FY 2011. In response to the manufacturer who worked with the consulting group, we point out that the process of evaluating MS-DRG reclassifications is not based on subsets of

facility-specific data, but rather, as stated earlier in section II.B.2 of the preamble to this final rule, in deciding whether to make modifications to the MS-DRGs we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS-DRG. In addition, in evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS-DRG. As the manufacturer noted, the consultant's analysis submitted for consideration was based on a subset of facility-specific claims reporting code 88.59. Therefore, it is not comparable to the analysis conducted by CMS. While the consultant's analysis included cases that reported procedure code 88.59, it did not reflect the differences in comparison to MedPAR claims data, as the CMS analysis did, that are representative of the remaining Medicare patients grouped in the above mentioned relevant MS-DRGs.

In addition, the manufacturer also submitted the consultant's summary of observations from the analysis which stated two key points:

- (1) The number of discharges they observed in the MedPAR data was slightly higher than the volumes reported in the proposed rule. They believed this may be the result of slightly different data files between what they examined and what CMS used. The volume differences are comparatively small.
- (2) They were unable to account for differences in their cost calculation for cases reporting procedure code 88.59 and the CMS published results. Their hypothesis was

that, because these represent a small number of cases, cost report differences may be playing a significant role in the calculation.

Currently, CMS' systems only process up to six procedure codes and, as the commenter stated, the consultant's methodology considered procedure code 88.59 in any sequencing position. Therefore, it is unclear how many cases may have been reported after the sixth position. Effective January 1, 2011, the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update will become effective. The version 5010 format will allow facilities to report up to 25 diagnoses and 25 procedure codes, and CMS' systems will begin to process all 25 diagnosis and procedure codes. (Further detail regarding this issue is discussed in section II.G.11. of this final rule.).

Lastly, the manufacturer concluded that "the cost data continue to be unreliable due to the sample size and inherent limitations of cost reporting." We reiterate that the analysis conducted by the manufacturer and consultant were not comparable to the analysis conducted by CMS that examined cases reporting procedure code 88.59 against all cases in the specified MS-DRGs versus the consultant's analysis that only provided data on those facilities that are using the technology and their associated costs.

Therefore, we are finalizing our proposal to not reassign cases reporting procedure code 88.59 for FY 2011.

b. New MS-DRG for Intraoperative Angiography, by any Method, with CABG

We also received a request to create a single MS-DRG for any type of
intraoperative angiography utilized in CABG surgery. The requestor suggested the

following title for the proposed new MS-DRG: XXX Coronary Bypass with Intraoperative Angiography, by any Method.

As we indicated in the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23901), currently, the only ICD-9-CM procedure code that identifies an intraoperative angiography is procedure code 88.59 (Intraoperative fluorescence vascular angiography), as described in the previous section. Due to the structure of the ICD-9-CM procedure classification system, it is not possible to distinguish when other types of angiography are performed intraoperatively. Therefore, we indicated that we were unable to evaluate any data, other than that for procedure code 88.59, as shown in the tables above. We did not propose to create a new MS-DRG in FY 2011 for coronary bypass with intraoperative angiography, by any method.

Comment: Several commenters agreed with CMS' proposal to not create a new MS-DRG in FY 2011 for coronary bypass with intraoperative angiography, by any method. Another commenter, the manufacturer, acknowledged the limitations of the ICD-9-CM coding structure and the ability to currently only identify one method of intraoperative angiography. The manufacturer stated that the creation of a new ICD-9-CM procedure code to identify intraoperative angiography by conventional X-ray angiography would allow CMS to obtain accurate data on intraoperative or completion angiography by either method.

