

application of this methodology. In the FY 2007 IPPS final rule, we discussed our rationale for implementing cost-based weights over a 3-year transition period. We stated that the 3-year transition would mitigate the annual payment effects from the changes to the relative weights while we further study whether to make adjustments to account for charge compression. We believe that the cost-based methodology reduces bias in the relative weights and makes Medicare's payments more accurate for both medical and surgical DRGs. Therefore, any delays in the transition would not further our goal of payment accuracy. We believe that current efforts to improve cost reporting and our decision not to implement regression-based CCRs will alleviate concerns about additional fluctuations in hospital payments from further changes to the relative weight methodology. Furthermore, we believe that, for some types of hospitals (such as rural hospitals), the payment changes from MS-DRGs are the opposite of those that will occur from the transition to cost-based weights. For this reason, we believe a 2-year transition of the MS-DRG system that coincides with the remaining two years of the transition to cost-based weights will reduce the magnitude of annual payment changes and achieve our long-term goal of improvements in payment accuracy. Therefore, we are continuing with the 3-year transition to cost-based weights. For FY 2008, the DRG relative weights will be a blend of 33 percent of charge-based weights and 67 percent of cost-based weights. For the first year of the MS-DRG transition, the relative weights will be a blend of 50 percent of the CMS-DRG weight and 50 percent of the MS-DRG weight.

F. Hospital-Acquired Conditions, Including Infections

1. General

Medicare's IPPS encourages hospitals to treat patients efficiently. Hospitals receive the same DRG payment for stays that vary in length. In many cases, complications acquired in the hospital do not generate higher payments than the hospital would otherwise receive for other cases in the same DRG. To this extent, the IPPS does encourage hospitals to manage their patients well and to avoid complications, when possible. However, complications, such as infections, acquired in the hospital can lead to higher Medicare payments in two ways. First, the treatment of complications can increase the cost of hospital stays enough to generate outlier payments. However, the outlier

payment methodology requires that hospitals experience large losses on outlier cases (for example, in FY 2007, the fixed-loss amount was \$24,485 before a case qualified for outlier payments, and the hospital then only received 80 percent of its estimated costs above the fixed-loss cost threshold). Second, under the MS-DRGs we are adopting in this final rule with comment period, there are 258 sets of DRGs that are split into 2 or 3 subgroups based on the presence or absence of a major CC (MCC) or CC. If a condition acquired during the beneficiary's hospital stay is one of the conditions on the MCC or CC list, the result may be a higher payment to the hospital under the MS-DRGs. (We refer readers to section II.D. of this final rule with comment period for a detailed discussion of DRG reforms.)

2. Legislative Requirement

Section 5001(c) of Pub. L. 109-171 requires the Secretary to select, by October 1, 2007, at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case will be paid as though the secondary diagnosis was not present. Section 5001(c) provides that we can revise the list of conditions from time to time, as long as the list contains at least two conditions. Section 5001(c) also requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

3. Public Input

In the FY 2007 IPPS proposed rule (71 FR 24100), we sought input from the public regarding conditions with evidence-based guidelines that should be selected in order to implement section 5001(c) of Pub. L. 109-171. The comments that we received were summarized in the FY 2007 IPPS final rule (71 FR 48051 through 48053). In the FY 2008 IPPS proposed rule (72 FR 24716), we again sought formal public comment on conditions that we proposed to select under section 5001(c). As discussed below, in this final rule with comment period, we first summarize the comments we received on the FY 2007 IPPS proposed rule. We then explain our detailed proposals

included in the FY 2008 proposed rule, followed by a summary of the public comments on each condition proposed and our responses to those public comments.

In summary, the majority of the comments that we received in response on the FY 2007 IPPS proposed rule addressed conceptual issues concerning the selection, measurement, and prevention of hospital-acquired infections. Many commenters encouraged CMS to engage in a collaborative discussion with relevant experts in designing, evaluating, and implementing this section. The commenters urged CMS to include individuals with expertise in infection control and prevention, as well as representatives from the provider community, in the discussions.

