Contents:

From the Medical Director
Quarterly Letter .............................................. 2

Medical Policy
Specialty Nutrients: Documentation .................................. 3
Knee Orthoses: New Policy ........................................ 3
Continuous Passive Motion Machine Coding Guidelines ................. 3
Intravenous Immune Globulin: New Policy .................. 4
Documentation Reminders: Nebulizer Drugs .................... 4
Documentation Tips: Blood Glucose Monitors and Supplies ......... 5
LCD Revisions Summary ........................................ 6

Coverage & Billing
Lower Limb Prosthesis: Billing Reminder .......................... 9
ADMC FAQs .................................................................. 10
Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD ESA Indications, and Reporting of Hematocrit or Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs ........................................ 12
Establish Pre-Payment Auto-Denial Edits in Applicable States for DMEPOS Suppliers of Oxygen and Oxygen Equipment (DME MACs only) ........................................ 14
Use of an 8-Digit Registry Number on Clinical Trial Claims ....... 16
Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions ........................................ 17
Clarification Regarding the Coordination of Benefits Agreement (COBA) Medigap Claim-based Crossover Process ........................................ 19
Medicare Fee-for-Service Legacy Provider IDs Prohibited on Form CMS-1500 Claims after NPI Required Date ........................................ 21
Outpatient Therapy Caps With Exceptions Start January 1, 2008 ...... 22
Additional Information on Reporting a National Provider Identifier (NPI) for Ordering/Referring and Attending/Operating/Other/Service facility for Medicare Claims ........................................ 24
Adjudicating Claims for Immunosuppressive Drugs When Medicare Did Not Pay for the Original Transplant ........................................ 25
Additional Clarification to Chapter 17, Section 40, Regarding Processing of Drug Claims with the JW Modifier ........................................ 26
Importance of Supplying Correct Provider Identification Information Required in Items 17, 17a, 24K, and 33 of the Form CMS-1500 (12-08), and the Electronic Equivalent ........................................ 27
Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) - The First in a series of articles on the Implementation of this program ........................................ 28
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Grandfathering, Repair and Replacement, Mail Order Diabetic Supplies and Advance Beneficiary Notices (ABNs) - The Second in a Series of Articles on the New DMEPOS Competitive Bidding Program ........................................ 31

HCPCS Updates
Nebulizers: HCPCS Code Changes .................................. 33
New HCPCS Codes for the April 2008 Update ........................ 34
New Healthcare Common Procedure Coding System (HCPCS) Modifiers When Billing for Patient Care in Clinical Research Studies ........................................ 36
New “K” Code for Replacement Interface Material .................. 36

Appeals
Requesting Individual Redeterminations for Each Different Line on a Claim Form ........................................ 37
Modification to the Model Medicare Redetermination Notice (for partly or fully unfavorable redeterminations) ........................................ 37
Change in the Amount in Controversy Requirement for Administrative law Judge Hearings and Federal District Court Appeals ........................................ 38

EDI
Vendor and Trading Partner Frequently Asked Questions ......... 39
Healthcare Provider Taxonomy Codes (NPI) Update April 2008 ...... 42

Overpayment Recovery
Offset Request Form .............................................. 42

Miscellaneous
Support Income Tax Reporting ........................................ 43
Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen ........................................ 44
Items and Special Services Having Special DME Review Considerations ........................................ 46
Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Update ........................................ 46
Claim Status Category Code and Claim Status Code Update ....... 47
Personally Identifiable Information on Written Correspondence ........................................ 47
April 2008 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files ........................................ 47
Individuals Authorized Access to CMS Computer Services - Provider Community (IACS-PC): The Second in a Series of Articles on the IACS ........................................................................... 50
Upcoming Critical Dates for Medicare’s Fee-for-Service (FFS) Implementation of the National Provider Identifier (NPI) ........................................ 52
Opportunity to Participate in Third Annual Medicare Contractor Provider Satisfaction Survey (MCPSS) Ends in April ........................................ 54
Announcing the Release of the Revised DMS-855 Medicare Enrollment Applications ........................................ 54
Pre-Bidding Activities for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bid Program ........................................ 55

Appendix
Revised ABN Frequently Asked Questions (FAQs) .................. 56
Announcement of the Implementation of the Revised ABN ................. 58
News Flash Items ................................................................ 58
DME MAC Jurisdiction C Contact Information .................. 60
From the Medical Director

A lot has changed since my departure as the Region D medical director over 2 years ago. CMS released the first round of contracts with suppliers for competitive bidding, the Deficit Reduction Act has changed the rules for capped rental and oxygen, and CIGNA Government Services (CGS) now administers Jurisdiction C as a Durable Medical Equipment Medicare Administrative Contractor (DME MAC). In addition, Medical Review functions (not in support of Benefit Integrity) have recently moved back to the DME MACs.

I look forward to serving as the Jurisdiction C Medical Director and continuing to educate suppliers, physicians and beneficiaries about Medicare and the benefits that CIGNA Government Services administers as the DME MAC for Jurisdiction C. Medical Review has several priorities over the next few months that we hope will benefit all stakeholders in Jurisdiction C:

1. Medical Review Staff Development: Our Medical Review staff includes a mixture of experience and expertise. Included in our new staff is a licensed occupational therapist to broaden our capabilities for claim review and education. Our plan to further develop the staff includes in-services so that our staff can get “hands on” experience with various pieces of equipment and supplies.

2. A New Medical Review Web Site Page: The primary role of Medical Review is reducing the claim payment error rate through claim review, policy development and education. Over the coming weeks, the MR web page will have new content to assist suppliers with information about key medical policies, tips for proper claim submission, how to reduce claim errors and more. You’ll also find helpful links to access local coverage determinations, policy articles and coding advice. You can access the Medical Review home page by clicking here http://www.cignagovernmentservices.com/jc/coverage/MR/index.html or going to the DME MAC Jurisdiction C home page at www.cignagovernmentservices.com and selecting “Medical Review” from the choices in the right-hand column under “Coverage and Pricing.” I would appreciate any feedback you have on the new site and what information you would like to see (or not see) included from Medical Review. Comments and suggestions can be sent through the “Web Site Feedback” link at http://www.cignagovernmentservices.com/feedback/index.html found on the DME MAC Jurisdiction C home page.

3. Reduce the CERT Error Rate: The Comprehensive Error Rate Testing (CERT) program is one way the Centers for Medicare & Medicaid Services (CMS) measures a Medicare contractor’s performance. Each month a sample of claims processed by CIGNA Government Services is audited and records are requested from suppliers billing in Jurisdiction C. Claims paid in error are calculated to arrive at an error rate. Jurisdiction C has the highest claim payment error rate of all Part B contractors; consequently, it is a high priority for Medical Review. We are currently reviewing claim data and will be partnering with our Provider Outreach and Education staff in launching a number of claim review and educational initiatives associated with policy groups with high error rates. To learn more, watch for e-mails from the CGS DME MAC Jurisdiction C ListServ. If you haven’t signed up for the ListServ, you can easily and quickly do so by clicking here http://www.cignagovernmentservices.com/jc/help/listserv/index.html or going to http://www.cignagovernmentservices.com, clicking on the link for the DME MAC Jurisdiction C contract and then selecting “Join the ListServ” at the top left of the page.

In future From the Medical Director columns I will provide updates on our progress with these goals and keep you informed of new initiatives in Jurisdiction C. I look forward to serving as your new medical director and getting to know the suppliers in Jurisdiction C.
Medical Policy

Specialty Nutrients: Documentation

According to the local coverage decision (LCD) for Enteral Nutrition, coverage of special formulas (HCPCS Codes B4149, B4153-B4157, B4161, and B4162) must be justified in each patient because they are produced to meet unique nutrient needs for specific disease conditions. The patient’s medical record must adequately document the specific condition and the need for the special nutrient. Failure to substantiate the medical necessity of the special formula will result in payment according to the least costly alternative, B4150.

The documentation necessary to justify special formulas includes:

1. Medical records documenting the medical condition requiring a HCPCS Code B4149, B4153-B4157, B4161, or B4162 formula as opposed to a B4150 formula and the severity of that condition as shown by history, physical exam and diagnostic/laboratory studies.

2. The response of the medical condition to a B4150 formula as compared to the response to the prescribed B4149, B4153-B4157, B4161, or B4162 formula. If this comparison has not been made, the medical reason for its absence should be documented in the patient’s medical record. The reason(s) should be individualized for the patient and not a generalized statement such as the diagnosis.

The most common request in Jurisdiction C is for specialty diabetic (B4154) formulas such as Glucerna® and Diabetisource®. If the DME MAC sends an additional documentation request (ADR) letter in regards to a claim for one of these formulas, the following documentation should be provided:

3. How long was the patient on a B4150 formula?
4. Were different B4150 formulas tried? What were they?
5. Were adjustments made in medications in an attempt to control blood sugars while on the B4150 formula?
6. Is there documentation in the form of serial blood sugars, preferably one month prior to and after beginning usage of a B4154 diabetic formula, demonstrating improvement in glycemic control?

Providing this additional information will assist Medical Review staff in their review of these claims and help insure that proper claims payment is made.

Knee Orthoses: New Policy

On March 20, 2008, notice was posted for the new Knee Orthoses LCD & Policy Article. The effective date will be July 1, 2008, for all DME MAC jurisdictions.

The comment period for this policy draft began on September 10, 2004, and ended on October 25, 2004. After a thorough review of the comments presented, this policy was finalized by the contractors.

The policy includes coding, coverage and documentation requirements for submission of claims for knee orthoses. The policy distinguishes between pre-fabricated orthoses and custom fabricated orthoses and outlines separate requirements for each category of orthoses. It is recommended that suppliers become familiar with the new Knee Orthoses Policy prior to its effective date to minimize effects on their billing process. To view the Future Dated LCD, please click on the following link:

Continuous Passive Motion Machine Coding Guidelines

Continuous Passive Motion devices are used to exercise joints following injury or surgery.

E0935 - continuous passive motion exercise device for use on knee only
E0936 - continuous passive motion exercise device for use other than knee.

Recent questions regarding the exact nature of these devices reveal confusion regarding the nature and functionality of these devices. These coding guidelines clarify the types of products described by the CPM codes.

The first test of any durable medical equipment is that it be durable and capable of repeated use over the expected five year useful life expectancy. Elastic, fabric, single use, or light plastic devices are not durable and do not meet the test for DME.

Secondly, the equipment must be capable of continuous passive motion of the affected limb. These characteristics mean that the device must have inherent within itself the ability to move the affected limb:

- in an appropriate plane of motion
- in a continuous fashion
- at the same rate of speed
- for a prescribed length of time
- with adjustable limits of range of motion
- with an identical range of motion in each cycle
without any input from the patient by the contralateral or other limbs
with easily accessible safety or cutoff switches

These characteristics require that the device be electrically powered, either by AC current or battery. Battery powered models must have an AC adapter for long term use. CPM machines must meet all these characteristics in order to be coded as E0935 or E0936.

Intravenous Immune Globulin: New Policy

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provided a new benefit for intravenous immune globulin (IVIG) administered in the home setting effective for dates of service on or after January 1, 2004. Since this benefit was created there have been numerous HCPCS code changes for the drugs. In addition questions about reimbursement for costs associated with administration are common.

This Local Coverage Determination (LCD) and related Policy Article (PA) summarize the statutory coverage requirements, provides HCPCS coding information and documentation requirements.

For complete information on the coverage of intravenous immune globulin, refer to the LCD and PA.

Documentation Reminders: Nebulizer Drugs

Insufficient or incomplete documentation accounts for the majority of nebulizer billing errors identified by the Comprehensive Error Rate Testing Review Contractor (CRC). In light of these findings, suppliers are reminded that, if requested by a Medicare contractor (DME MAC, CERT, PSC or ZPIC), they must be prepared to produce copies of all documentation specified in the Nebulizers Local Coverage Determination (LCD). Failure to produce this documentation in a timely manner can result in claim denials and, in the case of a post-payment review, an overpayment assessment.

The following "reminders" are based on errors identified in past reviews of claims for nebulizers and nebulizer drugs.

