



## Medicare Hospital and Chargemaster Version LifePoint Custom

### KEY CONCEPTS OUTLINE

#### Module 11: Inpatient Payment and Patient Responsibility

##### I. Part A Payment for Hospital Inpatient Services

The Inpatient Prospective Payment System (IPPS) applies to most acute care hospitals, except:

- Psychiatric hospitals – Inpatient Psychiatric Facility (IPF) PPS
- Rehabilitation hospitals – Inpatient Rehab Facility (IRF) PPS
- Long-term care hospitals – Long Term Care Hospital (LTCH) PPS
- Designated children’s hospitals and cancer hospitals – paid at cost
- Critical Access Hospitals (CAHs) – paid at cost
- Hospitals in US territories – paid at cost
- Maryland hospitals under the Health Services Cost Review Commission (HSCRC) – paid under a Total Cost of Care demonstration through 2026

##### A. Overview of Inpatient Prospective Payment System (IPPS)

1. The IPPS pays hospitals a prospectively determined fixed payment amount for each discharge covered by Medicare, regardless of the costs incurred by the hospital to treat the patient. <42 C.F.R. 412.1>
  - a. The IPPS payment constitutes payment in full for all covered services provided directly or under arrangement by the admitting hospital and furnished in connection with the admission. <42 CFR § 412.2(b)>
    - i. If the admitting hospital cannot provide needed therapeutic or diagnostic services, they must provide the services “under arrangement” with another provider either in the hospital or at a location outside the hospital. <42 CFR § 412.50(c), 76 Fed. Reg. 51714>
    - ii. “Routine services” (e.g., bed, board, nursing services, use of hospital facilities and medical social services) must be provided by the admitting hospital. Services are considered to be provided by the admitting hospital if:

- a) They are provided in the hospital; and
- b) The hospital exercises professional responsibility over the services, including quality control. <76 Fed. Reg. 51711-51714; 77 Fed. Reg. 53453>

### Case Study 1

**Facts:** A patient is transported (but not discharged) from the St. Charles hospital to a medical center hospital in downtown St. Louis to have a PET scan performed (assume that the PET scan was medically necessary and that all of the Medicare conditions of coverage applicable to the PET scan were met). The PET scan was performed on an outpatient basis and the patient was returned to the St. Charles hospital. Which hospital should bill Medicare for the PET scan?

- B. CMS publishes an annual IPPS update (including changes to the payment rates) in the Federal Register around August 1 each year.
  - 1. The update becomes effective on October 1 of each year – the first day of the federal government’s fiscal year.
  - 2. CMS maintains a final rule home page for each year on their website containing many documents including payment tables (e.g., wage index, standardized amounts) and other tables (e.g., CCs and MCCs) that will assist hospitals in preparing for changes each year.

Link: FY2024 IPPS Final Rule Home Page under Medicare-Related Sites – Hospital

## II. Medicare Severity Diagnosis Related Groups (MS-DRGs)

- A. Payment under IPPS is made using “Medicare Severity Diagnosis Related Groups” (“MS-DRGs”).
- B. The list of MS-DRGs is published as Table 5 to the annual IPPS final rule, included in the Supplement to these materials. There is a total of 764 valid MS-DRGs for FY 2024.
  - 1. The MS-DRGs number to 999, with gaps in the numbering for future inclusion of additional MS-DRGs near similar conditions.
  - 2. The individual MS-DRGs are generally further grouped into one of 25 “major diagnostic categories” or “MDCs” or categorized as “pre-MDC” to assist in the final assignment of the MS-DRG.

- a. The MDCs are generally based on the organ/body system affected (e.g., MDC 9 - diseases and disorders of the skin, subcutaneous tissue and breast) or the nature of the disease or injury (e.g., MDC 22 - burns).
- 3. Every discharge is assigned only one MS-DRG in a process called “grouping”, discussed below. <42 CFR § 412.60(c)(2)>
- 4. Each MS-DRG is assigned a relative weight reflecting the “estimated relative cost of hospital resources” required to care for a patient assigned to the particular MS-DRG. <42 CFR § 412.60(b)>

### C. MS-DRG Assignment

#### 1. The GROUPER

- a. The MACs (and most hospitals) use a software program called a GROUPER to determine MS-DRG assignment.
- b. CMS publishes the MS-DRG Definitions Manual and Software on their website.

Link: MS-DRG Classifications and Medicare Code Editor (MCE)  
Definitions link under Medicare-Related Sites – Hospital

#### 2. Five Factors Driving MS-DRG Assignment

- a. Each discharge is assigned a MS-DRG based on:
  - i. Principal diagnosis (reported using an ICD-10-CM diagnosis code)
    - a) The “principal diagnosis” is “the diagnosis established after study to be chiefly responsible for causing the patient’s admission to the hospital.” <42 CFR § 412.60(c)(1)>
  - ii. Complications and comorbidities (reported using ICD-10-CM diagnosis codes)
    - a) Some discharges with the same principal diagnosis or procedure are subdivided into different MS-DRGs based on the presence of additional secondary diagnoses known as complications or comorbidities (“CCs”) or major CCs (“MCCs”). The CCs and MCCs are listed in Tables 6J and 6I, respectively, of the IPPS Final Rule each year.