Many commenters supported the statutory requirement for hospitals to submit information regarding secondary diagnoses present on admission beginning in FY 2008, and suggested that it would better enable CMS and health care providers to more accurately differentiate between comorbidities and hospital-acquired complications. MedPAC, in particular, noted that this requirement was recommended in its March 2005 Report to Congress and indicated that this information is important to Medicare's value-based purchasing efforts. Other commenters cautioned us about potential problems with relying on secondary diagnosis codes to identify hospital-acquired complications, and indicated that secondary diagnosis codes may be an inaccurate method for identifying true hospital-acquired complications.

A number of commenters expressed concerns about the data coding requirement for this payment change and asked for detailed guidance from CMS to help them identify and document hospital-acquired complications. Other commenters expressed concern that not all hospital-acquired infections are preventable and noted that sicker and more complex patients are at greater risk for hospital-acquired infections and complications. Commenters suggested that CMS include standardized infection-prevention process measures, in addition to outcome measures of hospital-acquired infections.

Some commenters proposed that CMS expand the scope of the payment changes beyond the statutory minimum of two conditions. They noted that the death, injury, and cost of hospital-acquired infections are too high to limit this provision to only two conditions. Commenters also recommended that CMS annually select additional hospital

acquired complications for the payment change. Conversely, a number of commenters proposed that CMS initially begin with limited demonstrations to test CMS' methodology before nationwide implementation. One commenter recommended that CMS include appropriate consumer protections to prevent providers from billing patients for the nonreimbursed costs of the hospital-acquired complications and to prevent hospitals from selectively avoiding patients perceived at risk of complications.

In addition to the broad conceptual suggestions, some commenters recommended specific conditions for possible inclusion in the payment changes, which we discussed in detail in the preamble of the proposed rule and in section II.D.4. of this final rule with comment period. We also discuss throughout section II.D. of the preamble of this final rule with comment period other comments that we have considered in developing hospital-acquired conditions that would be subject to reporting.

As it is not addressed elsewhere, we are responding here to the comment about hospitals billing patients for costs of hospital-acquired complications that are not counted as MCCs and CCs. Section 5001(c) does not make the additional cost of a hospital acquired complication a noncovered cost. The additional costs that a hospital would incur as a result of a hospital-acquired complication remains a covered Medicare cost that is included in the hospital's IPPS payment. Medicare's payment to the hospital is for all inpatient hospital services provided during the stay. The hospital cannot bill the beneficiary for any charges associated with the hospital-acquired complication. With respect to the concern about a hospital avoiding patients that are at high risk of complications, we note that the policy is selecting only those conditions that are "reasonably preventable." Thus, we are only selecting those conditions where, if hospital personnel are engaging in good medical practice, the additional costs of the hospital-acquired condition will, in most cases, be avoided and the risk of selectively avoiding patients at high risk of complications will be minimized. We further note that Medicare's high cost outlier policy is unaffected by section 5001(c). The hospital's total charges for all inpatient services provided during the stay will continue to be used to determine whether the case qualifies for an outlier payment. Thus, there will continue to be limitations on a hospital's financial risk of treating high

cost cases even if, despite the hospital maintaining good medical practice to avoid complications, a reasonably preventable condition occurs after admission. Finally, as stated further below, we are continuing to work to identify exclusions for situations where the policy should not apply for the selected condition.

4. Collaborative Effort

CMS worked with public health and infectious disease experts from the Centers for Disease Control and Prevention (CDC) to identify a list of hospital-acquired conditions, including infections, as required by section 5001(c) of Pub. L. 109-171. As previously stated, the selected conditions must meet the following three criteria: (a) high cost or high volume or both; (b) result in the assignment of the case to a DRG that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines. CMS and CDC staff also collaborated on developing a process for hospitals to submit a Present on Admission (POA) indicator with each secondary condition. The statute requires the Secretary to begin collecting this information as of October 1, 2007. The POA indicator is required in order for us to determine which of the selected conditions developed during a hospital stay. The current electronic format used by hospitals to obtain this information (ASC X12N 837, Version 4010) does not provide a field to obtain the POA information. We issued instructions requiring acute care IPPS hospitals to submit the POA indicator for all diagnosis codes, effective October 1, 2007, through Change Request No. 5499, with a release date of May 11, 2007. The instructions specify how hospitals under the IPPS submit this information in segment K3 in the 2300 loop, data element K301 on the ASC X12N 837, Version 4010 claim. Specific instructions on how to select the correct POA indicator for a diagnosis code are included in the ICD-9-CM Official Guidelines for Coding and Reporting. These guidelines can be found at the following Web site: <http://www.cdc.gov/nchs/datawh/ftp/serv/ftp/cd9/ftp/cd9.htm>.