If the nebulizer and/or nebulizer drug(s) is dispensed prior to obtaining a detailed written order, make sure the beneficiary’s file includes written verification of the dispensing (preliminary written or verbal) order. The following elements must be included in the dispensing order:

- Description of the item
- Name of the beneficiary
- Name of the physician
- Start date of the order

While nebulizers, drugs and supplies may be delivered based on a dispensing order, the supplier cannot bill Medicare and receive payment prior to obtaining a detailed written order. Detailed written orders must include all of the following elements:
- Beneficiary’s name;
- Listing of all equipment and/or drugs being prescribed;
- Concentration of the drug(s) or the Dosage (number of milligrams/grams, etc.) in the dispensed solution;
- Volume of solution in each container;
- Amount of solution to use for each treatment;
- Frequency of administration;
- Signature of treating physician;
- Date the treating physician signed the order; and
- The start date of the order, if different from the signature date.

Items billed prior to the time that the supplier has a detailed written order in the beneficiary’s file must be billed with modifier EY.

Suppliers must obtain a new detailed written order whenever there is a change in the type of solution dispensed or the administration instructions.

A new detailed written order must be obtained every 12 months whether or not there is a change in the prescription.

In situations where a supplier is providing the nebulizer, but not the drug(s), policy does not require the supplier to routinely keep a file copy of the written order for the drug(s); however, it is strongly recommended that the supplier do so. In the event of a claim audit by the DME MAC, CERT, PSC or ZPIC contractor, the supplier will be required to submit documentation verifying the medical necessity for the nebulizer. The nebulizer is not considered medically necessary unless it is being used to deliver a prescribed drug covered under the nebulizer policy. Therefore, the documentation the supplier will be required to submit will include a copy of the detailed written order for the drug(s). Failure to provide this order, along with the other requested documentation, could result in denial of the nebulizer claim.

Whether or not to routinely obtain medical records for items billed to Medicare is a business decision the supplier must make. The CMS Manual System, Pub. 100-8: Medicare Program Integrity Manual, chapter 5, section 5.7 states that the documentation in the patient’s medical record does not have to be routinely
sent to the supplier or to the DME MACs, DME PSCs or ZPICs. However, chapter 5, section 5.8 directs suppliers to obtain as much documentation from the patient’s medical record as they determine they need to assure themselves that coverage criteria for the item have been met. In any event, if requested by a Medicare contractor, the supplier is required to submit medical records that support that the item(s) in question meets Medicare medical necessity and statutory coverage criteria. If the information is not received when requested or the information in the patient’s medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed Advanced Beneficiary Notice (ABN) of possible denial has been obtained.

The units billed should match the units prescribed by the treating physician. When a Medicare contractor’s clinical staff reviews a claim, they check all aspects of the documentation. This means they check the units billed against the written order to make sure that what the physician ordered and what the supplier billed match. For example, if the physician ordered 2.5 mg. Albuterol TID (three times/day), any billed units over that amount could be denied. The formula used to calculate the correct number of units to bill is:

\[
\text{# units per dose} \times \text{# doses per day} \times \text{# days supplied (30 or 90)}
\]

The Policy Article for Nebulizers states that 1 unit of Albuterol equals 1 milligram. So, if the supplier was billing for a 90 day supply of Albuterol based on a TID frequency, the number of units billed should not be more than 675.

\[
2.5 \times 3 \times 90 = 675
\]

Suppliers should be alert for beneficiaries receiving supplies from more than one company. This practice can result, especially in the event of a post-payment review, in denials due to billing for excess units of service.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, there must be clear documentation in the patient’s medical records corroborating the medical necessity of the amounts in excess of the maximum amount stated in the policy.

If more than one beta-adrenergic or more than one anticholinergic inhalation drug is billed during the same month, there must be clear documentation in the patient’s medical records corroborating the medical necessity of this current use.

Medication refills should not be routinely dispensed or automatically shipped on a pre-scheduled basis. The pharmacist is responsible for assessing how much inhalation solution a patient is actually using. Considering this information, the pharmacist is responsible for assuring that the patient has used almost all of his/her supply on hand prior to dispensing a new supply.

CIGNA Government Services is currently preparing online education tools that suppliers are encouraged to use to better comply with Medicare’s documentation requirements. These tools can be accessed through the DME MAC Medical Review link on CIGNA Government Services’ Web site (http://www.cignagovernmentservices.com). Please check this site frequently for new and updated information and educational materials. Suppliers are encouraged to sign up for the ListServ so they will receive notice as these materials are posted on the Web site.

**Documentation Tips: Blood Glucose Monitors and Supplies**

According to claim reviews conducted by the Comprehensive Error Rate Testing Review Contractor (CERT CRC), insufficient documentation continues to be the leading cause of CERT errors in Jurisdiction C. Claims for blood glucose monitors (BGM) and supplies account for a large percentage of these errors. It is critical that suppliers adhere to Medicare’s documentation rules and maintain required information in beneficiary files. The following reminders deal with the most common BGM documentation errors.

1. Suppliers must maintain written documentation of receipt of a dispensing order (written, fax or verbal) prior to dispensing a blood glucose monitor and/or supplies.
2. Suppliers must have a valid detailed written order on file prior to billing Medicare. Modifier EY must be used if claims are submitted prior to obtaining a valid detailed written order.
3. The detailed written order must contain all of the following elements:
   - All item(s) to be dispensed;
   - The specific frequency of testing;
   - The treating physician's signature;
   - The date of the treating physician’s signature;
   - A start date of the order – only required if the start date is different than the signature date.
4. A new order must be obtained when there is a change in the testing frequency.
5. If requested by the DME MAC, CERT, PSC or ZPIC contractor, the supplier must furnish medical
records that support that the beneficiary meets the medical necessity coverage criteria outlined in the Glucose Monitors LCD. Failure to provide this information will result in claim denial.

6. If the claim under review is for quantities above the normal allowances specified in the LCD, the supplier must provide documentation to support the medical necessity of the quantity billed. This documentation must include information from the treating physician as to the specific reason for the prescribed frequency of blood glucose testing and documentation (patient log, etc.) that shows the patient is actually testing at the prescribed frequency. Failure to provide this information will result in denial of amounts over the normal allowance specified in the LCD.

7. If the patient is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every six months.

8. The supplier must not submit claims using modifier KX unless the patient is being treated with insulin injections. Claims for patients not being treated with insulin injections must be billed with modifier KS.

9. Suppliers are required to maintain proof of delivery in the beneficiary’s file. If the DME MAC, CERT, PSC or ZPIC contractor requests documentation in conjunction with a claim review, a copy of this information must be included in the material you submit.

10. A beneficiary or their caregiver must specifically request refills of glucose monitor supplies before they are dispensed. The supplier cannot automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has “authorized” this in advance.

CIGNA Government Services is currently preparing online education tools that suppliers are encouraged to use to better comply with Medicare’s documentation requirements. These tools can be accessed through the DME MAC Medical Review link on CIGNA Government Services’ Web site (http://www.cignagovernmentservices.com). Please check this site frequently for new and updated information and educational materials. Suppliers are encouraged to sign up for the ListServ so they will receive notice as these materials are posted on the Web site.

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### LCD Revisions Summary

#### Summary Article for March 2008

Outlined below is a summary of the principal changes to the DME Local Coverage Determinations (LCDs) and Policy Articles (PAs) that have been revised for the March 2008 Publication. Please review the entire LCD and each related Policy Article for complete information.

**AFO/KAFO**

- **LCD**
  - Revision Effective Date: 01/01/2008
  - HCPCS CODES AND MODIFIERS:
    - Added: A9283

- **Policy Article**
  - Revision Effective Date: 01/01/2008
  - NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
    - Added: Noncoverage statement regarding A9283.
  - CODING GUIDELINES:
    - Added: Definition of A9283

**Cervical Traction Devices**

- **LCD**
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Added: Coverage statement regarding E0856.
  - HCPCS CODES AND MODIFIERS:
    - Added: E0856

**Continuous Positive Airway Pressure System (CPAP)**

- **LCD**
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Added: Usual maximum quantity parameters for new codes A7027, A7028, A7029
  - HCPCS CODES:
    - Added: A7027, A7028, A7029
    - Removed: K0553, K0554, K0555
  - CODING GUIDELINES:
    - Substituted: New code A7027

**Enteral Nutrition**

- **LCD**
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Added B4087, B4088 to utilization statement
    - Deleted B4086 from utilization statement
  - HCPCS CODES AND MODIFIERS:
    - Added B4087, B4088
    - Deleted B4086
    - Revised narrative for B4034
External Infusion Pumps

- LCD
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Removed statements about coverage of supplies used with insulin pumps from general coverage section.
    - Moved statement about appropriate pump for use with epoprostenol/treprostinil from general coverage section to epoprostenol/treprostinil section.
    - Moved statement about back-up pumps to Policy Article.
    - Added statements about the appropriate pump for use with subcutaneous immunoglobulin, insulin pumps, and pump for use with epoprostenol/treprostinil based upon the coding guidelines.
  - HCPCS CODES:
    - Added: A9274
    - Revised J1562
  - DOCUMENTATION REQUIREMENTS:
    - Removed ICD-9 requirement for insulin pump claims from paragraph describing general pump criteria.

- Policy Article
  - Revision effective date: 01/01/2008
  - NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
    - Added A9274 to statement about disposable infusion systems.
    - Added a statement about backup equipment.
  - CODING GUIDELINES:
    - Modified the definition of disposable infusion systems to include A9274.
    - Corrected subcutaneous immunoglobulin pump code to E0779 in paragraph that addresses K0552.

Glucose Monitors

- LCD
  - Revision Effective Date: 01/01/2008
  - HCPCS CODES:
    - Added: A9276-A9278
  - Policy Article
    - Revision Effective Date: 01/01/2008
    - NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
      - Added: Codes for continuous glucose monitors.

Hospital Beds

- LCD
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Added E0328 and E0329

- HPCCS CODES AND MODIFIERS:
  - Added E0328 and E0329

- Policy Article
  - Revision Effective Date: 01/01/2008

- CODING GUIDELINES:
  - Added E0328 and E0329

Intravenous Immunoglobulin

- New LCD and Policy Article.

Knee Orthosis

- New LCD and Policy Article.

Nebulizers

- LCD
  - Revision Effective Date: 07/01/2008
  - NATIONAL COVERAGE POLICY:
    - Added: NCD 200.2
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Substituted: J7611-J7614 for Q4093, Q4094
    - Added: Coverage criteria and maximum covered amount for formoterol.
    - Added: J7604, J7632, and J7676 to the list of compounded drugs that are not covered.
    - Added: Statement about denial if both formoterol and arformoterol are provided
    - Added: Least costly alternative statement for levalbuterol.
    - Added: Least costly alternative statement for unit dose combinations of albuterol and ipratropium.
    - Revised: Coverage criteria for arformoterol.
    - Revised: Statements concerning use of rescue medication to include use with formoterol.
  - HCPCS CODES AND MODIFIERS:
    - Added: J7604, J7605, J7632, J7676 (effective 1/1/08)
    - Added: J7611, J7612, J7613, J7614 (effective 4/1/08)
    - Revised: J2545, J7608, J7631, J7639, Q4080 (effective 1/1/08)
    - Deleted: Q4093, Q4094 (effective 1/1/08)
      (Note: Codes J7602 and J7603 were effective 1/1/08 – 3/31/08.)
  - ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:
    - Added: J7611-J7614, J7605
    - Removed: Q4093, Q4094
    - Added: Covered diagnosis codes for formoterol.
  - ICD-9 CODES/ DIAGNOSES THAT DO NOT SUPPORT MEDICAL NECESSITY:
    - Added: J7604, J7632, J7676
  - DOCUMENTATION REQUIREMENTS:
    - Added: Instructions for use of the KX modifier with Perforomist (formoterol).
    - Revised: Instructions for use of the KX modifier with Brovana (arformoterol).
Oxygen

- **LCD**
  - **Revision Effective Date:** 01/01/2008
  - **CMS NATIONAL COVERAGE POLICY:**
    - Added: NCD 240.2.1
  - **HCPCS CODES AND MODIFIERS:**
    - Added: Q4094
    - Deleted: QR modifier
  - **DOCUMENTATION REQUIREMENTS:**
    - Deleted: Instructions for use of QR modifier

Patient Lifts

- **LCD**
  - **Revision Effective Date:** 01/01/2008
  - **INDICATIONS AND LIMITATIONS OF COVERAGE:**
    - Added: E0135
  - **HCPCS CODES AND MODIFIERS:**
    - Added: E0135
    - Revised: E0630
  - **DOCUMENTATION REQUIREMENTS:**
    - Added: KX modifier instructions.
    - Added: Upgrade instructions

Power Mobility Devices

- **LCD**
  - **Revision Effective Date:** 04/01/2008
  - **INDICATIONS AND LIMITATIONS OF COVERAGE:**
    - Deleted: Requirement for ATP-certified individual to perform specialty evaluation.
    - Clarified: Requirement for ATS or ATP-certified individual to be involved with the evaluation of patients for rehab PWCs.