A base MS-DRG may be sub-divided in one of three ways to recognize the patient's severity of illness:

- The MS-DRG with MCC, with CC, or without CC or MCC
- The MS-DRG with, or without CC/MCC
- The MS-DRG with, or without MCC

- 1) Some CCs or MCCs do not affect MS-DRG assignment when reported with certain specific principal diagnoses because they are closely related. The secondary diagnoses excluded from being treated as a CC or MCC for a particular principal diagnosis are listed in Table 6K of the IPPS Final Rule each year.
- b) Handout 16 contains a Group Exercise illustrating the impact of CCs and MCCs on payment.
- c) Hospital Acquired Conditions (HACs)
  - 1) The Deficit Reduction Act of 2005 required that specified conditions will not be considered CCs or MCCs when acquired at the hospital. <79 Fed. Reg. 49876-880>
    - (a) CMS sometimes refers to these conditions as “DRA HACs” to distinguish them from other hospital acquired conditions used in other quality payment adjustments.
    - (b) The current list of 14 DRA HAC categories is included in the materials behind the outline. <80 Fed. Reg. 49351>
      - (i) The list of diagnosis codes included in each category is updated annually and can be obtained on the Hospital Acquired Conditions page on the CMS website using the “ICD-10 HAC List” link on the left navigation.

Link: Hospital Acquired Conditions Page under Medicare-Related Sites – Hospital

- 2) A condition is considered hospital acquired if it has a POA indicator of:
  - (a) “N” - Diagnosis was not present at time of inpatient admission, or

(b) “U” - Documentation insufficient to determine if the condition was present at the time of inpatient admission. <79 Fed. Reg. 49878>

3) Costs associated with HACs are considered covered inpatient costs and should be billed on the associated inpatient claim. <See 72 Fed. Reg. 47201>

(a) Costs associated with HACs may contribute to cost outlier payment for the particular case. <See 72 Fed. Reg. 47201>

### Case Study 2

**Facts:** A 66 year old male Medicare beneficiary was discharged from a St. Charles, Missouri hospital with a principal diagnosis of simple pneumonia. Simple pneumonia maps to MS-DRGs 193-195 depending on the additional diagnoses of the patient. The only other diagnosis the patient had was a stage III decubitus ulcer (an MCC) and the documentation was insufficient for the coder to determine if the ulcer was present on admission, however it was noted in the nurses’ admission notes and the physician’s discharge summary. What MS-DRG does this case group to?

**Modified Facts:** Would it be appropriate for a coder at the St. Charles hospital to query the physician as to whether the decubitus ulcer was present at the time of admission?

iii. Procedures performed (reported using ICD-10-PCS procedure codes)

a) MS-DRGs that involve surgical procedures are often referred to as “surgical MS-DRGs.” MS-DRGs that do not involve surgical procedures are often referred to as “medical MS-DRGs.”

iv. Gender and discharge status

a) In some cases, MS-DRG assignment is affected by the patient’s gender (e.g., MS-DRG 707) and/or discharge status (e.g., MS-DRG 280-285).

v. Transplant, ECMO or Tracheostomy cases

a) Certain transplant, ECMO and Tracheostomy cases are assigned directly to one of the “Pre-MDC” MS-DRGs.

### III. IPPS Payment Calculations

- A. Hospitals receive an MS-DRG payment under the IPPS, which is the sum of an “operating” portion (consisting of a labor and non-labor portion similar to the OPPI payment) and an additional “capital” portion.

The operating portion of the DRG may be adjusted by the following, if applicable:

- Electronic Health Record (EHR) meaning user standards;
- The Inpatient Quality Reporting Program;
- The hospital’s wage index;
- The relative weight of the DRG;
- The Disproportionate Share Hospital (DSH);
- Indirect Medical Education (IME);
- Hospital Readmission Reduction Program (HRRP);
- Value Based Purchasing (VBP);
- New Technology Add-on payment; and
- Cost based outlier payment.

The capital portion of the DRG may be adjusted by the following, if applicable:

- The geographic adjustment factor (GAF);
- The relative weight of the DRG;
- Capital DSH adjustment;
- Capital IME adjustment; and
- Cost based outlier payment.

The hospital’s total payment may be adjusted by the Hospital Acquired Condition (HAC) Reduction Program adjustment, if applicable.

### IV. Inpatient Pricer

- A. CMS makes available a web based Pricer that can be used to calculate applicable inpatient payment amounts or look up inpatient adjustment factors on their website.

Link: [IPPS - Pricer under Medicare-Related Sites - Hospital](#)

- B. CMS updates the Pricer periodically with annual updates and hospital specific information from settled cost reports.

## V. New Technology Add-On Payments

- A. Hospitals can receive an additional “add-on” payment for designated “new medical services and technology” if the hospital’s costs exceed a specified threshold. <42 CFR 412.87(a)>
  1. This new technology add-on payment is conceptually similar to the outpatient “pass-through” payment concept.
  2. CMS designates new technology services and devices if the prospective payment rate is determined to be inadequate and the technology is substantially new based on one of following:
    - a. The new technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries; or
    - b. The new medical device has received Food and Drug Administration (FDA) marketing authorization and is part of the FDA’s Breakthrough Devices Program<42 CFR 412.87(c)(1)>; or
    - c. The new medical product has received FDA marketing authorization and is designated as a Qualified Infectious Disease Product (QIDP) by the FDA. <42 CFR 412.87(d)(1)(i)>
      - i. For more information on QIDPs and CMS initiatives to address antimicrobial resistance *MLN Matters SE20004*, available on the CMS website.
    - d. The new medical device is approved under the FDA’s Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and is used for indications approved under the LPAD pathway. <42 CFR 412.87(d)(1)(ii)>
- B. Each year, CMS announces additions and deletions to the list of qualifying new technology in the IPPS Final Rule. The current list of designated new technologies is included on Attachment A behind the outline.
- C. The new technology add-on payment is intended to be temporary. Once CMS has gathered enough data on the new technology to “recalibrate” the applicable weight of the DRG involving the new technology, the add-on payment will no longer be available. <42 CFR 412.87(b)(2)>
  1. The regulations provide that a new technology should only be treated as “new” for 2 or 3 years from the time that product came on the market. <42 CFR 412.87(b)(2)>