CMS and CDC staff also received input from a number of groups and organizations on hospital-acquired conditions, including infections. Many of these groups and organizations recommended the selection of conditions mentioned in the FY 2007 IPPS final rule, including the following because of the high cost or high volume

(frequency) of the condition, or both, and because in some cases preventable guidelines already exist:

- Surgical site infections. The groups and organizations stated that there were evidence-based measures to prevent the occurrence of these infections which are currently measured and reported as part of the Surgical Care Improvement Program (SCIP).

- Ventilator-associated pneumonias. The groups and organizations indicated that these conditions are currently measured and reported through SCIP. However, other organizations counseled against selecting these conditions because they believed it was difficult to obtain good definitions and that it was not always clear which ones are hospital acquired.

- Catheter associated bloodstream infections.

- Pressure ulcers.
- Hospital falls. The injury prevention groups included this condition among a group referred to as "serious preventable events," also commonly referred to as "never events" or "serious reportable events." A serious preventable event is defined as a condition which should not occur during an inpatient stay.

- Bloodstream infections/septicemia. Some commenters suggested that we focus on one specific organism, such as staph aureus septicemia.

- Pneumonia. Some commenters recommended the inclusion of a broader group of pneumonia patients, instead of restricting cases to ventilator-associated pneumonias. Some commenters mentioned that while prevention guidelines exist for pneumonia, it is not clear how effective these guidelines may be in preventing pneumonia.

- Vascular catheter associated infections. Commenters indicated that there are CDC guidelines for these infections. Other commenters stated that while this condition certainly deserves focused attention by health care providers, there is not a unique ICD 9 CM code that identifies vascular catheter-associated infections. Therefore, these commenters suggested that there would be difficulty separately identifying these conditions.

- Clostridium difficile-associated disease (CDAD). Several commenters identified this condition as a significant public health issue. Other commenters indicated that, while prevalence of this condition is emerging as a public health problem, there is not currently a strategy for reasonably preventing these infections.

- Methicillin-resistant staphylococcus aureus (MRSA). Several commenters indicated that MRSA has

become a very common bacteria occurring both in and outside the hospital environment. However, other organizations stated that the code for MRSA (V09.0, Infection with microorganism resistant to penicillins Methicillin-resistant staphylococcus aureus) is not currently classified as a CC. Therefore, the commenters stated that MRSA does not lead to a higher reimbursement when the code is reported.

- **Serious preventable events.** As stated earlier, some commenters representing injury prevention groups suggested including a broader group of conditions than hospital falls which should not be expected to occur during a hospital admission. They noted that these conditions are referred to as “serious preventable events,” and include events such as the following: (a) leaving an object in during surgery; (b) operating on the wrong body part or patient, or performing the wrong surgery; (c) air embolism as a result of surgery; and (d) providing incompatible blood or blood products. Other commenters indicated serious preventable events are so rare that they should not be selected as a hospital condition that cannot result in a case being assigned to a higher paying DRG.

5. Criteria for Selection of the Hospital-Acquired Conditions

CMS and CDC staff greatly appreciate the many comments and suggestions offered by organizations and groups that were interested in providing input into the selection of the initial hospital-acquired conditions.