Respiratory Assist Devices

- **LCD**
  - **Revision Effective Date:** 01/01/2008
  - **INDICATIONS AND LIMITATIONS OF COVERAGE:**
    - Revised: Least Costly Alternative statements for E0741 and E0740 to reflect changed payment category for E0741.
    - Removed: 1999 transition criteria.
    - Added: A7027-A7029 to usual quantities table
    - Removed: K0553-K0555 from usual quantities table.
    - Added: A7027-A7029 to humidifier coverage statement.
  - **HCPCS CODES AND MODIFIERS:**
    - Added: A7027-A7029
    - Removed: K0553-K0555
  - **DOCUMENTATION REQUIREMENTS:**
    - Removed: 1999 transition requirements.
CODING GUIDELINES:
- Removed definition for K0553
- Added definition of A7027

**Surgical Dressings**
- **LCD**
  - Revision Effective Date: 01/01/2008
  - HCPSC CODES:
    - Added: A6413
  - Policy Article
  - Revision Effective Date: 01/01/2008
  - NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
    - Added: Noncoverage of A6413
    - Added: Policy concerning payment for surgical dressings that are covered under other benefits.
- **CODING GUIDELINES**:
  - Removed: Guidelines concerning dressings that slightly exceed the upper limits of the size range for a code.
  - Added: Definition of A6413
  - Added: Instructions on coding dressings that contain silver.
  - Revised: Guidelines concerning coding of surgical dressings that are covered under other benefits.

**Urological Supplies**
- **LCD**
  - Revision effective date: 04/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Revised indications for intermittent catheterization
  - HCPSC CODES:
    - Revised A5105 (Code effective 01/01/2008)
  - APPENDICES:
    - Removed definitions.
- **Policy Article**
  - Revision Effective Date: 01/01/2008
  - CODING GUIDELINES:
    - Revised guidelines for A5105.
    - Added A4326.

**Wheelchair Options and Accessories**
- **LCD**
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Added: Coverage criteria for gear reduction wheel for manual wheelchair (E2227)
    - Added: Replacement guidelines for lithium-based battery (E2397)
  - HCPSC CODES:
    - Added: E2227, E2228, E2312, E2313, E2397
    - Revised: E0705, E2205, E2373
  - **Policy Article**
  - Revised Effective Date: 01/01/2008
  - NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
    - Added: Statement concerning dual mode battery chargers.
  - **CODING GUIDELINES**:
    - Added: Guidelines for codes E2227, E2228, E2312, E2313, E2377
    - Added: Guidelines for standard proportional remote joysticks.
    - Revised: Guidelines for E2373

**Wheelchair Seating**
- **LCD**
  - Revision Effective Date: 01/01/2008
  - INDICATIONS AND LIMITATIONS OF COVERAGE:
    - Added: Muscular dystrophy to the list of covered diagnoses for prefabricated skin protection and combination skin protection and positioning seat cushions.
    - Removed: Instructions concerning solid seat support base (E2618)
  - HCPSC CODES AND MODIFIERS:
    - Added: K0108
    - Deleted: E2618
  - ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:
    - Added: Muscular dystrophy (359.0, 359.1) to the list of covered diagnoses for prefabricated skin protection and combination skin protection and positioning seat cushions.
    - Removed: E2618
  - **Policy Article**
  - Revision Effective Date: 01/01/2008
  - CODING GUIDELINES:
    - Revised: Guidelines for solid seat support base.

**Coverage & Billing**

**Lower Limb Prosthesis: Billing Reminder**

When submitting a claim for lower limb prosthetic HCPCS codes for knees, feet and ankles (HCPCS codes L5610-L5616, L5710-L5780, L5810-L5840, L5848, L5856, L5857, L5858, L5930, L5970-L5987), each HCPCS code must be submitted with one of the modifiers K0 - K4 to indicate the beneficiary’s expected functional level. If any of the
above listed HCPCS codes are billed without a functional level modifier, the entire claim will deny with a missing information denial - ANSI reason code CO16, N366. The denied claim may be resubmitted with the appropriate modifier.

Before filing a claim, review the Local Coverage Determination (LCD) and Policy Article (PA) for Lower Limb Prosthesis for complete coverage and coding criteria.

ADMC FAQs

1. Can I submit an ADMC request for DMEPOS items other than wheelchairs?
   
   No, only wheelchairs, specifically the wheelchair codes listed below, are eligible for ADMC.
   - E1161: Manual adult size wheelchair, includes tilt in space
   - E1231 – E1234: Manual pediatric size wheelchair, includes tilt in space
   - K0005: Manual adult size wheelchair, ultra lightweight
   - K0009: Manual adult size wheelchair, not otherwise classified
   - K0835 – K0843: Power adult size wheelchair, group 2 – Single or Multiple power options
   - K0848 – K0855: Power adult size wheelchair, group 3 (only eligible for ADMC if an alternative drive control interface will be provided at the time of initial issue).
   - K0856 – K0864: Power adult size wheelchair, group 3 – Single or Multiple power options
   - K0868 – K0871: Power adult size wheelchair, group 4 (only eligible for ADMC if an alternative drive control interface will be provided at the time of initial issue)
   - K0877 – K0880 and K0884 – K0886: Power adult size wheelchair, group 4 – Single or Multiple power options
   - K0890 – K0891: Power pediatric size wheelchair, group 5 – Single or Multiple power options

   ADMC requests cannot be submitted electronically.

2. How do I submit an ADMC request?
   
   You can either mail an ADMC request to:
   
   CIGNA Government Services
   ATTN: ADMC
   PO Box 20010, Nashville, TN 37202

   or fax the request to: 1.615.782.4647

   If the information listed above is not present, the request will be rejected and the supplier will receive written notification.

   The request should also include all required documents as listed in either the Manual Wheelchair or Power Mobility Devices Local Coverage Determination (LCD) and Policy Article. Chapter Nine of the DME MAC Jurisdiction C Supplier Manual contains a detailed list of items that must be included in an ADMC request for both Power and Manual Wheelchairs. This manual is available online at:


3. What information do I need to send with an ADMC request?
   
   The first page of all ADMC requests should clearly indicate “ADMC Request” and must contain the following demographic information:
   - Beneficiary information
   - Name
   - HICN
   - Address
   - Date of birth
   - Height and Weight (if needed to support the medical necessity for items that are ordered)
   - Place of service
   - ICD-9 diagnosis code (narrative description is not sufficient)
   - Supplier information
     • Name
     • NSC number
     • Address
     • Phone number
   - Physician’s information
     • Name
     • UPIN
     • Address
     • Phone number

   The ADMC decision should be made within 30 days of receipt and is valid for 6 months from the date on the ADMC decision letter.

4. How long do I have to wait for an ADMC decision and how long is the decision valid?
   
   The ADMC decision should be made within 30 days of receipt and is valid for 6 months from the date on the ADMC decision letter.

5. The medical records I’m getting do not contain all the clinical information required by the LCD to support medical necessity. Can I create a form for the physicians to complete?
   
   No, a supplier-generated form alone is not sufficient documentation of medical necessity. Chapter Three of the Jurisdiction C Supplier Manual states:
For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). . . neither a physician’s order, nor a CMN nor a DIF nor a supplier-prepared statement nor physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier.

Additionally, the Power Mobility Devices LCD states that even if a physician completes a supplier-generated form and the physician puts a copy in his/her chart, “this supplier-generated form is not a substitute for the comprehensive medical record. . .”

6. **Can I appeal a negative ADMC?**
   A negative ADMC may not be appealed because it does not meet the regulatory definition of an initial determination since no request for payment is being made. However, if the ADMC request for the wheelchair base is denied and if the supplier obtains additional medical documentation, an ADMC request may be resubmitted. ADMC requests may only be resubmitted once during the six-month period following a negative determination.

7. **My ADMC request was approved but I forgot to include all the accessories in the request. Can I request an ADMC for these accessories?**
   No, a supplier cannot submit a separate ADMC request for additional accessories.

8. **My ADMC request for a power wheelchair was denied because the physician’s order was missing required elements. What are the policy requirements for a power wheelchair detailed written order?**
   The detailed written order for a power wheelchair must be received by the supplier within 45 days following the completion of a face-to-face examination. There must be a date stamp or equivalent on the order to indicate when the supplier received it. The order must contain the following elements:
   - Beneficiary name
   - Description of item
   - Date of the face-to-face exam
   - Pertinent diagnoses/conditions
   - Length of need
   - Physician’s signature
   - Date of physician signature

Additionally, the supplier must prepare a detailed product description for the physician to sign and date. This list should include the wheelchair base and all options/accessories. For a more in-depth description of the written order requirements for both Manual and Power wheelchairs, please refer to Chapter Nine of the DME MAC Jurisdiction C Supplier Manual and the respective LCDs and Policy Articles.

9. **When my request includes one or more accessories coded K0108 (wheelchair component or accessory, not otherwise specified), what information do I need to send?**
   Claims for HCPCS code K0108 and any other miscellaneous code should include the following information:
   - Manufacturer,
   - Product name/number,
   - Suggested retail price, and
   - Information justifying the medical necessity for the item.

10. **What are the coverage criteria for a K0005 (ultralightweight) manual wheelchair?**
    Payment for a K0005 manual wheelchair is determined on an individual consideration basis. When submitting ADMC requests for this HCPCS code, suppliers should request that the patient’s physician include this additional information in the clinical evaluation and it should be submitted with the ADMC request:
    - A description of the patient’s routine activities,
    - The types of activities the patient frequently encounters,
    - Information concerning whether or not the patient would be fully independent in the use of this wheelchair, and
    - A description of the K0005 base features which are needed as compared to a K0004 base.
Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD ESA Indications, and Reporting of Hematocrit or Hemoglobin Levels on all Non-ESRD, Non-ESA Claims 

Requesting Payment for Anti-Anemia D

MLN Matters Number: MM5699 Revised 
Related Change Request (CR) #: 5699 
Related CR Release Date: January 11, 2008 
Effective Date: January 1, 2008 
Related CR Transmittal #: R1412CP 
Implementation Date: April 7, 2008

**NOTE** - This article was revised on February 15, 2008, to add clarifying information to bullet points 1 and 3 on pages 3 and 4, respectively. All other information remains the same.

**Provider Types Affected**
Physicians, providers, and suppliers who bill Medicare contractors (carriers, including durable medical equipment Medicare administrative contractors (DME MACs), fiscal intermediaries (FIs), Competitive Acquisition Plan (CAP) Designated Carriers, and A/B Medicare administrative contractors (A/B MACs)) for providing ESAs and related anti-anemia administration services to Medicare beneficiaries.

**Impact on Providers**
Effective for services on or after January 1, 2008, you must report the most recent hemoglobin or hematocrit levels on any claim for a Medicare patient receiving: (1) ESA administrations, or (2) Part B anti-anemia drugs other than ESAs used in the treatment of cancer that are not self-administered. In addition, non-ESRD claims for the administration of ESAs must also contain one of three new Healthcare Common Procedure Coding System (HCPCS) modifiers effective January 1, 2008. Failure to report this information will result in your claim being returned as unprocessed. **(Note that renal dialysis facilities are already reporting this information on claim types 72X, so CR5699 applies to providers billing with other types of bills.)** See the rest of this article for reporting details.