D. CMS will extend new technology add-on payment to any substantially similar product, assigned to the same ICD-10-PCS code as the brand name specifically approved in the final rule, if it receives FDA approval before or during the applicable fiscal year. <70 Fed. Reg. 47357>

E. Calculating the New Technology Add-On Payment

1. Qualifying for new technology add-on payment

- a. A case will qualify for new technology add-on payment if the hospital's operating costs (based on charges multiplied by the operating CCR) exceed the full DRG payment (including IME and DSH adjustments but excluding outlier payment) for a case that is billed with the qualifying new technology codes. <42 CFR 412.88>

2. Amount of new technology add-on payment

- a. For designated new technologies, other than QIDPs and LPADs, the add-on payment amount is the lesser of 65% of the cost of the new technology or 65% of the amount the hospital's costs exceed the full DRG payment (including IME and DSH but excluding outlier). <42 CFR 412.88>
- b. For designated QIDPs and LPADs, the add-on payment amount is the lesser of 75% of the cost of the new technology or 75% of the amount the hospital's operating costs exceed the full DRG payment for the case (including any IME and DSH but excluding any outlier payment). <42 CFR 412.88>

#### Case Study 4

**Facts:** A Medicare inpatient with osteomyelitis was taken to the OR for treatment with CERAMENT® G, an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate. The hospital submitted an inpatient claim and full payment (operating and capital) under MS-DRG 464 for the case was \$26,300, including all adjustments. The hospital has a combined operating cost-to-charge ratio of 0.40. The hospital's total charges for the case were \$93,800. The case did not qualify as an outlier. Assuming ICD-10-PCS code XW0V0P7 was reported on the claim for use of the CERAMENT® G, would this case qualify for a new technology add-on payment and, if so, how much?



## VI. Patient Responsibility (i.e., Deductibles and Coinsurance)

### A. Benefit Periods

1. The inpatient deductible and coinsurance are based on a “benefit period” concept.
  - a. The benefit period begins to run when the patient is first admitted to a hospital or SNF for inpatient care. The benefit period ends when the patient has not been an inpatient of a hospital or SNF for 60 consecutive days. <42 CFR §§ 409.60(a), 409.60(b)>

A benefit period can be as short as 61 days and there can be multiple benefit periods in a calendar year, resulting in payment of the deductible multiples times in a single calendar year.

- i. SNF admissions and discharges affect the benefit period determination regardless of whether the beneficiary’s SNF care qualified for Medicare coverage. <Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3 § 10.4.3.2 (Example 3)>

### B. Deductible and Coinsurance Amounts

1. The first 60 inpatient hospitalization days of a benefit period are considered full benefit days and the patient is only responsible for paying the inpatient deductible. <42 CFR § 409.61(a)(1)(i)>
  - a. For 2023, the inpatient deductible is \$1600 per benefit period. <87 Fed. Reg. 59096>
  - b. The deductible is based on the calendar year in which the benefit period began. <Medicare General Information, Eligibility and Entitlement Manual, Chapter 3 § 10.3>
2. Inpatient hospitalization days 61 to 90 in a benefit period are considered coinsurance days and the patient pays a daily coinsurance. <42 CFR § 409.61(a)(1)(ii)>
  - a. For 2023, the daily coinsurance is \$400 (25% X \$1600) per day. <87 Fed. Reg. 59096>

### Case Study 3

**Facts:** A Medicare beneficiary who had never before been hospitalized was admitted to and stayed in a hospital for 58 days (Admission #1). The patient was discharged from Admission #1 to a skilled nursing facility for 14 days. Thirty days after leaving the SNF, the patient was admitted (Admission #2) to a hospital for a four-day stay and then discharged to home. All services were provided during 2023.

What is the patient's hospital deductible and/or coinsurance liability for Admission #1? For Admission #2?

**Modified Facts:** The patient is admitted for a third time (Admission #3) 65 days after discharge from Admission #2. The length of stay for Admission #3 was 5 days. What is the beneficiary's total deductible and coinsurance liability for Admission #3?

#### 3. Lifetime reserve days <42 CFR §409.61(a)(2)>

- a. Medicare beneficiaries have 60 “lifetime reserve days” that may be used after the full benefit and coinsurance days for a particular benefit period have been used.

Full benefit and coinsurance days are renewed each benefit period, but once the 60 lifetime reserve days are used, they are exhausted forever.

