Federal Register

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rev. 09/08 LIT0-2158

consider doing so an unintended consequence.

We appreciate all the public comments on this condition, and have considered all of these points of view. We believe this condition meets the criteria of the DRA:

- There are unique codes that identify catheter-associated urinary tract infections that are currently considered to be a CC under the MS–DRGs;
- Prevention guidelines currently exist and will be updated prior to the October 1, 2008 implementation date of this provision; and
- As shown above, catheter-associated urinary tract infections are high cost/high volume conditions.

Therefore, in this final rule with comment period, we are selecting the condition of catheter-associated urinary tract infections to be subject to the provision beginning October 1, 2008.

(b) Pressure Ulcers

Coding—Pressure ulcers are also referred to as decubitus ulcers. The following codes clearly identify pressure ulcers.

- 707.00 (Decubitus ulcer, unspecified site)
- 707.01 (Decubitus ulcer, elbow)
- 707.02 (Decubitus ulcer, upper back)
- 707.03 (Decubitus ulcer, lower back)
- 707.04 (Decubitus ulcer, hip)
- 707.05 (Decubitus ulcer, buttock)
- 707.06 (Decubitus ulcer, ankle)
- 707.07 (Decubitus ulcer, heel)
- 707.09 (Decubitus ulcer, other site)

Burden (High Cost/High Volume)—This condition is both high-cost and high volume. For FY 2006, there were 322,946 reported cases of Medicare patients who had a pressure ulcer as a secondary diagnosis. These cases had average charges for the hospital stay of $40,381.

Prevention guidelines—Prevention guidelines can be found at the following Web sites: *http://www.npuap.org/positn1.html* and *http://www.ncbi.nlm.nih.gov/books/*

[illegible] payments than CCs.

Considerations—Pressure ulcers are an important hospital acquired complication. Prevention guidelines exist (non-CDC) and can be implemented by hospitals. Clinicians may state that some pressure ulcers present on admission cannot be identified (skin is not yet broken (Stage I) but damage to tissue is already done and skin will eventually break down). However, by selecting this condition, we would provide hospitals the incentive to perform careful examination of the skin of patients on admission to identify decubitus ulcers. If the condition is present on admission, the provision will not apply. In the proposed rule, we proposed to include pressure ulcers as one of our initial hospital-acquired conditions. This condition can be clearly identified through ICD–9–CM codes. These codes are classified as a CC under the CMS DRGs and as a CC or MCC under the MS–DRGs. Pressure ulcers meet the burden criteria because they are both high cost and high frequency cases. There are clear prevention guidelines. While there is some question as to whether all cases with developing pressure ulcers can be identified on admission, we believe the selection of this condition will result in a closer examination of the patient's skin on admission and better quality of care. We welcomed comments on the proposed inclusion of this condition.

Comment: A majority of commenters supported the intent of selecting the condition of pressure ulcers, but had concerns about how the provision would be implemented in practice. A large majority of commenters believed hospitals will more carefully examine the skin of patients if this condition is selected. However, many commenters cited difficulty in detecting stage 1 pressure ulcers on admission, particularly in certain patient populations.

The commenters cited the Guidance to Surveyors for Long-Term Care Facilities (CMS Manual System Pub. 100–07, State Operations Provider Certification issued November 2004, page 5), noting CMS'' previous acknowledgment that some pressure ulcers are ''unavoidable.'' The commenters cited evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer.

The commenters expressed concern about how this condition will be coded upon admission. The commenters also suggested that present-on-admission coding of pressure ulcers will rely solely on physicians' notes and diagnoses, according to Medicare coding rules. The commenters were concerned that the current ICD–9–CM codes for pressure ulcers are not precise enough to delineate differences in wound depth, which is an important factor for determining the severity of an ulcer.

The commenters recommended that CMS supplement ICD–9–CM codes for pressure ulcers with severity adjustments for complications and comorbidities that are present on admission. Because patients with pressure ulcers often have other complicating conditions, the commenters stated that it is unlikely that pressure ulcers would potentially be the only secondary diagnosis that would change the DRG assignment from one without a CC to one with a CC. Lastly, the commenters noted that accurate identification of a pressure ulcer requires the education and expertise of a trained physician.

The commenters suggested that CMS should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome, with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

Response: We appreciate the overwhelming public support for the intent of selecting this condition, provided we can address the concerns raised in the public comments. We acknowledge the commenters' concern that CMS previously stated some pressure ulcers are ''unavoidable.'' However, we believe improved screening to identify pressure ulcers upon admission for inpatient care will increase the quality of care. By screening patients entering the hospital for pressure ulcers, the ulcers will be discovered earlier and improve treatment of this preventable condition. We agree that the POA coding of pressure ulcers will rely on the attending physician, who has primary responsibility for documenting and diagnosing a patient's clinical conditions. Pressure ulcers that are identified through screening upon admission that are documented properly will continue to be assigned to a higher paying DRG.