**Background**
Medicare Part B provides payment for certain drugs used to treat anemia caused by the cancer itself or by various anti-cancer treatments, including chemotherapy, radiation, and surgical therapy. The treatment of anemia in cancer patients commonly includes the use of drugs, specifically ESAs such as recombinant erythropoietin and darbepoetin. Emerging data and recent research has raised the possibility that ESAs administered for a number of clinical indications may be associated with significant adverse effects, including a higher risk of mortality in some populations.

Most recently, section 110 of Division B of the Tax Relief and Health Care Act (TRHCA) of 2006 directs the Secretary to amend Section 1842 of the Social Security Act by adding at the end the following new subsection: “Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.”

In light of the health and safety factors and the TRHCA legislation, effective January 1, 2008, the Centers for Medicare & Medicaid Services (CMS) is implementing an expanded reporting requirement for all claims billing for administrations of an ESA. Hematocrit and/or hemoglobin readings are already required for ESRD claims for administrations of an ESA. Effective with the implementation of change request (CR) 5699, all other claims for ESA administrations will also require the reporting of the most recent hematocrit or hemoglobin reading, along with one of three new HCPCS modifiers effective January 1, 2008.

In addition, CR 5699 requires the reporting of the most recent hematocrit or hemoglobin readings on all claims for the administration of Part B anti-anemia drugs OTHER THAN ESAs used in the treatment of cancer that are not self-administered.

**What You Need to Know**
CR 5699, from which this article is taken, instructs all providers and suppliers that:

1. Effective January 1, 2008, all claims billing for the administration of an ESA with HCPCS codes J0881, J0882, J0885, J0886 and Q4081 must report the most recent hematocrit or hemoglobin reading available when the billed ESA dose was administered. Facilities should bill at a frequency that allows for the reporting of the most recent hematocrit or hemoglobin reading prior to the start of the billing period that is applicable to the administrations billed on the claim. For new patients this would be the most recent reading
prior to the onset of treatment. Note that a provider may have to submit more than one claim for the month if there were multiple readings that were applicable to the administrations given during the month. Claims submitted prior to the publication of change request 5699 that were not completed per the instructions in change request 5699 should be re-submitted.

- For institutional claims, the hemoglobin reading is reported with a value code 48 and a hematocrit reading is reported with the value code 49. Such claims for ESAs not reporting a value code 48 or 49 will be returned to the provider.

- Effective for services on or after January 1, 2008, for professional paper claims, test results are reported in item 19 of the Form CMS-1500 claim form. For professional electronic claims (837P) billed to carriers or A/B MACs, providers report the hemoglobin or hematocrit readings in Loop 2400 MEA segment. The specifics are MEA01=TR (for test results), MEA02=R1 (for hemoglobin) or R2 (for hematocrit), and MEA03=the test results. The test results should be entered as follows: TR= test results, R1=hemoglobin or R2=hematocrit (a 2-byte alpha-numeric element), and the most recent numeric test result (a 3-byte numeric element, decimal implied [xx.x]). Results exceeding 3-byte numeric elements (10.50) are reported as 10.5.

**Examples:** If the most recent hemoglobin test results are 10.50, providers should enter: TR/R1/10.5, or, if the most recent hematocrit results are 32.3, providers would enter: TR/R2/32.3.

- Effective for dates of service on and after January 1, 2008, contractors will return to provider paper and electronic professional claims, or return as unprocessable paper and electronic institutional claims for ESAs when the most recent hemoglobin or hematocrit results are not reported.

- When Medicare returns a claim as unprocessable for ESAs with HCPCS codes J0881, J0882, J0885, J0886, or Q4081 for failure to report the most recent hemoglobin or hematocrit test results, it will include Claim Adjustment Reason Code 16 (Claim/service lacks information which is needed for adjudication) and Remittance Advice Code MA130 (Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with complete/correct information.)

2. Effective January 1, 2008, all non-ESRD ESA claims billing HCPCS J0881 and J0885 must begin reporting one (and only one) of the following three modifiers on the same line as the ESA HCPCS:
   - EA: ESA, anemia, chemo-induced;
   - EB: ESA, anemia, radio-induced; or
   - EC: ESA, anemia, non-chemo/radio

- Non-ESRD ESA institutional claims that do not report one of the above three modifiers along with HCPCS J0881 or J0885 will be returned to the provider.

- Non-ESRD ESA professional claims that are billed without one of the three required modifiers as line items along with HCPCS J0881 or J0885 will be returned as unprocessable with reason code 4 and remark code MA130. If more than one modifier is reported, the claim will be returned with reason code 125 and remark code N63.

3. Effective January 1, 2008, all non-ESRD, non-ESA claims billing for the administration of Part B anti-anemia drugs used in the treatment of cancer that are not self-administered must report the most recent hematocrit or hemoglobin reading. Facilities should bill at a frequency that allows for the reporting of the most recent hematocrit or hemoglobin reading prior to the start of the billing period that is applicable to the administrations billed on the claim. For new patients this would be the most recent reading prior to the onset of treatment. Note that a provider may have to submit more than one claim for the month if there were multiple readings that were applicable to the administrations given during the month.

- Institutional claims that do not report the most recent hematocrit or hemoglobin reading will be returned to the provider.

- Professional claims that do not report the most recent hematocrit or hemoglobin reading will be returned as unprocessable using Reason Code 16, and Remarks Codes MA130 and N395

Your Medicare contractor will not search for claims with dates of service on or after January 1, 2008, processed prior to implementation of this CR, but will adjust such claims when you bring them to the attention of your contractor.

**Additional Information**

For complete details regarding this CR please see the official instruction (CR5699) issued to your Medicare carrier, FI, DME MAC, CAP Designated Carrier, and A/B MAC. That instruction may be viewed by going to [http://www.cms.hhs.gov/Transmittals/downloads/R1412CP.pdf](http://www.cms.hhs.gov/Transmittals/downloads/R1412CP.pdf) on the CMS Web site.
Establish Pre-Payment Auto-denial Edits in Applicable States for DMEPOS Suppliers of Oxygen and Oxygen Equipment (DME MACs only)

MLN Matters Number: MM5929 Revised
Related Change Request (CR) #: 5929
Related CR Release Date: April 18, 2008
Effective Date: April 1, 2008
Related CR Transmittal #: R1493CP
Implementation Date: April 7, 2008

NOTE - This article was revised on April 21, 2008, to amend the last bullet point in the “Key Points” section. All other information remains the same.

Provider Types Affected
Medicare Durable Medical Equipment Prosthetic, Orthotics & Supplies (DMEPOS) suppliers who submit claims for Medicare payment for oxygen and/or oxygen related equipment to DME Medicare Administrative Contractors (DME MACs).

Key Points

- Presently, 38 states require licensure and/or certification to provide oxygen and/or oxygen related equipment. A table listing the licensure/certification requirements, if any, is at the end of this article.
- CR 5929 clarifies that Medicare DMEPOS suppliers who submit claims for Medicare payment for oxygen and/or oxygen related equipment must notify the National Supplier Clearinghouse (NSC) via the supplier enrollment process (using the CMS 855S application) and provide a copy of their state license and/or certification to the NSC.
- DME MACs are currently processing these claims from enrolled and approved DMEPOS suppliers without regard to the specialty identified and services to be provided on the enrollment application form (CMS-855S).
- CR5929 requires the National Supplier Clearinghouse (NSC) to assign an oxygen specialty code to all suppliers who have indicated they will be providing oxygen and/or oxygen related services on their CMS 855S enrollment application.
- In addition, this instruction requires DME MACs to edit claims to look for the oxygen specialty code, which will assure that those suppliers specifying the provision of oxygen and/or oxygen related products on their enrollment application and supplying the license/certification are the only entities that will receive Medicare payment for such supplies in the applicable states. The DME MACs will establish a claims processing pre-payment auto-denial edit in place to deny claims in those states where oxygen and/or oxygen related equipment must be provided by a supplier with oxygen specific licensure and/or certification and where Medicare files do not reflect such license/certification.

Background
In the absence of national Medicare policy regarding who may bill and be paid for oxygen and/or oxygen related equipment, the National Supplier Clearinghouse (NSC) looks to state requirements. The Center for Medicare & Medicaid Services (CMS) regulations (see 42 CFR § 424.57(c)) require all DMEPOS suppliers wishing to bill Medicare meet all supplier standards. The standard in § 424.57(c) requires all DMEPOS suppliers wishing to bill Medicare meet all supplier standards. The standard in § 424.57(c)(1) requires suppliers to operate their business and furnish Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements. This claims processing edit will ensure that suppliers in the (currently) 38 states are in compliance with this requirement.

Additional Information
CR5929 is the official instruction issued to your DME MAC. That instruction may be viewed by going to http://www.cms.hhs.gov/transmittals/downloads/R1493CP.pdf on the CMS Web site.
Should you have any questions regarding this issue, please contact your DME MAC on their toll-free number, which is available at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

The following is the list of the (currently) 38 states that have licensure requirements for oxygen and oxygen related equipment.

<table>
<thead>
<tr>
<th>State</th>
<th>DME Supplier License</th>
<th>Oxygen License</th>
<th>Other</th>
<th>Notes</th>
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<td>CA</td>
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<td>“Drug Manufacturing License” issued by CA Department of Health; if wholesaler, permit from Board of Pharmacy is required</td>
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<td>DC</td>
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<td>Regulatory Affairs, Building and Land Regulation Administration Zoning Division, and if operating business from a principal residence, a “Home Occupation Permit” is also required, issued by the Dept. of Consumer and Regulatory Affairs, Building and Land Regulation Administration Zoning Division</td>
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<td>Pharmacy license – HI Dept. of Commerce and Consumer Affairs</td>
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<td>Distributor License required if supplying item/drug classified by FDA as a prescription device, issued by KS Board of Pharmacy</td>
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<td>“Controlled Substances” license, issued by MA Dept. of Public Health, Division of Food and Drugs</td>
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### Use of an 8-Digit Registry Number on Clinical Trial Claims

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<td>“Home Health Care Provider” license if respiratory therapy or services provided in patient’s residence, issued by NH DHHS, Division of Public Health Services</td>
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<td>NV</td>
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<td>Must have physician or respiratory therapist on staff, with “Medical License” or respiratory therapist license, both issued by NV State Board of Medical Examiners</td>
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<td>If transfiling oxygen, company must be registered and listed with the FDA and have validated registration letter on file</td>
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<td>Oxygen license not needed if supplier has “SC Pharmacy Permit”</td>
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**MLN Matters Number:** MM5790  
**Related CR Release Date:** January 18, 2008  
**Related CR Transmittal #:** R310OTN

**Related Change Request (CR) #:** 5790  
**Effective Date:** April 1, 2008  
**Implementation Date:** April 7, 2008

**Provider Types Affected**

Physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), Medicare Administrative Contractors (A/B MACs) and Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for services provided to Medicare beneficiaries in clinical research studies.

**Provider Action Needed**

This article is based on Change Request (CR) 5790 that notifies providers and suppliers that Medicare claims forms will be modified to accommodate the 8-digit clinical trial number for claims that Medicare receives on or after April 1, 2008. Reporting this number is voluntary and claims submitted without the clinical trial number will be paid the same as claims containing a number.
While reporting is voluntary, the number will assist the Centers for Medicare & Medicaid Services (CMS) in informing beneficiaries about the availability of clinical trials and to use claims information to inform coverage decisions. Be sure your billing staff is aware of this rule.

**Background**

The purpose of CR5790 is to instruct providers and suppliers on new, voluntary reporting for placing a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination Manual, Publication 100-03, section 310.1. That publication is available at [http://www.cms.hhs.gov/Manuals/IOM/list.asp](http://www.cms.hhs.gov/Manuals/IOM/list.asp) on the CMS Web site. The clinical trial number that the CMS is requesting to be voluntarily reported is the number assigned by the National Library of Medicine (NLM) Clinical Trials Data Bank when a new study is registered by a sponsor or investigator. Information regarding NLM clinical trials is available at [http://clinicaltrials.gov/](http://clinicaltrials.gov/) on the Internet.