- b. For each lifetime reserve day, the patient is responsible for a daily coinsurance. <Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3 §§ 10.2.1, 10.3>
  - i. For 2023, the lifetime reserve day coinsurance is \$800 (50% X \$1600) per day. <87 Fed. Reg. 59096>
- c. Use of Lifetime Reserve Days for Admissions with Exhaustion of Regular Benefits
  - i. If the beneficiary has at least one regular benefit day at the beginning of the stay and exhausts their benefits *during* the stay, the beneficiary will be deemed not to use their lifetime reserve days for the *non-outlier* portion of the stay. <Medicare Benefit Policy Manual, Chapter 5 § 30.1 (2)>

- ii. If the admission reaches outlier status, the beneficiary may elect not to use their lifetime reserve days for the days after the outlier is reached. If the beneficiary elects not to use their lifetime reserve days, Medicare will not make an outlier payment to the hospital and the hospital may charge the beneficiary for the charges that would have been paid as outlier by Medicare. <Medicare Benefit Policy Manual, Chapter 5 § 30.4.2>
- d. Election Not to Use Lifetime Reserve Days
  - i. Hospitals are required to notify beneficiaries that they may elect not to use their lifetime reserve days for all or part of a stay. <Medicare Benefit Policy Manual, Chapter 5 § 30.1, MLN Matters Article SE0663>
    - a) Ideally, the notice should be given when the beneficiary has five regular coinsurance days left and is expected to be hospitalized beyond that period. <Medicare Benefit Policy Manual, Chapter 5 § 30.1, MLN Matters Article SE0663>
    - b) CMS provides model language for use by beneficiaries in making an election not to use lifetime reserve days. <Medicare Benefit Policy Manual, Chapter 5 § 40.1, MLN Matters Article SE0663>
    - c) A retroactive election not to use lifetime reserve days may be made if certain criteria are met. <Medicare Benefit Policy Manual, Chapter 5 § 30.3, MLN Matters Article SE0663>
  - ii. If the beneficiary elects not to use lifetime reserve days, then the hospital may bill the patient for any services provided after the beneficiary's full benefit days and coinsurance days are exhausted. <42 CFR §409.65(a)(4)>

## CASE STUDIES WITH ANALYSIS

### Case Study 1

**Facts:** A patient is transported (but not discharged) from the St. Charles hospital to a medical center hospital in downtown St. Louis to have a PET scan performed (assume that the PET scan was medically necessary and that all of the Medicare conditions of coverage applicable to the PET scan were met). The PET scan was performed on an outpatient basis and the patient was returned to the St. Charles hospital. Which hospital should bill Medicare for the PET scan?

**Analysis:** The St. Charles hospital would include the PET scan on its inpatient claim. The PET scan would be considered to have been provided “under arrangements.” It would not be appropriate for the St. Louis hospital to bill Medicare directly for the PET scan. <42 C.F.R. 412.50(c)>

## Case Study 2

**Facts:** A 66 year old male Medicare beneficiary was discharged from a St. Charles, Missouri hospital with a principal diagnosis of simple pneumonia. Simple pneumonia maps to MS-DRGs 193-195 depending on the additional diagnoses of the patient. The only other diagnosis the patient had was a stage III decubitus ulcer (an MCC) and the documentation was insufficient for the coder to determine if the ulcer was present on admission, however it was noted in the nurses' admission notes and the physician's discharge summary. What MS-DRG does this case group to?

**Analysis:** MS-DRG 195 Simple Pneumonia and Pleurisy w/o CC/MCC. The decubitus ulcer would be coded with a POA indicator of "U" because the documentation is insufficient to determine if it was present at the time of admission. A stage III decubitus ulcer is a HAC that is excluded from grouping when reported with a POA indicator of "U".

**Modified Facts:** Would it be appropriate for a coder at the St. Charles hospital to query the physician as to whether the decubitus ulcer was present at the time of admission?

**Analysis:** Yes, queries in this situation are specifically approved by the official POA coding guidelines. <Official ICD-9-CM Guidelines, Appendix I "POA Examples">

**Modified Facts:** In response to the query, the physician documented that the decubitus was indeed present when the patient was admitted. What is the MS-DRG assignment for the case now?

**Analysis:** MS-DRG 193 Simple Pneumonia and Pleurisy w/ MCC.

### Case Study 3

**Facts:** A Medicare beneficiary who had never before been hospitalized was admitted to and stayed in a hospital for 58 days (Admission #1). The patient was discharged from Admission #1 to a skilled nursing facility for 14 days. Thirty days after leaving the SNF, the patient was admitted (Admission #2) to a hospital for a four-day stay and then discharged to home. All services were provided during 2023.

What is the patient's hospital deductible and/or coinsurance liability for Admission #1?  
For Admission #2?

**Analysis:** For Admission #1, the patient would pay the deductible of \$1,600 on day one of the stay and it covers all 58 days of the admission. For Admission #2, the patient would pay \$400 for day three and four, for a total of \$800. Note that day one and two of Admission #2 are paid for with the deductible paid during Admission #1. <Medicare General Information, Eligibility and Entitlement Manual, Chapter 3 § 10.1 and 10.3>

**Modified Facts:** The patient is admitted for a third time (Admission #3) 65 days after discharge from Admission #2. The length of stay for Admission #3 was 5 days. What is the beneficiary's total deductible and coinsurance liability for Admission #3?

**Analysis:** For Admission #3, the patient would pay the deductible of \$1,600. The patient began a new benefit period with the 60-day break between Admission # 2 and #3. <Medicare General Information, Eligibility and Entitlement Manual, Chapter 3 § 10.1 and 10.3>

## Case Study 4

**Facts:** A Medicare inpatient with osteomyelitis was taken to the OR for treatment with CERAMENT® G, an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate. The hospital submitted an inpatient claim and full payment (operating and capital) under MS-DRG 464 for the case was \$26,300, including all adjustments. The hospital has a combined operating cost-to-charge ratio of 0.40. The hospital's total charges for the case were \$93,800. The case did not qualify as an outlier. Assuming ICD-10-PCS code XW0V0P7 was reported on the claim for use of the CERAMENT® G, would this case qualify for a new technology add-on payment and, if so, how much?

