

6.05 New Opportunities for Drugs under Old Medicare: Changes to Inpatient New Technology Pass-Throughs and 'Incident to' Coverage

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STATUTORY & REGULATORY AUTHORITY

A. Mandated by Sec. 533(b) of BIPA.

1. P.L. 106-554

2. Added new sections to the PPS law

B. Amended by Section 503 of MMA(?) / DIMA(?)
on December 8, 2003.

1. P.L. 108-173

STATUTORY & REGULATORY AUTHORITY (cont.)

- C. CMS implemented at 66 FR 46902 (9/7/01).
- D. Amended at 68 FR 45393 (8/1/03).
- E. Regulations are contained in 42 C.F.R. Sections 412.87 and 412.88.

BASIC RULE

- A. For those new services and items which qualify, an additional payment will be made to the hospital which furnishes such item to one of its inpatients, but only when total covered costs for that discharge exceed the total payment (including adjustments).
- B. This is **NOT** a separate DRG.
- C. Adjustment is temporary (2 to 3 years).
- D. Pursuant to recent statutory revisions, these payments are no longer budget neutral.

CRITERIA FOR QUALIFICATION

- A. “Substantial Improvement” over existing technologies; i.e., one of the following:
1. Offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
 2. Offers the ability to diagnose a medical condition where that condition is currently undetectable OR the ability to diagnose the condition earlier AND such diagnosis affects the management of the patient; or

CRITERIA FOR QUALIFICATION (cont.)

A. “Substantial Improvement” (cont.)

3. Significantly improves clinical outcomes; for example:
 - a. Reduced mortality rate;
 - b. Reduced rate of complications;
 - c. Reduced rate of subsequent interventions;
 - d. Decreased number of hospital admissions;
 - e. More rapid resolution of the case; or
 - f. Decreased pain, bleeding or other symptoms.

CRITERIA FOR QUALIFICATION (cont.)

A. “Substantial Improvement” (cont.)

4. No automatic status because of fast track or accelerated approval or priority review.
5. New legislation requires CMS to:
 - a. Make public a list of all pending applications;
 - b. Accept comments from the public regarding the item or service; and
 - c. Provide for a meeting for interested parties to present comments prior to the issuance of a proposed rulemaking on the technology. Interested parties include:
 - 1) Hospitals;
 - 2) Physicians; and
 - 3) Manufacturers.

CRITERIA FOR QUALIFICATION

(cont.)

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B. “NEW”

1. Two to 3 years after the point data begins to become available reflecting the ICD-9 code assigned to the service or item.
2. In short, once CMS uses the data to recalibrate the DRG’s, the technology is no longer “new.”
3. CMS only requires a “significant sample” of cases in its MedPAR data before new technology is disqualified.

CRITERIA FOR QUALIFICATION

(cont.)

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C. Existing DRG payment rate is “inadequate”

1. Must exceed a threshold that is the lesser of:
 - a. 75% of the standardized amount, or
 - b. 75% of one standard deviation for the DRG (or DRGs) involved.
2. Revisions have benefited manufacturers.
 - a. Originally threshold was one standard deviation for the DRG (or DRGs) involved.
 - b. Then CMS modified regulation in 2003 to reduce to 75% of one standard deviation for the DRG (or DRGs) involved.
 - c. Revised again in recent legislation.
3. If more than one DRG affected, case-weighted average is used.

CRITERIA FOR QUALIFICATION

(cont.)

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D. Recent legislation now requires that there be no other suitable DRG.

1. CMS must look for a DRG that encompasses similar clinical or anatomical characteristics and costs.

PAYMENT ADJUSTMENT

- A. Hospital receives **NOTHING** unless total “costs” for the case exceed the full DRG payments (including IME & DSH adjustments).
- B. If “costs” do exceed payment, then hospital will also receive the lesser of –
 1. 50% of the “costs” of the new technology, or
 2. 50% of the amount by which the “costs” of the case exceed the standard DRG payment.
- C. Legislative history to recent bill requires CMS to consider raising percentage paid.

PAYMENT EXAMPLES

- A. Assume a new technology costs \$3,000 and the relevant DRG pays \$20,000. Assume further that the hospital has an RCC of .75.
- B. Example One:
1. Hospital has charges of \$22,500. What is payment?
 2. Answer is: DRG payment of \$20,000. Even with the device costing \$3,000, total “costs” were less than the basic DRG rate.

PAYMENT EXAMPLES (cont.)

C. Example Two:

1. Hospital has charges of \$28,000. What is payment?
2. Answer is \$20,500. Imputed costs for case are \$21,000. Half the difference is \$500.

PAYMENT EXAMPLES (cont.)

E. Example Three:

1. Hospital has charges of \$32,000. What is payment?
2. Answer is \$21,500. Imputed costs are \$24,000.
However, half of the cost of the device is \$1,500.

REGULATORY TIMETABLE

- A. Must submit initial application in early October.
- B. Final data set by mid-December .
- C. A panel composed of CMS clinical staff reviews the application against the criteria.
- D. Decisions of panel will be published in the annual proposed rule.

APPLICATION

- A. Includes description of new technology.
- B. Requires a statement as to FDA approval status.
- C. Asks whether an ICD-9-CM code has been obtained.
- D. Requires cost and charge data.
- E. Requires discussion of why technology represents a substantial clinical improvement.

REVIEWED APPLICATIONS

A. Only two items have been approved:

1. A sepsis drug, Xigris
2. Spinal fusion device, InFUSE
 - a. Rejected once because costs determined not to exceed threshold
 - Based only on data for one of the several uses of device.
 - b. Use of more complete data subsequently led to a finding that the threshold had been met.

REVIEWED APPLICATIONS (cont.)

B. Three have been rejected.

1. An antibiotic, Zyvox.

- Rejected because costs already taken into account in calibrating DRGs.

2. A pain management device, Renew Spinal Cord Stimulation Therapy

- Rejected because costs already taken into account in calibrating DRGs.

3. A chemotherapy agent, GLIADEL

- Creation of new DRGs, which included cost data for item, meant costs no longer above threshold.

IDEAL ORGANIZATIONAL TIMING

- A. Coverage minus three years – apply for ICD-9-CM code.
- B. Coverage minus two years.
 - 1. Obtain FDA approval.
 - 2. Begin obtaining data on costs.
- C. Coverage minus one year – submit application to CMS.
- D. Post-submission period.
 - 1. Co-ordinate follow-up efforts with other interested parties.
 - 2. Closely monitor status of application.
- E. Congratulations!