CMS will use this number to identify all items and services provided to beneficiaries during their participation in a clinical trial. Furthermore, this identifier will permit CMS to meet the recommendations of the 2000 Institute of Medicine report that led to the Executive Memorandum to increase participation of Medicare beneficiaries in clinical trials and the development and implementation of the CMS clinical trials policy.

**Recommendations from The White House Executive Memorandum included:**

- Tracking Medicare payments;
- Ensuring that the information gained from the research is used to inform coverage decisions;
- Making certain that the research focuses on issues of importance to the Medicare population; and,
- Enabling CMS to better inform Medicare beneficiaries about the clinical studies available for their participation.

**Key Points**

Claims submitted without the clinical trial number will be paid the same as claims containing a number. The practitioner/DME clinical trial claims are identified through the presence of all of the following elements:

- ICD-9 diagnosis code V70.7;
- HCPCS modifier Q1; and
- 8-digit clinical trial number (when present on the claim).

On institutional claims, the 8-digit numeric clinical trial number should be placed in the value amount of value code D4 on the paper claim UB-40 (Form Locators 39-41) or in Loop 2300, HI – Value Information segment, qualifier BE on the 837I.

On professional claims, the clinical trial registry number should be preceded by the two alpha characters of “CT” and placed in Field 19 of the paper Form CMS-1500 or it should be entered WITHOUT the “CT” prefix in the electronic 837P in Loop 2300 REF02(REF01=P4).

**Additional Information**

If you have questions, please contact your Medicare A/B MAC, FI, DME/MAC, or carrier at their toll-free number which may be found at: [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.


**Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions**

**MLN Matters Number:** MM5818 Revised

**Related Change Request (CR) #:** 5818

**Related CR Release Date:** January 14, 2008

**Effective Date:** July 30, 2007

**Related CR Transmittal #:** R80NCD and R1413CP

**Implementation Date:** April 7, 2008

**NOTE -** This article was March 18, 2008, to correct the bullet on page 3 regarding the “Maintenance of ESA therapy” (See bullet in bold). It should have stated that the “starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is < 30%)” after initiation of therapy and the rise in hemoglobin is > 1g/dL (hematocrit > 3%)” All other information remains the same.

**Provider Types Affected**

Providers and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FI), Regional Home Health Intermediaries (RHHI), Medicare Administrative Contractors...
(A/B MAC) and Durable Medical Equipment Medicare Administrative Contractors (DME MAC) for administering or supplying Erythropoiesis Stimulating Agents (ESAs) for cancer and related neoplastic conditions to Medicare beneficiaries.

What You Need to Know
Following a National Coverage Analysis (NCA) to evaluate the uses ESAs in non-renal disease applications, the Centers for Medicare & Medicaid Services (CMS), on July 30, 2007, issued a Decision Memorandum (DM) that addressed ESA use in non-renal disease applications (specifically in cancer and other neoplastic conditions).

CR 5818 communicates the NCA findings and the coverage policy in the National Coverage Determination (NCD). Specifically, CMS determines that ESA treatment is reasonable and necessary for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia under specified conditions; and not reasonable and necessary for beneficiaries with certain other clinical conditions, as listed below.

The HCPCS codes specific to non-end-stage renal disease (ESRD) ESA use are J0881 and J0885. Claims processed with dates of service July 30, 2007, through December 31, 2007, do not have to include the ESA modifiers as the modifiers are not effective until January 1, 2008. However, providers are to begin using the modifiers as of January 1, 2008, even though full implementation of related system edits are not effective until April 7, 2008.

Make sure that your billing staffs are aware of this guidance regarding ESA use.

Background
Emerging safety concerns (thrombosis, cardiovascular events, tumor progression, and reduced survival) derived from clinical trials in several cancer and non-cancer populations prompted CMS to review its coverage of ESAs. In so doing, on March 14, 2007, CMS opened an NCA to evaluate the uses of ESAs in non-renal disease applications, and on July 30, 2007, issued a DM specifically narrowed to the use of ESAs in cancer and other neoplastic conditions.

Reasonable and Necessary ESA Use
CMS has determined that ESA treatment for the anemia secondary to a regimen of myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is reasonable and necessary only under the following specified conditions:

- The hemoglobin level immediately prior to the first administration is < 10 g/dL (or the hematocrit is < 30%); and the hemoglobin level prior to any maintenance administration is < 10 g/dL (or the hematocrit is < 30%);
- The starting dose for ESA treatment is up to either of the recommended Food and Drug Administration (FDA) approved label starting doses for cancer patients receiving chemotherapy, which includes the, 150 U/kg/3 times weekly or the 40,000 U weekly doses for epoetin alfa and the 2.25 mcg/kg/weekly or the 500 mcg once every three week dose for darbepoetin alpha;
- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is < 30%) 4 weeks after initiation of therapy and the rise in hemoglobin is > 1 g/dL (hematocrit > 3%);
- For patients whose hemoglobin rises < 1 g/dL (hematocrit rise < 3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains < 10 g/dL after 4 weeks of treatment (or the hematocrit is < 30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises < 1 g/dL (hematocrit rise < 3%) compared to pretreatment baseline by 8 weeks of treatment;
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin > 1 g/dL (hematocrit > 3%) over any 2 week period of treatment unless the hemoglobin remains below or subsequently falls to < 10 g/dL (or the hematocrit is < 30%). Continuation and reinstatement of ESA therapy must include a dose reduction of 25% from the previously administered dose; and
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Not Reasonable and Necessary ESA Use
Either because of a deleterious effect of ESAs on the underlying disease, or because the underlying disease increases the risk of adverse effects related to ESA use, CMS has also determined that ESA treatment is not reasonable and necessary for beneficiaries with the following clinical conditions:

- Any anemia in cancer or cancer treatment patients due to folate deficiency (diagnosis code 281.2), B-12 deficiency (281.1 or 281.3), iron deficiency (280.0-280.9), hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9, 283.10, 283.19), bleeding (280.0 or 285.1), or bone marrow fibrosis;
Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91), or erythroid cancers (207.00-207.81);

Anemia of cancer not related to cancer treatment;

Any anemia associated only with radiotherapy;

Prophylactic use to prevent chemotherapy-induced anemia;

Prophylactic use to reduce tumor hypoxia;

Erythropoietin-type resistance due to neutralizing antibodies; and

Anemia due to cancer treatment if patients have uncontrolled hypertension.

Claims Processing

Effective for claims with dates of service on or after January 1, 2008, Medicare will deny non-ESRD ESA services for J0881 or J0885 when:

Billed with modifier EC (ESA, anemia, non-chemo/radio) when a diagnosis on the claim is present for any anemia in cancer or cancer treatment patients due to folate deficiency (diagnosis code 281.2), B-12 deficiency (281.1 or 281.3), iron deficiency (280.0-280.9), hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9, 283.10, 283.19), bleeding (280.0 or 285.1), anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91), or erythroid cancers (207.00-207.81).

Billed with modifier EC for any anemia in cancer or cancer treatment patients due to bone marrow fibrosis, anemia of cancer not related to cancer treatment, prophylactic use to prevent cancer-induced anemia, prophylactic use to reduce tumor hypoxia, erythropoietin-type resistance due to neutralizing antibodies, and anemia due to cancer treatment if patients have uncontrolled hypertension.

Billed with modifier EA (ESA, anemia, chemo-induced) for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia when a hemoglobin 10.0g/dL or greater or hematocrit 30.0% or greater is reported.

Billed with modifier EB (ESA, anemia, radio-induced).

Medicare contractors have discretion to establish local coverage policies for those indications not included in NCD 110.21

Medicare contractors will not search files to retract payment for claims paid prior to April 7, 2008. However, contractors shall adjust claims brought to their attention.

Additional Information

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

This addition/revision of section 110.21 of Pub.100-03 is an NCD. NCDs are binding on all carriers, FIs, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

The official instruction, CRS818, was issued to your contractor in two transmittals. The first is the NCD transmittal and that is available at http://www.cms.hhs.gov/Transmittals/downloads/R80NCD.pdf on the CMS Web site. The second transmittal revises the Medicare Claims Processing Manual and it is at http://www.cms.hhs.gov/Transmittals/downloads/R1413CP.pdf on the same site.

Clarification Regarding the Coordination of Benefits Agreement (COBA) Medigap Claim-based Crossover Process

MLN Matters Number: MMS837 Revised
Related Change Request (CR) #: 5837
Related CR Release Date: January 25, 2008
Effective Date: October 1, 2007
Related CR Transmittal #: R1420CP and R135FM
Implementation Date: February 1, 2008

NOTE - This article was revised on January 30, 2008, to show the correct implementation date (see above), which is February 1, 2008. All other information remains the same.

Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, Durable Medical Equipment Medicare Administrative Contractors (DME MACs), and/or Part A/B Medicare Administrative Contractors (A/B
MACs) for Medicare Part B services provided to Medicare beneficiaries.

Provider Action Needed

STOP – Impact to You

This article is based on Change Request (CR) 5837 which clarifies instructions regarding the Coordination of Benefits Agreement (COBA) Medigap claim-based crossover process.

CAUTION – What You Need to Know

CR 5837 provides formal confirmation of a recent Centers for Medicare & Medicaid Services (CMS) decision to not require Medicare Part B contractors (including Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) to update their internal insurer tables/files with medigap insurer’s newly assigned Coordination of Benefits Agreement (COBA) Medigap claim-based ID, as was previously prescribed in CR 5662. In addition, CR 5837 conveys clarifying provider billing requirements in relation to Medigap claim-based crossovers.

GO – What You Need to Do

See the Background and Additional Information Sections of this article for further details regarding these changes.

Background

Effective October 1, 2007, the CMS transferred responsibility for the mandatory Medigap crossover process (also known as the "Medicare claim-based crossover process") to its Coordination of Benefits Contractor. With this change, Part B contractors, including A/B MACs and DME MACs:

★ No longer maintain crossover relationships with Medigap insurers, and
★ No longer bill such entities for crossover claims effective with the last claims file that they transmit to these entities no later than October 31, 2007.

In a directive issued on September 18, 2007, CMS communicated to Medicare Part B contractors (carriers, DME MACs, and A/B MACs) its decision that they are not required to update their internal insurer files/tabs with the Coordination of Benefits Contractor (COBC)-assigned COBA Medigap claim-based identifiers (IDs). This is because, as discussed in Change Request (CR) 5601, the contractors’ front-end system now simply verifies that a Medigap claim-based crossover identifier on an incoming claim is syntactically correct (5 digits, beginning with a “5”). CMS’ Common Working File (CWF) system is now tasked with validation of the actual ID submitted on incoming claims.

The September 18, 2007, directive represented a departure from previous guidance communicated in CR 5662 (see MLN Matters article, MM5662, at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5662.pdf on the CMS Web site), in which CMS provided for transitional updating of the contractors’ internal insurer files/tabs prior to October 1, 2007, once the COBC had:

★ Assigned COBA Medigap claim-based IDs to the various Medigap insurers, and
★ Deemed Medigap insurers “production-ready.”

CMS also required Medicare contractors to post language on their provider Web sites stipulating that:

★ Providers are not to begin including the new COBA Medigap claim-based IDs on incoming Part B claims or claims for durable medical equipment, prosthetics, orthotics, and medical supplies (DMEPOS) before October 1, 2007.

CR 5837 instructs Part B contractors (including A/B MACs and DME MACs) that they are not required to update their internal insurer files/tabs following a Medigap insurer’s readiness to move into production with the COBC. This requirement formerly applied to situations where CMS expected that contractors update their internal insurer files/tabs prior to October 1, 2007, in accordance with CR 5662 (Transmittal 283). These Part B contractors may retain their older Other Carrier Name and Address (OCNA) or N-key identifiers within their internal insurer files/tabs for purposes of avoiding system issues or for the printing of post-hoc beneficiary-requested Medicare Summary Notices (MSNs). However, in accordance with CR 5601, at http://www.cms.hhs.gov/transmittals/downloads/R1242CP.pdf on the CMS Web site, contractors will have disabled the logic that they formerly used to tag claims for crossover to Medigap insurers effective prior to claims they received for processing on October 1, 2007.