**Analysis:** This case would qualify for add on payment in the amount of \$4,918.55.

Total Operating Cost = \$93,800 X 0.40 = \$37,520

Difference Between Operating Cost and Payment = \$37,520 - \$26,300 = \$11,220

Add-on payment = 65% x \$11,220 = \$7,293

The add-on payment for CERAMENT® G is capped at \$4,918.55.







## Medicare Hospital Version

### FY2024 IPPS New Technology Summary

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
GOSELA™ (trilaciclib, used to decrease the incidence of chemotherapy-induced myelosuppression in adult patients administered prior to a certain treatment for extensive-stage small cell lung cancer (ES-SCLC). <b>Continued for FY2023</b> <b>Discontinued</b>	XW03377, or XW04377	\$5,526.30 (FY2022) \$5,612.10 (FY2023)	86 Fed. Reg. 45008-17; 87 Fed. Reg. 48912-913; 88 Fed. Reg. 58803
ABECMA® (idecabtagene vicleucel, a B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell immunotherapy for relapsed or refractory multiple myeloma and is a 5 <sup>th</sup> -line plus treatment). <b>Continued for FY2023</b> <b>Discontinued</b>	XW033K7, or XW043K7	\$272,675.00* (FY2022) \$289,532.75 (FY2023)	86 Fed. Reg. 45028-35; * as corrected in 86 Fed. Reg. 58032; 87 Fed. Reg. 48912-913; 88 Fed. Reg. 58803
TECARTUS® (brexucabtagene autoleucel, a CD19-directed genetically modified autologous T-cell immunotherapy for relapsed and refractory mantle cell lymphoma, a form of CAR-T). <b>Continued for FY2023</b> <b>Discontinued</b>	XW033M7, or XW043M7	\$259,350*	86 Fed. Reg. 45090-104; *as corrected in 86 Fed. Reg. 58033; 87 Fed. Reg. 48913; 88 Fed. Reg. 58803
VEKLURY® (remdesivir, a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as SARS-CoV-2 (COVID-19)). <b>Continued for FY2023</b> <b>Discontinued</b>	XW033E5, or XW043E5	\$2,028.00	86 Fed. Reg. 45104-116; 87 Fed. Reg. 48913; 88 Fed. Reg. 58803
ZEPZELCA (turbinecetin, a marine derived, synthetic antineoplastic compound for treatment of metastatic small cell lung cancer (SCLC) with disease progression on chemotherapy). <b>Continued for FY2023</b> <b>Discontinued</b>	XW03387, or XW04387	\$8,622.90 (FY2022) \$9,145.50 (FY2023)	86 Fed. Reg. 45116-126; 87 Fed. Reg. 48912-913; 88 Fed. Reg. 58803

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
aScope Duodeno (a sterile, single-use endoscope for endoscopy and endoscopic treatment of the upper gastrointestinal tract): <del>Continued for FY2023</del> Discontinued	XFJB8A7, or XFJD8A7	\$1,715.59 (FY2022) \$1,296.75 (FY2023)	86 Fed. Reg. 45133-135; 87 Fed. Reg. 48913; 48915; 88 Fed. Reg. 58803
Caption Guidance™ (an artificial intelligence (AI) guided medical imaging acquisition software system for cardiac ultrasound images, providing real-time guidance during transthoracic echocardiography): <del>Continued for FY2023</del> Discontinued	X2JAX47	\$1,868.10	86 Fed. Reg. 45135-138; 87 Fed. Reg. 48913; 88 Fed. Reg. 58803
Harmony™ Transcatheter Pulmonary Valve System (a bioprosthetic heart valve from porcine pericardial tissue for treatment of congenital heart disease): <del>Continued for FY2023</del> Discontinued	02RH38M	\$26,975.00	86 Fed. Reg. 45146-149; 87 Fed. Reg. 48913; 88 Fed. Reg. 58803
Shockwave C2 Intravascular Lithotripsy System (for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting): <del>Continued for FY2023</del> Discontinued	02F03ZZ, 02F13ZZ; 02F23ZZ, or 02F33ZZ	\$3,666.00	86 Fed. Reg. 45151-153; 87 Fed. Reg. 48913; 88 Fed. Reg. 58803
CARVYKT™ (ciltacabtagene autoleucel) (an autologous chimeric-antigen receptor (CAR) T-cell therapy directed against B cell maturation antigen (BCMA) for treatment of patients with multiple myeloma): <del>New for FY2023</del> Discontinued	XW033A7, or XW043A7	\$289,532.75	87 Fed. Reg. 48920-925; 88 Fed. Reg. 58803
DARZALEX FASPRO® (a combination of daratumumab (a monoclonal CD38-directed cytolytic antibody) and hyaluronidase (an endoglycosidase) for the treatment of light chain amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD): <del>New for FY2023</del> Discontinued	XW01318	\$5,159.41	87 Fed. Reg. 48925-937; 88 Fed. Reg. 58803