With respect to the comment about patients with pressure ulcers having other complications and comorbidities, we note that many of the new MS–DRGs are subdivided into two or more severity levels. We will continue to evaluate the need for additional severity levels within base MS–DRGs. On the specific issue of the MS–DRGs that include pressure ulcers, we note that these MS–DRGs are already divided into three severity levels as follows:

- MS–DRG 573 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with MCC)
- MS–DRG 574 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis with CC)
- MS–DRG 575 (Skin Graft &/or Debridement for Skin Ulcer or Cellulitis without CC/MCC)

We are aware that many patients with pressure ulcers may also have other comorbid and complicating conditions that will continue to assign the patient to a higher paying DRG. We do not believe this fact should preclude physicians and hospitals from screening patients for pressure ulcers upon admission. As we indicated in the proposed rule (72 FR 24726), we believe only a minority of cases will have one of the selected conditions as the only CC or MCC present on the claim. However, we believe it will continue to lead to improvements in the quality of care. We believe the selection of this condition will lead the physician and hospital to perform a proper skin exam upon admission, leading to earlier identification and treatment of pressure ulcers.

With respect to the comment that accurate identification of a pressure ulcer requires the education and expertise of a trained physician, we agree. Hospitals should be using properly educated and trained physicians to identify and treat pressure ulcers (as well as all other medical conditions).

We appreciate all the public comment on this condition, and have considered all of these points of view. We believe the condition of pressure ulcers meets the criteria of the DRA:

- There are unique codes that identify pressure ulcers that are currently considered to be a CC or an MCC under the MS–DRGs;
- Prevention guidelines to avoid pressure ulcers currently exist; and
- As shown above, pressure ulcers are high-cost/high-volume conditions.

Therefore, in this final rule with comment period, we are selecting the condition of pressure ulcers to be subject to the payment adjustment for hospital acquired conditions beginning October 1, 2008. We referred the matter concerning the need for additional, detailed ICD–9–CM codes to the CDC. We believe further specificity in the ICD–9–CM codes will aid in distinguishing early from late stage pressure ulcers prior to the implementation date of this provision on October 1, 2008.

Serious Preventable Events

Serious preventable events are events that should not occur in health care. The injury prevention community has developed information on serious preventable events. CMS reviewed the list of serious preventable events and identified those events for which there was an ICD–9–CM code that would assist in identifying them. We identified four types of serious preventable events to include in our evaluation. These include leaving an object in a patient; performing the wrong surgery (surgery on the wrong body part, wrong patient, or the wrong surgery); air embolism following surgery; and providing incompatible blood or blood products. Three of these serious preventable events have unique ICD–9–CM codes to identify them. There is not a clear and unique code for surgery performed on the wrong body part, wrong patient, or the wrong surgery. Each of these events is discussed separately.

(c) Serious Preventable Event—Object Left in during Surgery

Coding Retention of a foreign object in a patient after surgery is identified through ICD–9–CM code 998.4 (Foreign body accidentally left during a procedure).

Burden (High Cost/High Volume)—For FY 2006, there were 764 cases reported of Medicare patients who had an object left in during surgery reported as a secondary diagnosis. The average charges for the hospital stay were $61,962. This is a rare event. Therefore, it is not high volume. However, an individual case will likely have high costs, given that the patient will need additional surgery to remove the foreign body. Potential adverse events stemming from the foreign body could further raise costs for an individual case.

Prevention guidelines—There are widely accepted and clear guidelines for the prevention of this event. This event should not occur. Prevention guidelines for avoiding leaving objects in during surgery are located at the following Web site: *http://www.qualityindicators.ahrq.gov/psi_download.htm.*

CC—This code is a CC under the CMS DRGs as well as under the MS DRGs.

Considerations—There are no significant considerations for this condition. There is a unique ICD–9–CM code and wide agreement on the prevention guidelines. We proposed to include this condition as one of our initial hospital-acquired conditions. The cases can be clearly identified through an ICD–9–CM code. This code is a CC under both the CMS DRGs and the MS–DRGs. There are clear prevention guidelines. While the cases may not meet the high frequency criterion, they do meet the high-cost criterion. Individual cases can be high cost. In the proposed rule, we welcomed comments on including this condition as one of our initial hospital-acquired conditions.

Comment: A large majority of commenters supported CMS' efforts to identify the condition of ''object left in surgery'' as one that should not occur in the hospital setting. The commenters supported selecting this condition in this year's IPPS rule.

The commenters applauded CMS for identifying a hospital acquired condition that has discrete ICD–9–CM codes and known methods of prevention. In addition, a few commenters noted that prevention guidelines for this condition are fully identified and endorsed by the NQF. MedPAC also complimented CMS for its efforts to identify ''object left in surgery'' and stated that CMS should not allow a case to be classified as a CC/MCC if this ''never event'' occurs during a patient's stay.

The commenters urged CMS to make exceptions for objects deliberately left in place in surgery as opposed to accidental retained foreign objects. The commenters noted that a patient may return to the hospital months or years after an object was left in during surgery, and it is necessary to have POA codes to identify patients that return to a different hospital to have the object removed. All of the commenters recognized that this event can cause great harm to patients.

Response: We believe exceptions for this condition are not necessary. The code that identifies this event, 998.4 (Foreign body accidentally left during a procedure) specifically states that the object was accidentally left in during the surgery. This code would not be assigned if a device or implant was deliberately implanted into a patient. In addition, as stated earlier, we recognize the important role of the attending physician in designating whether or not the serious preventable event occurred during the current admission. We agree with the commenters that a patient may return to the hospital months or years after the surgery to have the foreign object removed. In this circumstance, the hospital would code the condition as present on admission and the provision would not apply. By documenting the event early, the correct POA code can be applied. We agree with the commenters that this serious preventable event should be selected as a hospital-acquired condition in this final rule with comment period. Therefore, we are including this condition in the list of those to be implemented in FY 2009.