Effective with CR 5837, all Part B contractors (including A/B MACs and DME MACs) will discontinue publication of their routine Medigap newsletters. These contractors may, however, at their discretion, publish one last edition of this newsletter if desired to include the provider education language that follows:

In accordance with the language modification to MSN message 35.3:

A copy of this notice will not be forwarded to your Medigap insurer because the information submitted on the claim was incomplete or invalid. Please submit a copy of this notice to your Medigap insurer”—which contractors made as part of Transmittal 1242, CR 5601, all Part B contractors, including A/B MACs, and DME MACs shall make available a Spanish translation of the modified MSN message, which shall read as
follows: "No se enviará copia de esta notificación a su asegurador de Medigap debido a que la información estaba incompleta o era inválida. Favor de someter una copia de esta notificación a su asegurador Medigap.

All Part B contractors (including A/B MACs, and DME MACs) are to inform their associated billing providers that are exempted from billing their claims electronically under the Administrative Simplification Compliance Act (ASCA) that they should only be entering the newly assigned 5-byte COBA Medigap claim-based ID (range 55000 to 59999) with item 9-D of the CMS-1500 claim form for purposes of triggering a crossing over of the claim to a Medigap insurer.

All Part B contractors (including A/B MACs, and DME MACs) are also to provide a link on their provider Web sites (preferably under "Hot Topics") to the recently published special edition MLN article (SE0743 at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0743.pdf on the CMS Web site) that clarifies for providers the differences between:

- Medigap crossover that is accomplished via the automatic, eligibility file-based crossover process, and
- The Medigap claim-based crossover process, which is triggered by information that they include on incoming claim.

Providers should note that the listing at http://www.cms.hhs.gov/COBAagreement/Downloads/Medigap%20Claim-based%20COBA%20IDs%20for%20Billing%20Purpose.pdf on the CMS COB Web site is:

- Complete and up-to-date, and
- The only source for the identifiers to be included on incoming claims for purposes of triggering crossovers to those Medigap insurers that do not participate fully in the automatic crossover process.

Additional Information

The official instruction, CR 5837, was issued in two transmittals issued to your Medicare carrier, DME MAC, or A/B MAC. Those transmittals may be viewed at http://www.cms.hhs.gov/Transmittals/downloads/R1420CP.pdf and http://www.cms.hhs.gov/Transmittals/downloads/R135FM.pdf on the CMS Web site. These transmittals make revisions to the Medicare Claims Processing and Medicare Financial Management Manuals, respectively.

If you have any questions, please contact your Medicare carrier, DME MAC, or A/B MAC at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Medicare Fee for Service Legacy Provider IDs Prohibited on Form CMS-1500 Claims after NPI Required Date

MLN Matters Number: MM5858
Related Change Request (CR) #: 5858
Related CR Release Date: February 1, 2008
Effective Date: Claims received on or after May 23, 2008
Related CR Transmittal #: R1432CP
Implementation Date: April 7, 2008

Provider Types Affected

Physicians, providers, and suppliers submitting CMS-1500 and CMS-1450 (UB-04) claims to Medicare carriers, Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), Durable Medical Equipment Medicare Administrative Contractors (DME MACs), and/or Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

STOP – Impact to You
Effective May 23, 2008, if you report a Provider Legacy Identifier on Medicare CMS-1500 or CMS-1450 (UB-04) claims, your contractors will return them as unprocessable.

CAUTION – What You Need to Know
CR 5858, from which this article is taken, announces that Provider Legacy Identifiers are not to be reported on Medicare CMS-1500 or Form CMS-1450 (UB-04) claims received on or after May 23, 2008 (the date at which the NPI is required to be reported on claims). After that date, claims containing Legacy Identifiers will be returned as unprocessable.

GO – What You Need to Do
Make sure that your billing staffs are aware that effective May 23, 2008, only NPIs are to be reported on Medicare CMS-1500 and CMS-1450 claims.

Background

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 required issuance of a unique national provider identifier (NPI) to each physician, supplier, and other health care provider who conducts HIPAA standard electronic transactions. In accordance with this act, CMS began issuing NPIs on May 23, 2005.

Further, on April 2, 2007, the Department of Health and Human Services (DHHS) provided covered entities guidance regarding contingency planning for NPI implementation. In this guidance, as long as a health plan was compliant, meaning they could accept and send NPIs on electronic transactions, they could establish
contingency plans to facilitate the compliance of their trading partners.

As a compliant health plan, on April 20, 2007 Medicare fee for service (FFS) established a contingency plan that followed this guidance. Since then, CMS has been allowing transactions adopted under HIPAA to be submitted with a variety of identifiers, including:

- NPI only;
- Medicare legacy only (PINs, UPINs, or National Supplier Clearinghouse number); and
- NPI and legacy combination.

CR 5858, from which this article is taken, announces that beginning on May 23, 2008, CMS requires the NPI to be submitted on the Form CMS-1500 and CMS-1450 paper claims; and legacy numbers will NOT be permitted on claims received on or after that date. Effective that date, Form CMS-1500 and CMS-1450 claims containing legacy identifiers will be returned as unprocessable, without appeal rights.

When returning these claims, your contractors will use an appropriate message and Remittance Advice Remark code, such as:

N257 Missing/incomplete/invalid billing provider primary identifier.

Note that contractors will not return claims in certain situations where an NPI is not required (e.g., foreign claims, deceased provider claims, and other situations as allowed by CMS in the future). Such claims will be processed with established procedures for such claims.

Additional Information

You can find more information about the prohibition of Medicare fee for service legacy provider IDs on Form CMS-1500 and CMS-1450 claims after the NPI required date by going to CR 5858, located at http://www.cms.hhs.gov/Transmittals/downloads/R1432CP.pdf on the CMS Web site.

You will find updated Medicare Claims Processing Manual (100-04), Chapter 26 (Completing and Processing Form CMS-1500 Data Set), Section 10.4 (Items 14-33 - Provider of Service or Supplier Information) as an attachment to that CR.

If you have any questions, please contact your carrier, FI, A/B MAC, or DME MAC at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Outpatient Therapy Caps With Exceptions Start January 1, 2008

MLN Matters Number: MM5871 Revised
Related Change Request (CR) #: S871
Related CR Release Date: January 10, 2008
Effective Date: January 1, 2008
Related CR Transmittal #: R1414CP
Implementation Date: January 25, 2008

NOTE - This article was revised on January 18, 2008, to reflect changes to CR5871, which CMS revised on January 17. The CR release date, transmittal number, implementation date, and Web address for accessing CRS871 were changed. All other information remains the same.

Provider Types Affected

Therapists and other providers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), or Medicare Administrative Contractors (A/B MAC)) for therapy services for Medicare beneficiaries.

Provider Action Needed

CR 5871, from which this article is taken announces the dollar amount of outpatient therapy caps for 2008, and clarifies the Medicare Claims Processing Manual regarding exceptions to outpatient therapy services.

On January 1, 2008, the financial limits on outpatient therapy services will be $1,810 for combined physical therapy and speech-language pathology services; and $1,810 for occupational therapy services.

You should make sure that your billing staffs are aware of these new outpatient therapy caps. You might also want to refer to the updated Medicare Claims Processing Manual, Chapter 5 (Part B Outpatient Rehabilitation and CORF/OPT Services), Section 10.2 (The Financial Limitation), for the complete documentation of the outpatient therapy services exceptions clarifications (which are summarized below). The complete revised manual sections are attached to CR5871, which is available at http://www.cms.hhs.gov/Transmittals/downloads/R1414CP.pdf on the Centers for Medicare & Medicaid Services (CMS) Web site.

Background

The Balanced Budget Act of 1997 enacted financial limitations on outpatient physical therapy, occupational therapy, and speech-language pathology services in all settings except outpatient hospital services. The 2006 Deficit Reduction Act enacted exceptions to the limits, and the Medicare, Medicaid, and SCHIP Extension Act of 2007 extended the cap exceptions process through June 30, 2008. The dollar amount of the cap is updated annually in accordance with the Medicare Economic Index.
CR 5871, from which this article is taken announces the dollar amount of outpatient therapy caps for 2008. Effective January 1, 2008, the financial limits on outpatient therapy services will be $1,810 for combined physical therapy and speech-language pathology services; and $1,810 for occupational therapy services. Exceptions are allowed for medically necessary outpatient therapy services.

The financial limits on outpatient therapy services over the last three years are displayed in Table 1.

Table 1
Financial Limits on Outpatient Therapy Services*

<table>
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<th>Year</th>
<th>Physical Therapy and Speech Language Pathology Combined</th>
<th>Occupational Therapy</th>
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<tr>
<td>2008</td>
<td>$1,810</td>
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<td>2007</td>
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<td>2006</td>
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NOTE: Medicare pays up to 80% of the limits after the deductible has been met.

The Medicare Summary Notice (MSN) message 38.18 has been updated to read:

ALeRt: Coverage by Medicare is limited to $1,780 in 2007 and $1,810 in 2008 for outpatient physical therapy and speech-language pathology combined. Occupational therapy services have the same limits. Medicare pays up to 80 percent of the limits after the deductible has been met. Exceptions to these limits apply to therapy billed by hospital outpatient departments and may also apply to medically necessary services.

CR 5871 also clarifies the Medicare Claims Processing Manual, Chapter 5 (Part B Outpatient Rehabilitation and CORF/OPT Services), Section 10.2 (The Financial Limitation), regarding exceptions to outpatient therapy services (except when billed by outpatient hospitals). A summary of the major manual clarifications follows:

1. Section 10.2, Subsection B. Moratoria and Exceptions for Therapy Claims
   Future exceptions language added as follows:
   The cap exception for therapy services billed by outpatient hospitals was part of the original legislation (Balanced Budget Act of 1997), and applies as long as caps are in effect. Exceptions to caps based on the medical necessity of the service are in effect only when Congress legislates the exceptions, as they did for 2007 and as they again extended through June 30, 2008, as part of the Medicare, Medicaid, and SCHIP Extension Act of 2007.

2. Section 10.2, Subsection C-1 Exceptions to Therapy Caps – General
   When the exceptions process (as directed by legislation) is in effect the policies in this section apply. Further, with the exception of the use of the KX modifier, the guidance in this section applies to all therapy services addressed by this section. The beneficiary may qualify for use of the cap exceptions at any time during the episode when documented medically necessary services exceed caps. All covered and medically necessary services qualify for exceptions to caps.

3. Section 10.2, Subsection C-2 Automatic Process Exceptions
   Beginning January 1, 2007, all exceptions are processed automatically. You should be aware that the term “automatic process exceptions” indicates that the claims processing for the exception is automatic, and not that the exception, itself, is automatic.

   In making a decision about whether to utilize the automatic process for exception, clinicians should consider, (among other considerations) whether services are appropriate to the patient’s condition including the diagnosis, complexities and severity. You should be aware that the list of the ICD-9 codes (for conditions and complexities that might qualify a beneficiary for exception to caps) that is found in the table in subsection 10.2 C-3 is only a guideline; and neither assures that services on the list will be excepted; nor limits the provision of covered and medically necessary services for conditions that are not on the list.

   Not all patients who have a condition or complexity on the ICD-9 code list are “automatically” excepted from therapy caps. You should see the Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services), Section 230.3 (Practice of Speech-Language Pathology) for documenting the patient’s condition and complexities. Note that Medicare contractors may scrutinize claims from providers whose services exceed caps more frequently than is typical. Further guidance on billing therapy services are found in the Local Coverage Determinations of some contractors.

4. Subsection C-3. ICD-9 Codes That are Likely to Qualify for the Automatic Process Therapy Cap Exception Based Upon Clinical Condition or Complexity
   Some Medicare contractors’ Local Coverage Determinations do not allow the use of some of the codes on the list in this Subsection to be in the primary diagnosis position on a claim. If your contractor has determined that these codes do
not characterize patients who require medically necessary services, you may not use these codes. Rather, to describe the patient’s condition, you must use a billable diagnosis code that your contractor allows.