Response: We appreciate the commenter's support of our proposal to not create a new MS-DRG in FY 2011 for coronary bypass with intraoperative angiography, by any method. We also acknowledge the manufacturer's concern regarding the inability to

identify intraoperative angiography by conventional X-ray angiography. As discussed previously (75 FR 23901) and in further detail below, proposals for creating a new procedure code must be submitted to the ICD-9-CM Coordination and Maintenance Committee for consideration.

c. New Procedure Codes

In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23901), we indicated that, in response to our invitation to submit public comments regarding the proposal not to make any MS-DRG modifications for cases reporting procedure code 88.59 in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106-24107), one requestor presented another option involving the creation of new ICD-9-CM procedure codes. According to the requestor, the purpose of these new codes would be to separately identify the two technologies used to perform intraoperative coronary angiography in CABG surgery: X-ray coronary angiography with cardiac catheterization and fluoroscopy versus intraoperative fluorescence coronary angiography (IFVA). The requestor stated that due to the structure of the current codes and MS-DRGs for CABG, it is difficult to identify *when* x-ray angiography is performed.

X-ray angiography is commonly performed as a separate procedure in a catheterization laboratory. Currently, there are no procedure codes to distinguish if this angiography was performed preoperatively, intraoperatively, and/or postoperatively. We informed the requestor that they could submit a proposal for creating a new procedure code(s) to the ICD-9-CM Coordination and Maintenance Committee for its consideration. Therefore, in the FY 2011 proposed rule, we indicated that this topic would be further

evaluated through the ICD-9-CM Coordination and Maintenance Committee meeting process.

Comment: Similar to comments made at the March 9-10, 2010 ICD-9-CM Coordination and Maintenance Committee meeting, one commenter, the manufacturer, stated that the resource utilization costs for a diagnostic cardiac catheterization, which is routinely performed in a catheterization laboratory may differ from those costs incurred for performing intraoperative completion angiography concomitant with a coronary artery bypass graft procedure in a surgical suite. However, the manufacturer noted that, regardless of the technology (IFVA or X-ray angiography), performance of intraoperative completion angiography in a surgical suite involves similar resources. The commenter further noted that an intraoperative completion angiography performed with X-ray angiography cannot be separately identified from a diagnostic cardiac catheterization due to the coding structure. According to the commenter, this scenario creates a payment incentive for physicians to select X-ray technology to perform a completion angiography, despite the known risks to patients associated with exposure to radiation because the code used to report X-ray angiography (cardiac catheterization) is recognized in the MS-DRG assignment. The commenter urged CMS to remove this incentive by ensuring that procedure code 88.59 will impact MS-DRG assignment in the same way that the code for X-ray angiography does.

Response: As stated above, requests for updates and changes to the procedure coding system are discussed through the ICD-9-CM Coordination and Maintenance Committee meeting process. At the March 9-10, 2010 meeting, a proposal was submitted

by the manufacturer and presented. Details of the initial proposal regarding intraoperative angiography with coronary artery bypass graft discussed at the March 2010 ICD-9-CM Coordination and Maintenance Committee meeting along with the summary report of the meeting can be located at the following CMS website:

http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp.

Currently, there is not a mechanism to analyze if both technologies utilize similar resources in the surgical suite as the manufacturer asserts since, as stated several times, the coding structure does not currently distinguish between intraoperative X-ray angiography and IFVA. Despite the inability to currently differentiate between the two technologies in an intraoperative setting, we disagree that physicians have a payment incentive to utilize X-ray angiography over IFVA to perform a completion angiography. The current MS-DRG assignments are based on claims data for the purposes of maintaining clinically coherence, accounting for patient's severity of illness, ensuring similar utilization of resources and complexity of services and are not formulated to provide incentives as the commenter indicated. We believe that physicians provide the most clinically appropriate, quality of care and make decisions with respect to the individual patient's needs and not subject patients to inherent risk.

In response to the manufacturer's request urging CMS to ensure that IFVA impacts the MS-DRG assignment in the same way as a cardiac catheterization currently does, as stated in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43787), it would be inappropriate to reassign cases reporting the use of IFVA to higher weighted MS-DRGs merely as an incentive for hospitals to invest in the IFVA technology.