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
FETROJA® (cefiderocol) (an injectable siderophore cephalosporin for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia): <b>Continued for FY2023</b> <b>Discontinued</b>	XW033A6, or XW043A6 *reported with ICD-10-CM codes Y95 and J14, J15.0; J15.1, J15.5, J15.6, or J15.8; OR J95.851 and B96.1; B96.20, B96.21, B96.22; B96.23, B96.29, B96.3; B96.5, or B96.89	\$8,579.84** (75% add-on limit)	86 Fed. Reg. 45156-157; *as corrected in 86 Fed. Reg. 67875; **as corrected in 86 Fed. Reg. 58032; 87 Fed. Reg. 48913-914; 88 Fed. Reg. 58803
REGARBRIO™ (imipenem, cilastatin, and relebactam) (a novel $\beta$ -lactamase inhibitor for treatment of hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia caused by susceptible Gram-negative bacteria): <b>Continued for FY2023</b> <b>Discontinued</b>	XW033U5, or XW043U5 *reported with ICD-10-CM codes Y95 and J14, J15.0; J15.1, J15.5, J15.6, or J15.8 for HABP; OR XW033A6 or XW043A6 reported with ICD-10-CM codes J95.851 and B96.1, B96.20, B96.21; B96.22, B96.23, B96.29; B96.3, B96.5, or B96.89 for VABP	\$9,576.51** (75% add-on limit)	86 Fed. Reg. 45157-159; *as corrected in 86 Fed. Reg. 58023; further corrected in 86 Fed. Reg. 67875; **as corrected in 86 Fed. Reg. 58032; 87 Fed. Reg. 48913-914; 88 Fed. Reg. 58803
Hemolung Respiratory Assist System (Hemolung RAS) (for treatment of acute hypercapnic respiratory failure using extracorporeal circuit to remove CO <sub>2</sub> directly from the blood): <b>New for FY2023</b> <b>Discontinued with Dx of U07.1 (COVID-19)</b>	5A0920Z	\$6,500	87 Fed. Reg. 48937-948; 88 Fed. Reg. 58803
Hemolung Respiratory Assist System (Hemolung RAS) (for treatment of acute hypercapnic respiratory failure using extracorporeal circuit to remove CO <sub>2</sub> directly from the blood). <b>Continued for FY2024 without U07.1 (COVID-19)</b>	5A0920Z without U07.1	\$6,500	87 Fed. Reg. 48937-948; 88 Fed. Reg. 58800-801
Aprevo™ (an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures for spinal deformity, custom made from patient CT scans): <b>Continued for FY2023</b> <b>Discontinued for Anterior Lumbar Interbody Fusion (ALIF) and Lateral Lumbar Interbody Fusion (LLIF)</b>	XRG(A,B,C,D)0R7 XRG(A,B,C,D)3R7 XRG(A,B,C,D)4R7	\$40,950.00*	86 Fed. Reg. 45127-133; *as corrected in 86 Fed. Reg. 67875; 87 Fed. Reg. 48913; 88 Fed. Reg. 58803

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
Aprevo™ (an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures for spinal deformity, custom made from patient CT scans). <b>Continued for FY2024 for Transforaminal Lumbar Interbody Fusion (TLIF)</b>	XRG(A,B,C,D)0R7 XRG(A,B,C,D)3R7 XRG(A,B,C,D)4R7	\$40,950.00 *	86 Fed. Reg. 45127-133; * as corrected in 86 Fed. Reg. 67875; 87 Fed. Reg. 48913; 88 Fed. Reg. 58800
INTERCEPT Fibrinogen Complex (PRCFC) (a blood product for treatment of fibrinogen deficiency-related bleeding, including massive hemorrhage). <b>Continued for FY2024</b>	NDC 30233D1 or 30243D1 with ICD-10-CM codes D62*, D65, D68.2, D68.4*, or D68.9*	\$2,535.00	86 Fed. Reg. 45149-150; * as corrected in 86 Fed. Reg. 67875; 87 Fed. Reg. 48913; 88 Fed. Reg. 58800
RYBREVANT™ (amivantamab, for the treatment of metastatic non-small cell lung cancer (NSCLC)). <b>Continued for FY2024</b>	XW033B7, or XW043B7	\$6,405.89	86 Fed. Reg. 44988-996; 87 Fed. Reg. 48913; 88 Fed. Reg. 58800
StrataGraft™ Skin Tissue (a viable bioengineered, regenerative skin construct (BRSC) for treatment of severe thermal burns). <b>Continued for FY2024</b>	XHRPXF7	\$44,200.00	86 Fed. Reg. 45079-90; 87 Fed. Reg. 48913; 88 Fed. Reg. 58800
LIVTENCITY™ (maribavir) (a cytomegalovirus (CMV) pUL97 kinase inhibitor for treatment of post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) to ganciclovir, valganciclovir, cidofovir, or foscarnet). <b>Continued for FY2024</b>	XW0DX38, XW0G738, or XW0H738	\$32,500	87 Fed. Reg. 48937-954; 88 Fed. Reg. 58800
CERAMENT® G (an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate for surgical treatment of osteomyelitis). <b>Continued for FY2024</b>	XW0V0P7	\$4,918.55	87 Fed. Reg. 48961-966; 88 Fed. Reg. 58800
GORE® TAG® Thoracic Branch Endoprosthesis (TBE) (a modular device consisting of three components, an Aortic Component, a Side Branch Component, and an optional Aortic Extender Component, each pre-mounted on a catheter delivery system for treatment of thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection). <b>Continued for FY2024</b>	02VW3DZ in combination with 02VX3EZ	\$27,807.00	87 Fed. Reg. 48966-969; 88 Fed. Reg. 58800