Medicare will apply therapy caps to services based on the medical necessity of the service for the patient’s condition, not on the condition itself. If a service would be payable before the cap is reached and is still medically necessary after the cap is reached, that service is excepted.

You may use the automatic process for exception for medically necessary services when the patient has a billable condition that is not on the list in this subsection. The diagnosis on this list may be put in a secondary position on the claim and/or in the medical records, as your contractor directs.

**Additional Information**


If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

### Additional Information on Reporting a National Provider Identifier (NPI) for Ordering/Referring and Attending/Operating/Other/Service facility for Medicare Claims

**MLN Matters Number:** MM5890 Revised  
**Related Change Request (CR) #:** 5890  
**Related CR Release Date:** January 18, 2008  
**Effective Date:** May 23, 2008  
**Related CR Transmittal #:** R23SPI  
**Implementation Date:** April 7, 2008

**NOTE -** This article was revised on March 5, 2008, to remove the parenthetical phrase of “MD and DO” from the note box on page 3. All other information remains the same.

**Provider Types Affected**

Physicians, providers and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FI), Medicare Administrative Contractors (A/B MAC), or Durable Medical Equipment Medicare Administrative Contractors (DME MAC)) for services or items furnished to Medicare beneficiaries.

### Provider Action Needed

**STOP – Impact to You**

Effective with claims received on or after May 23, 2008, Medicare will not pay for referred or ordered services or items; unless the fields for the name and NPI of the ordering, referring and attending, operating, other, or service facility providers are completed on the claims.

**CAUTION – What You Need to Know**

CR 5890, from which this article is taken, provides that it is the claim/bill submitter’s responsibility to obtain the ordering, referring and attending, operating, other, service facility providers, or purchased service providers NPIs for claims. Further, it requires that the provider or supplier who is furnishing the services or items, after unsuccessfully attempting to obtain the NPI from these providers; report their own name and NPI in the ordering/referring/attending/operating/other/service facility provider/purchased service provider fields of the claims.

**GO – What You Need to Do**

Make sure that your billing staffs are aware of this requirement to place the “furnishing” provider or supplier’s name and NPI in the appropriate fields and to use your name and NPI if those of the ordering/referring and attending/operating/other/service facility provider/purchased service providers are not obtainable.

### Background

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate the adoption of a standard unique health identifier for each health care provider. The National Provider Identifier (NPI) final rule (45 CFR Part 162, CMS-045-F), published on January 23, 2004, established the NPI as this standard; and mandates that all entities covered under HIPAA (including health care providers) comply with the requirements of this NPI final rule.

Medicare previously required a unique physician identification number (UPIN) be reported on claims for any ordering, referring/attending, operating, other, and service facility providers (i.e., or for any provider that is not a billing, pay-to, or rendering provider). Further, in accordance with the NPI final rule; effective May 23, 2008, when reported on a claim, the identifier for such a provider must be an NPI, regardless of whether the provider is a covered entity, or participates in the Medicare program. Therefore, Medicare will not pay for referred or ordered services, or items,
unless the name and NPI number of the ordering, referring and attending, operating, other, or service facility provider are on the claim.

**NOTE** - Physicians and the following non-physician practitioners: 1) nurse practitioners (NP); 2) clinical nurse specialist (CNS); 3) physician assistants (PA); 4) and certified nurse midwives (CNM) are the only types of providers eligible to refer/order services or items for beneficiaries.

You should be aware that it is the claim/bill submitter’s responsibility to obtain the ordering, referring and attending, operating, other, service facility providers, or purchased service providers’ NPIs on the claim. If these providers do not directly furnish their NPIs to the billing provider at the time of the order, the billing provider must contact them to obtain their NPIs prior to delivery of the services or items.

If, after several unsuccessful attempts to obtain the NPI from the ordering, referring, attending, operating, other, service facility provider, or purchased service provider; CR 5890, from which this article is taken, requires that (effective May 23, 2008) the provider or supplier who is furnishing the services or items report their own name and NPI in the claim’s ordering/referring/attending/operating/other/service facility provider/purchased service provider fields.

**Additional Information**


If you have any questions, please contact your carrier, FI, A/B MAC, or DME MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

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**Provider Types Affected**

Suppliers who bill Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for immunosuppressive drugs.

**What Suppliers Need to Know**

CR 5916, from which this article is taken, implements an automated process for adjudicating claims for immunosuppressive drugs when the beneficiary was enrolled in Medicare Part A at the time of their transplant, even though Medicare did not pay for the transplant.

Make sure that your billing staffs are aware that you must be able to document the date of the patient’s transplant, and must include the “KX” Modifier on the claim to attest that you have documentation on file that proves that the beneficiary had the transplant for which the immunosuppressive drug was prescribed while the beneficiary was enrolled in Medicare Part A.

**Background**

Medicare covers a beneficiary’s immunosuppressive drugs following an organ transplant, provided that the beneficiary receiving the drug was enrolled in Medicare Part A at the time of the organ transplant procedure. Moreover, Medicare will pay for medically necessary immunosuppressive drugs for such a beneficiary whether or not Medicare paid for the transplant itself.

Prior to April of 2006, the Durable Medical Equipment (DME) Regional Carriers (DMERCs) received information about the date of a beneficiary’s transplant through a DMERC Information Form (DIF), which included a field in which the supplier could enter a transplant date. However, on February 17, 2006, the Centers for Medicare & Medicaid Services (CMS) issued Transmittal 867, Change Request (CR) 4241, which: 1) eliminated the DIF; and 2) implemented an edit at the Medicare’s Common Working File (CWF) system to search the Medicare’s Master Beneficiary Record (MBR) for a transplant upon receipt of a claim for an immunosuppressive drug. If the CWF system does not find evidence of a transplant in the MBR, the claim line for immunosuppressive drug is rejected.

Because CWF does not have a transplant record for a beneficiary if Medicare did not actually pay for the procedure, the DME Medicare Administrative Contractors (DME MACs) have been inappropriately denying claims even when such beneficiaries were enrolled in Medicare Part A at the time of their transplant.

To resolve this issue, CR 5916, from which this article is taken, implements an automated process for adjudicating claims for immunosuppressive drugs when the beneficiary was enrolled in Medicare Part A at the time of their...
transplant, but Medicare did not pay for the transplant.

Specifically, CR 5916 requires that:

★ For claims filed on and after July 1, 2008, suppliers who furnish an immunosuppressive drug to a Medicare beneficiary (in association with a previous organ transplant): 1) Secure from the prescriber the date of the organ transplant, 2) Retain documentation of the transplant date in its files, and 3) Annotate the Medicare claim for the drug with the “KX” modifier to signify both that the supplier retains the documentation of the beneficiary’s transplant date and that the transplant date precedes the Date of Service (DOS) for furnishing the drug.

★ For claims received on and after July 1, 2008, DME MACs will accept claims for immunosuppressive drugs without a KX modifier but will deny such claims if the MBR shows that Medicare has made payment for an organ transplant on a date that precedes the date of service (DOS) of the immunosuppressive drug claim.

Suppliers should note that the use of the KX modifier, in the context of a claim submitted to Medicare in order to receive payment for an immunosuppressive drug, signifies that the supplier attests that it has on file documentation that the beneficiary has undergone an organ transplant on a particular date while enrolled in Medicare Part A and that the immunosuppressive drug has been prescribed associated with that transplant.

A supplier who has not determined (or does not have documentation on file to support a determination) that the beneficiary either did not receive an organ transplant, or was not enrolled in Medicare Part A as of the date of the transplant; may not: 1) Bill Medicare for furnishing an immunosuppressive drug, 2) bill or collect any amount from the beneficiary for such a drug, or 3) issue an Advance Beneficiary Notice (ABN) to the beneficiary.

Additional Information

The official instruction, CR 5916, issued to your DME MAC is available at [http://www.cms.hhs.gov/Transmittals/downloads/R1448CP.pdf](http://www.cms.hhs.gov/Transmittals/downloads/R1448CP.pdf) on the CMS Web site. The revised Medicare Claims Processing Manual, Chapter 17 (Drugs and Biologicals), Section 80.3 (Billing for Immunosuppressive Drugs) is an attachment to that CR.

If you have any questions, please contact your Medicare Carrier, DME/MAC, Fl and/or A/B MAC at their toll-free number which may be found at [http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

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**Additional Clarification to Chapter 17, Section 40, Regarding Processing of Drug Claims with the JW Modifier**

**MLN Matters Number:** MM5923  
**Related Change Request (CR) #:** 5923  
**Related CR Release Date:** March 14, 2008  
**Effective Date:** January 1, 2008  
**Related CR Transmittal #:** R1478CP  
**Implementation Date:** April 14, 2008

**Provider Types Affected**  
Physicians, providers and suppliers billing Medicare Contractors (Medicare Administrative Contractors (A/B MACs), fiscal intermediaries (FIs), carriers and/or Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for drugs or biologicals provided to Medicare beneficiaries.

**Impact on Providers**  
When processing all drugs except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals, Medicare contractors may require the use of the modifier JW to identify unused drug or biologicals from single use vials or single use packages that are appropriately discarded. This modifier will provide payment for the discarded drug or biological.

**Background**  
The Centers for Medicare & Medicaid Services (CMS) issued this CR 5923 to notify providers of the Medicare Claims Processing Manual update that clarifies the use of the JW modifier when processing all drugs except CAP drugs.

**Additional Information**  
To see the official instruction (CR5923) issued to your Medicare Carrier, DME/MAC, Fl and/or A/B MAC, visit [http://www.cms.hhs.gov/Transmittals/downloads/R1478CP.pdf](http://www.cms.hhs.gov/Transmittals/downloads/R1478CP.pdf) on the CMS Web site.

If you have questions, please contact your Medicare Carrier, DME/MAC, Fl and/or A/B MAC at their toll-free number which may be found at [http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.
Importance of Supplying Correct Provider Identification Information Required in Items 17, 17a, 24K, and 33 of the Form CMS-1500 (12-90), and the Electronic Equivalent

Related Change Request (CR) #: N/A Revised
MLN Matters Number: SE0529
Related CR Release Date: N/A

NOTE – This article was revised on March 11, 2008, to clarify that all references to the form should state CMS-1500 (12-90). Providers may also want to refer to MLN Matters article MW5060 at http://www.cms.hhs.gov/MLNMattersArticles/downloads/mw5060.pdf, which states the requirements for the newer form, CMS-1500 (08-05). The previous revision to the article added a reference to MLN Matters MM5890 (http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5890.pdf). MM5890 stated that effective with claims received on or after May 23, 2008, Medicare will not pay for referred or ordered services or items unless the fields for the name and NPI of the ordering, referring and attending, operating, other, or service facility providers are completed on the claims.

Provider Types Affected
Physicians, providers, and suppliers who bill Medicare Carriers, including Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

Provider Action Needed
The Centers for Medicare & Medicaid Services (CMS) would like to remind providers and their billing staffs of the importance of reporting the correct provider identification information in items 17, 17a, 24K, and 33 of the Form CMS-1500 (12-90), or the electronic equivalent. This information is critical for accurate and timely processing and payment of your claims.

Additional Information
Please be aware of the following instructions:

Items 17 and 17a
On the Form CMS-1500 (12-90), or electronic equivalent, the provider must submit the appropriate referring or ordering physician name in item 17, and the Unique Physician Identification Number (UPIN) of that referring/ordering physician in item 17a. These are required fields when a service was ordered or referred by a physician. When a claim involves multiple referring and/or ordering physicians, you must prepare a separate claim submission for each ordering/referring physician.

Item 17
Enter the name of the referring or ordering physician if the service or item was ordered or referred by a physician.

Item 17a
Enter the UPIN of the referring/ordering physician listed in item 17.

• Referring physician - is a physician who requests an item or service for the beneficiary for which payment may be made under the Medicare program.
• Ordering physician - is a physician or, when appropriate, a non-physician practitioner who orders nonphysician services for the patient. See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15 for non-physician practitioner rules. Examples of services that might be ordered include diagnostic laboratory tests, clinical laboratory tests, pharmaceutical services, durable medical equipment, and services incident to that physician’s or non-physician practitioner’s service.