CMS and CDC staff evaluated each recommended condition under the three criteria established by section 1886(d)(4)(D)(iv) of the Act. In order to meet the higher payment criterion, the condition selected must have an ICD-9-CM diagnosis code that clearly identifies the condition and is classified as a CC, or as an MCC (as proposed for the MS DRGs in the proposed rule). Some conditions recommended for inclusion among the initial hospital-acquired conditions did not have codes that clearly identified the conditions. Because there has not been national reporting of a POA indicator for each diagnosis, there are no Medicare data to determine the incidence of the reported secondary diagnoses occurring after admission. To the extent possible, we used information from the CDC on the incidence of these conditions. CDC’s data reflect the incidence of hospital-acquired conditions in 2002. We also examined FY 2006 Medicare data on the frequency that these conditions were reported as secondary diagnoses. We

developed the following criteria to assist in our analysis of the conditions. The conditions described were those recommended for inclusion in the initial hospital-acquired infection provision.

- **Coding—**Under section 1886(d)(4)(D)(ii)(I) of the Act, a discharge is subject to the payment adjustment if “the discharge includes a condition identified by a diagnosis code” selected by the Secretary under section 1886(d)(4)(D)(iv) of the Act. We only selected conditions that have (or could have) a unique ICD-9-CM code that clearly describes the condition. Some conditions recommended by the commenters would require the use of two or more ICD-9-CM codes to clearly identify the conditions. Although we did not exclude these conditions from further consideration, the need to utilize multiple ICD-9-CM codes to identify them may present operational issues. For instance, the complexities associated with selecting septicemia as a hospital-acquired condition subject to section 5001(c) of the DRA may present operational issues in identifying whether or not the condition was present upon admission. The vast number of clinical scenarios that we would have to account for could complicate implementation of the provision.

- **Burden (High Cost/High Volume)—**Under section 1886(d)(4)(D)(iv)(I) of the Act, we must select cases that have conditions that are high cost or high volume, or both.

- **Prevention guidelines—**Under section 1886(d)(4)(D)(iv)(II) of the Act, we must select codes that describe conditions that could reasonably have been prevented through application of evidence-based guidelines. We evaluated whether there is information available for hospitals to follow to prevent the condition from occurring.

- **MCC or CC—**Under section 1886(d)(4)(D)(iv)(III) of the Act, we must select codes that result in assignment of the case to a DRG that has a higher payment when the code is present as a secondary diagnosis. The condition must be an MCC or a CC that would, in the absence of this provision, result in assignment to a higher paying DRG.

- **Considerations—**We evaluated each condition above according to how it meets the statutory criteria in light of the potential difficulties that we would face if the condition were selected.

6. Selection of Hospital-Acquired Conditions

We discuss below our analysis of each of the conditions that were raised as possible candidates for selection under

section 5001(c) of Pub. L. 109–171 according to the criteria described above in section II.D.5. of the preamble of this final rule with comment period. We also discuss any considerations, which would include any administrative issues surrounding the selection of a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the development of special GROUPER logic to also exclude similar or related ICD-9-CM codes from being classified as a CC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. Following a discussion of each condition, we provide a summary that describes how each condition was considered for the proposed rule, whether we are selecting it to be subject to the provision in this FY 2008 IPPS final rule or if it will continue to be considered for the future. In the proposed rule, we presented 13 conditions. The summary discussion and table reflect changes to the order of the conditions. The summary presents the conditions that best meet the statutory criteria and which conditions we are selecting to be subject to the payment adjustment for hospital-acquired conditions beginning in FY 2009. In the proposed rule, we encouraged comments on these conditions. We asked commenters to recommend how many and which conditions should be selected in the FY 2008 IPPS final rule along with justifications for these selections. We also encouraged additional comments on clinical, coding, and prevention issues that may affect the conditions selected. While, in this final rule with comment period, we present these 13 conditions in the order they were proposed, we have re-ranked these conditions based on how well they meet the statutory criteria according to compelling public health reasons in addition to public comment and internal analysis.

We received approximately 127 timely public comments on this section from hospitals and health care systems, provider associations, consumer groups, purchasers, medical device manufacturers, pharmaceutical companies, information technology companies, and health care research organizations.

Comment: Some commenters urged CMS to use discretion in selecting hospital-acquired conditions that will be subject to the statutory provision and suggested that CMS limit the number of conditions selected. A large majority of