As stated earlier, at the March 2010 meeting, an initial proposal was presented and, as a result, one aspect of the two-part proposal was finalized that involves an update to an existing code and the creation of a new code for IFVA. Effective October 1, 2010 (FY 2011), procedure code 88.59 has been revised to uniquely identify intraoperative *coronary* fluorescence vascular angiography and new code 17.71 has been created to identify *noncoronary* intraoperative fluorescence vascular angiography. We do not agree with the manufacturer's comment that these new code changes for FY 2011 will facilitates the MS-DRG case reassignment that the commenter proposed for procedure code 88.59 and believed was appropriate for policy. CMS does believe additional data are needed to fully evaluate the volume of cases and resources involved to perform intraoperative completion angiography using X-ray technology versus IFVA. Therefore, CMS is planning to discuss other options at a future ICD-9-CM Coordination and Maintenance Committee meeting.

In summary, we are finalizing our proposal not to make any changes to MS-DRGs 233, 234, 235 or 236 for cases reporting the use of procedure code 88.59.

d. MS-DRG Reassignment of Intraoperative Fluorescence Vascular Angiography (IFVA)

In the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23901 and 23902), we indicated that we had received a request suggesting that we reassign procedure code 88.59 (Intraoperative Fluorescence Vascular Angiography), to the "Other Cardiovascular MS-DRGs": MS-DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, CC, and without CC/MCC, respectively). The requestor noted that these MS-DRGs have

three levels of severity and that other procedures assigned to these MS-DRGs (for example, transmyocardial revascularization) are frequently performed at the same time as a CABG. The requestor believed that reassigning cases that report IFVA (procedure code 88.59) to these MS-DRGs would not result in a significant overpayment to hospitals.

In the FY 2011 proposed rule, we pointed out that, in the surgical hierarchy, MS-DRGs 228, 229, and 230 rank higher than MS-DRGs 233, 234, 235, and 236, which were evaluated in the above tables for CABG procedures performed with IFVA (procedure code 88.59). The surgical hierarchy reflects the relative resource requirements of various surgical procedures. For example, if a CABG surgery were performed along with another procedure currently assigned to MS-DRGs 228, 229, and 230, the case would be assigned to one of the "Other Cardiothoracic Procedures MS-DRGs" (228, 229, and 230) because patients with multiple procedures are assigned to the highest surgical hierarchy to which one of the procedures is assigned.

Therefore, as the data shown above did not demonstrate that IFVA utilized an equivalent (or additional) amount of resources as a cardiac catheterization to warrant a proposal to reassign IFVA cases to MS-DRGs 233 and 234 and the fact that IFVA cases with CABG performed with a procedure assigned to MS-DRGs 228, 229, and 230 would already be grouped to those same MS-DRGs, we did not propose to reassign cases reporting procedure code 88.59 to MS-DRGs 228, 229, and 230 for FY 2011.

<u>Comment</u>: Several commenters supported the proposal not to reassign cases reporting procedure code 88.59 to MS-DRGs 228, 229, and 230.

Response: We appreciate the commenters' support.

We are finalizing our proposal to not reassign cases reporting procedure code 88.59 to MS-DRGs 228, 229, and 230 for FY 2011.

4. MDC 6 (Diseases and Disorders of the Digestive System): Gastrointestinal Stenting In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR43799), we discussed a request we received to create new MS-DRGs in FY 2011 to better identify patients who undergo the insertion of a gastrointestinal stent. The request was considered outside the scope of issues addressed in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule; therefore, we stated our intent to consider this request during the FY 2011 rulemaking process.

Gastrointestinal stenting is performed by inserting a tube (stent) into the esophagus, duodenum, biliary tract or colon to reestablish or maintain patency of these structures and allow swallowing, drainage, or passage of waste. The commenter requested that the new MS-DRGs be subdivided into three severity levels (with MCC, with CC, and without CC/MCC) to better align payment rates with resource consumption and improve the clinical coherence of these cases.

In its own analysis using FY 2008 MedPAR data, the commenter identified gastrointestinal stenting cases using relevant diagnosis codes and a combination of procedure codes with revenue code 0278 in MS-DRGs 374, 375, and 376 (Digestive Malignancy with MCC, with CC, and without CC/MCC, respectively), MS-DRGs 391and 392 (Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders with MCC and without MCC, respectively), and MS-DRGs 393, 394, and 395 (Other Digestive System Diagnoses with MCC, with CC, and without CC/MCC, respectively) in