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
iFuse Bedrock Granite Implant System (a sterile, single-use permanent implant intended to provide sacropelvic fusion of the sacroiliac joint and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element). <b>Continued for FY2024</b>	XNH6058, XNH6358, XNH7058, XNH7358, XRGE058, XRGE358, XRGF058, or XRGF358	\$9,828.00	87 Fed. Reg. 48969-974; 88 Fed. Reg. 58800
Thoraflex™ Hybrid Device (a sterile single-use, gelatin sealed Frozen Elephant Trunk (FET) surgical medical device, deployed through an opened aortic arch and positioned into the descending thoracic aorta for repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection). <b>Continued for CY2024</b>	X2RX0N7, in combination with X2VW0N7	\$22,750	87 Fed. Reg. 48974-975; 88 Fed. Reg. 58800
ViviStim® Paired VNS System (a paired vagus nerve stimulation therapy intended to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment). <b>Continued for CY2024</b>	X0HQ3R8	\$23,400.00	87 Fed. Reg. 48975-977; 88 Fed. Reg. 58800
Taurolidine/heparin (applied in FY2023 as DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/ML))(a proprietary formulation of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant for use as catheter lock solution, to reduce the risk of catheter-related bloodstream infections (CRBI) from in-dwelling catheters in patients undergoing hemodialysis (HD) through a central venous catheter (CVC). <b>Conditional approval, subject to receiving FDA marketing authorization by July 1, 2024</b>	XY0YX28	\$17,111.25 (75% add-on limit)	87 Fed. Reg. 48978-82; 87 Fed. Reg. 66561; 88 Fed. Reg. 58942-944
Aveir™ AR Leadless Pacemaker (a programmable system comprised of a single leadless pacemaker implanted into the right atrium). <b>New for CY2024</b>	X2H63V9	\$10,725.00	88 Fed. Reg. 58919-923

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
Aveir™ Leadless Pacemaker (Dual-Chamber) (a modular programmable system comprised of two implanted leadless pacemakers; a ventricular leadless pacemaker for direct implantation into the right ventricle, and an atrial leadless pacemaker for direct implantation into the right atrium). <b>New for CY2024</b>	X2H63V9 in combination with X2HK3V9	\$15,600	88 Fed. Reg. 58923-925
Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System (a tibial extension implant containing electronics and software, used with the Zimmer Persona Personalized Knee System, collecting kinematic data pertaining to the patient's gait and activity level following TKA using internal motion sensors (3-D accelerometers and 3-D gyroscopes)), <b>New for CY2024</b>	XNHG0F9 XNHH0F9	\$850.85 \$850.85 (each leg eligible for separate NTAP)	88 Fed. Reg. 58925-927
Ceribell Status Epilepticus Monitor (a medical device system comprised of proprietary software and two cleared proprietary products; a single-use signal acquisition headband (the Ceribell EEG Headband) and a recorder (the Ceribell Pocket EEG). <b>New for CY2024</b>	XX20X89	\$913.90	88 Fed. Reg. 58927-930
CYTALUX® (pafolacianine) (lung indication) ((a targeted intraoperative molecular imaging agent that illuminates lung cancer in real time, enabling the detection of more cancer for resection, comprised of a folic acid analog conjugated with a fluorescent dye which binds to the folate receptor positive cancer cells and illuminates malignant lesions during surgery, used with a near-infrared imaging system). <b>New for CY2024</b>	8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN, or 8E0W8EN	\$2,762.50	88 Fed. Reg. 58810-818
CYTALUX® (pafolacianine)(ovarian indication) (a targeted intraoperative molecular imaging agent that illuminates ovarian cancer in real time, enabling the detection of more cancer for resection, comprised of a folic acid analog conjugated with a fluorescent dye which binds to the folate receptor positive cancer cells and illuminates malignant lesions during surgery, used with a near-infrared imaging system). <b>New for CY2024</b>	8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN, or 8E0W8EN	\$2,762.50	88 Fed. Reg. 58804-810

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
DETOUR System (a fully percutaneous approach to femoral-popliteal bypass under fluoroscopic guidance resulting in a large lumen endograft bypass delivering unobstructed, pulsatile flow from the superficial femoral artery ostium to the popliteal artery). <b>New for CY2024</b>	X2KH3D9, X2KH3E9, X2KJ3D9, X2KJ3E9	\$16,250.00	88 Fed. Reg. 58930-932
EchoGo Heart Failure 1.0 (an automated machine learning-based decision support system, as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography for detecting heart failure with preserved ejection fraction (HFpEF)). <b>New for CY2024</b>	XXE2X19	\$1,023.75	88 Fed. Reg. 58932-935
EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm) (bispecific antibodies used for the treatment of patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) after two or more prior therapies, with COLUMVI™ specifically targeting the largest subset of LBCL, diffuse LBCL (DLBCL)). <b>New for CY2024</b>	XW013S9, XW033P9, or XW043P9	\$6,504.07	88 Fed. Reg. 58818-835
Lunsumio™ (mosunetuzumab) (a novel, full-length, humanized, immunoglobulin G1 (IgG1) bispecific antibody that is designed to concomitantly bind CD3 on T cells and CD20 on B cells, in the treatment of adults with relapsed/refractory (R/R) follicular lymphoma (FL) who have received at least 2 prior systemic therapies (also referred to herein as 3L+FL)).	XW03358 or XW04358	\$17,492.10	88 Fed. Reg. 58835-845
Phagenyx® System (a system that treats neurogenic dysphagia using electrical pulses to stimulate sensory nerves in the oropharynx). <b>New for CY2024</b>	XWHD7Q7	\$3,250.00	88 Fed. Reg. 58935-937
REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk)(microbiota-based treatments indicated for the reduction or prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI (rCDI)). <b>New for CY2024</b>	XW0H7X8 or XW0DXN9	\$6,789.25	88 Fed. Reg. 58848-868

Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
REZZAYO™ (rezafungin for injection) (an echinocandin antifungal drug for the treatment of candidemia and invasive candidiasis in patients 18 year of age and older). <b>New for CY2024</b>	XW033R9 or XW043R9	\$4,387.50 (75% add-on limit)	88 Fed. Reg. 58944-946
SAINT Neuromodulation System (a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to targets within the left dorsolateral prefrontal cortex (L-DLPFC) to treat Major Depressive Disorder (MDD)). <b>New for CY2024</b>	X0Z0X18	\$12,675.00	88 Fed. Reg. 58937-939
SPEVIGO® (spesolimab) (a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36R signaling for the treatment of flares in adult patients with generalized pustular psoriasis (GPP)). <b>New for CY2024</b>	XW03308	\$33,236.45	88 Fed. Reg. 58879-885
TECVAYLI™ (teclistamab-cqyv)(a bispecific antibody approved for the treatment of multiple myeloma (MM), specifically adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anit-cluster of differentiation (CD)38 monoclonal antibody). <b>New for CY2024</b>	XW01348	\$8,940.54	88 Fed. Reg. 58885-891
TERLIVAZ® (terlipressin) (a pharmacologic therapy administered via IV bolus for the treatment of hepatorenal syndrome (HRS) with rapid reduction in kidney function; a V1-receptor synthetic vasopressin analogue that acts as a pro-drug of lysine-vasopressin). <b>New for CY2024</b>	XW03367 or XW04367	\$16,672.50	88 Fed. Reg. 58891-906
TOPS™ System (a motion preserving device inserted and affixed during spinal surgery after open posterior decompression to preserve normal spinal motion and provide stabilization of the lumbar intervertebral segment). <b>New for CY2024</b>	XRHB018 in combination with M48.062	\$11,375.00	88 Fed. Reg. 58940-942



Technology/Product	Qualifying Cases	Add-On Payment Limit	Source Authority
XACDURO® (sulbactam/durlobactam) (a penicillin derivative and classified as a beta-lactamase inhibitor with intrinsic antibacterial activity against <i>Acinetobacter baumannii</i> and other members of the <i>Acineobacter baumannii</i> -calcoaceticus complex (ABC). <b>New for CY2024</b>	XW033K9 or XW043K9 in combination with Y95 and J15.61 ; OR J95.851 and B96.83	\$13,680.00 (75% add-on limit)	88 <i>Fed. Reg.</i> 58946 -948

## List of Hospital Acquired Conditions Deficit Reduction Act of 2005

Excerpted from the CMS website:

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired\\_Conditions](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions)



### Hospital-Acquired Conditions

Section 5001(c) of Deficit Reduction Act of 2005 requires the Secretary to identify 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.

On July 31, 2008, in the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2009 Final Rule, CMS included 10 categories of conditions that were selected for the HAC payment provision. Payment implications began October 1, 2008, for these Hospital Acquired Conditions. The IPPS FY 2009 Final Rule is available in the **Statute/Regulations/Program Instructions** section, accessible through the navigation menu at left.

These 14 categories of HACs listed below include the HACs from the IPPS FY 2013 Final Rule which are Surgical Site Infection Following Cardiac Implantable Electronic Device (CIED) and Iatrogenic Pneumothorax with Venous Catheterization. For FY 2014 through FY 2023, there are no additional HAC categories added:

- Foreign Object Retained After Surgery
- Air Embolism
- Blood Incompatibility
- Stage III and IV Pressure Ulcers
- Falls and Trauma
  - Fractures
  - Dislocations
  - Intracranial Injuries
  - Crushing Injuries
  - Burn
  - Other Injuries
- Manifestations of Poor Glycemic Control

- Diabetic Ketoacidosis
  - Nonketotic Hyperosmolar Coma
  - Hypoglycemic Coma
  - Secondary Diabetes with Ketoacidosis
  - Secondary Diabetes with Hyperosmolarity
- Catheter-Associated Urinary Tract Infection (UTI)
- Vascular Catheter-Associated Infection
- Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG):
- Surgical Site Infection Following Bariatric Surgery for Obesity
  - Laparoscopic Gastric Bypass
  - Gastroenterostomy
  - Laparoscopic Gastric Restrictive Surgery
- Surgical Site Infection Following Certain Orthopedic Procedures
  - Spine
  - Neck
  - Shoulder
  - Elbow
- Surgical Site Infection Following Cardiac Implantable Electronic Device (CIED)
- Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) Following Certain Orthopedic Procedures:
  - Total Knee Replacement
  - Hip Replacement
- Iatrogenic Pneumothorax with Venous Catheterization

The ICD-10 HAC Lists for FY 2016 through the current FY year are available in the ICD-10 HAC List section, accessible through the navigation menu at left.

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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