The ordering/referring requirement became effective January 1, 1992, and is required by §1833(q) of the Act. All claims for Medicare covered services and items that are the result of a physician’s order or referral shall include the ordering/referring physician’s name and UPIN. This includes parenteral and enteral nutrition, immunosuppressive drug claims, and the following:

☆ Diagnostic laboratory services
☆ Diagnostic radiology services
☆ Portable x-ray services
☆ Consultative services
☆ Durable medical equipment.

Claims for other ordered/referred services not included in the preceding list shall also show the ordering/referring physician’s name and UPIN. For example, a surgeon shall complete items 17 and 17a when a physician refers the patient. When the ordering physician is also the performing physician (as often is the case with in-office clinical laboratory tests), the performing physician’s name and assigned UPIN appear in items 17 and 17a.

When a service is incident to the service of a physician or non-physician practitioner, the name and assigned UPIN of the physician or non-physician practitioner who performs the initial service and orders the non-physician service must appear in items 17 and 17a.

All physicians who order or refer Medicare beneficiaries or services must obtain a UPIN even though they may never bill Medicare directly. A physician who has not been assigned a UPIN must contact the local Medicare carrier to obtain the UPIN. A list of toll free numbers of the Medicare carriers is available at: http://www.cms.hhs.gov/apps/contacts/ on the CMS Web site.

When a physician extender or other limited licensed practitioner refers a patient for consultative service, the name and UPIN of the physician supervising the limited licensed practitioner must appear in items 17 and 17a.

When a patient is referred to a physician who also orders and performs a diagnostic service, a separate claim form...
is required for the diagnostic service. Enter the original ordering/referring physician's name and UPIN in items 17 and 17a of the first claim form. Enter the ordering (performing) physician's name and UPIN in items 17 and 17a of the second claim form (the claim for reimbursement for the diagnostic service).

**Item 24K (See note above to reference MM5060, which changes the requirement for Item 24K.)**

Enter the provider identification number (PIN) of the performing provider of service/supplier in item 24K if the provider is a member of a group practice. When several different providers of service or suppliers within a group are billing on the same Form CMS-1500 (12-90), or electronic equivalent, show the individual PIN of each performing provider in the corresponding line item. In the case of a service provided incident to the service of a physician or non-physician practitioner, when the person who ordered the service is not supervising, enter the PIN of the supervisor in item 24K.

**UPINs are not appropriate identifiers for item 24K.**

**Item 33**

Enter the provider of service/supplier’s billing name, address, ZIP code, and telephone number. This is a required field.

For a provider who is not a member of a group practice (e.g., private practice), enter the PIN at the bottom of item 33 for paper claims. The PIN should be entered on the left side, next to the PIN# field.

If a group practice is billing, then the group PIN is to be placed in item 33 for paper claims. Enter the group PIN at the bottom of item 33 on the right side, next to the GRP# field. Enter the PIN for the performing provider of service/supplier who is a member of that group practice in item 24K.

Suppliers billing a DME MAC will use the National Supplier Clearinghouse (NSC) number in this item.

**NOTE** – When implemented, the National Provider Identification (NPI) number will replace the PIN and UPIN. At that time, you will use the NPI number in items 17a, 24K, and 33.


If you have questions, please contact your carrier/DME MAC at their toll free number, available at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

## Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) – The first in a series of articles on the implementation of this program.

**MLN Matters Number:** SE0805  
**Related Change Request (CR) #:** N/A  
**Related CR Release Date:** N/A  
**Effective Date:** N/A  
**Related CR Transmittal #:** N/A  
**Implementation Date:** N/A

### Provider Types Affected

Any Medicare Fee-for-Service (FFS) provider that may be in a position of ordering, referring, or supplying DMEPOS to a Medicare beneficiary may be affected by this program. This includes DMEPOS suppliers, physicians (including podiatric physicians), other treating practitioners (nurse practitioners, physician assistants, and clinical nurse specialists), physical and occupational therapists, and institutional providers (especially skilled nursing facilities and their social workers or care coordinators, hospitals and their discharge planners, home health agencies and pharmacists).

Note that those who refer or order DMEPOS for Medicare beneficiaries are being described as “referral agents” throughout this series.

### Provider Action Needed

**STOP – Impact to You**

Effective July 1, 2008, Medicare will begin implementation of a new program for purchasing DMEPOS for Medicare patients. For Medicare beneficiaries whose permanent residence is in one of the 10 metropolitan statistical areas (MSAs) affected by the first phase of this program, only contract suppliers, in most from Medicare. While new payment rules may not impact referral agents directly, they may impact your patients. Therefore, the Centers for Medicare & Medicaid Services (CMS) is providing this information to make you aware of the program so you can discuss it with your patients when necessary.
CAUTION – WHAT YOU NEED TO KNOW

This program, initially, will affect patients obtaining DMEPOS in 10 Competitive Bidding Areas (CBAs) that align with the 10 MSAs affected by the first phase of this program and will include 10 product categories of DMEPOS. These areas and product categories will be identified later in this article. In general, if your patients reside in one of the CBAs, they must use a Medicare contract supplier for competitive bid items, unless they are willing to be responsible for full payment of these items. This means that some of your patients may have to change from a noncontract supplier to a contract supplier. Also, certain suppliers that rent DMEPOS that were not awarded contracts may be “grandfathered” under this program and may be able to continue to supply certain DMEPOS items/services should the beneficiary choose to continue to receive these items from a grandfathered supplier.

GO – WHAT YOU NEED TO DO

It is important that all affected providers know this information. This program determines how much Medicare will pay for competitive bidding items and which suppliers are eligible to receive Medicare payments for these items. Be aware that the new program impacts payment amounts for certain DMEPOS items received by beneficiaries residing in one of the CBAs no matter where in the country they obtain their DMEPOS.

Be prepared for this program if you treat Medicare patients in one of the 10 areas affected by the first phase of this program, which are listed later in this article. Note that the program will expand to 70 additional MSAs in 2009.

BACKGROUND

Currently, Medicare payment for most DMEPOS is based on fee schedules. Recent amendments to the Social Security Act (the Act), however, will alter the process for determining payment amounts for certain DMEPOS items. Specifically, Section 1847 of the Act mandates that competitive bidding payment amounts replace the current DMEPOS fee schedule payment amounts for selected items in selected areas. The intent is to improve the effectiveness of the Medicare methodology for setting DMEPOS payment amounts, which will reduce beneficiary out-of-pocket expenses and save the Medicare program money while ensuring beneficiary access to quality items and services. The new method brings the payment amount for these items in line with that of a competitive market and reduces your patients’ out-of-pocket expenses. The program also ensures the availability of a sufficient number of accredited suppliers for access to quality items and services. For more information on accreditation of DME suppliers, visit http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp on the CMS Web site.

The law also provides for phasing in competitive bidding beginning in 10 of the largest MSAs. The program will be expanded into 70 additional MSAs in 2009 and the program will be expanded into additional areas after 2009. Areas that may be exempt from competitive acquisition of DMEPOS include rural areas and areas with low population density that are not competitive, unless there is a significant national market through mail order for a particular item or service. An area is chosen for the Competitive Bidding Program based on several variables, including the size of its Medicare population and the amount of money spent on medical equipment and supplies in those areas.

DEFINITIONS

The following definitions are provided to explain several terms and their usage in this series of articles:

- **Contract Supplier** - An entity that is awarded a contract by CMS to furnish items under a competitive bidding program.
- **Noncontract Supplier** - A supplier that is not awarded a contract by CMS to furnish items included in a competitive bidding program.
- **Referral Agents** – This term applies to the range of physicians, practitioners or providers who prescribe DMEPOS (in essence, “order” or “refer”) for their patients.
- **Grandfathered Supplier** - A noncontract supplier that chooses to continue to furnish grandfathered items to a beneficiary in a CBA.
- **Grandfathered Item** - Any one of the items (as described in CFR §414.220, 222, 226, and 229) for which payment is made on a rental basis prior to the implementation of a competitive bidding program and for which payment is made after implementation of a competitive bidding program to a grandfathered supplier that continues to furnish the items in accordance with §414.408(j).
- **Single payment amount** means the allowed payment for an item furnished under a competitive bidding program.

For more information on single payment amounts, visit http://dmecompetitivebid.com/SPA on the Internet.

INITIAL COMPETITIVE BIDDING AREAS (CBAs)

Effective July 1, 2008, the competitive bidding program will be implemented in the following CBAs within these 10 MSAs:

- Charlotte-Gastonia-Concord, North Carolina and South Carolina;
Cincinnati-Middletown, Ohio, Kentucky, and Indiana;
Cleveland-Elyria-Mentor, Ohio;
Dallas-Fort Worth-Arlington, Texas;
Kansas City, Missouri and Kansas;
Miami-Fort Lauderdale-Miami Beach, Florida;
Orlando-Kissimmee, Florida;
Pittsburgh, Pennsylvania;
Riverside-San Bernardino-Ontario, California;
San Juan-Caguas-Guaynabo, Puerto Rico.

**Product Categories**

Effective July 1, 2008, the competitive bidding program will be implemented for the following product categories:

- Oxygen supplies and equipment;
- Standard power wheelchairs, scooters, and related accessories;
- Complex rehabilitative power wheelchairs and related accessories;
- Mail-order diabetic supplies;
- Enteral nutrients, equipment, and supplies;
- Continuous positive airway pressure (CPAP), respiratory assist devices (RADS), and related supplies and accessories;
- Hospital beds and related accessories;
- Negative pressure wound therapy (NPWT) pumps and related supplies and accessories;
- Walkers and related accessories;
- Support surfaces (Group 2 mattresses and overlays (Miami MSAs only)).

**Traveling Beneficiaries**

As previously mentioned, any beneficiary obtaining competitive bidding items in one of the CBAs is affected by the rules of the Medicare DMEPOS Competitive Bidding Program. Beneficiaries who reside in a CBA and travels outside their CBAs may obtain competitive bid items and the supplier will be paid the single payment amount under the program.

In addition, beneficiaries who do not reside in CBAs and who travel to CBAs are also affected. If they require competitive bid items, they must obtain competitive bid items from a contract supplier for that CBA. In such instances, Medicare will pay that contract supplier the DMEPOS fee schedule amount.

The following table details how DMEPOS supplies may be acquired, given different scenarios:

<table>
<thead>
<tr>
<th>If a beneficiary permanently lives in…</th>
<th>And travels to…</th>
<th>Type of supplier a beneficiary may go to…</th>
</tr>
</thead>
<tbody>
<tr>
<td>A competitive bidding area</td>
<td>A competitive bidding area</td>
<td>A beneficiary must get competitively bid items from a contract supplier located in the competitive bidding area to which he/she traveled.</td>
</tr>
<tr>
<td>A competitive bidding area</td>
<td>An area NOT covered by the competitive bidding program</td>
<td>A beneficiary may get items from any Medicare-enrolled DME supplier, and the supplier will be paid by Medicare as if it were in the beneficiary’s competitive bidding area.</td>
</tr>
<tr>
<td>An area NOT covered by the competitive bidding program</td>
<td>A competitive bidding area</td>
<td>A beneficiary must get the competitively bid item from a contract supplier in the competitive bidding area. If the beneficiary does not use a contract supplier, the noncontract supplier must ask him/her to sign an Advance Beneficiary Notice. Medicare will not pay for competitively bid items furnished by noncontract suppliers.</td>
</tr>
<tr>
<td>An area NOT covered by the competitive bidding program</td>
<td>An area NOT covered by the competitive bidding program</td>
<td>A beneficiary may get items from any Medicare-enrolled DMEPOS supplier.</td>
</tr>
</tbody>
</table>

CMS is conducting extensive outreach to Medicare beneficiaries who reside in the CBAs and will be offering to help them identify contract suppliers.

If DMEPOS suppliers or referral agents are unsure whether a beneficiary resides in a CBA and is affected by this program effective July 1, they can make that determination by comparing the ZIP code of the patient’s residence to the list of ZIP codes for the CBAs, which is available at [http://dmecompetitivebid.com/Palmetto/Cbic.nsf/docsCat/DMEPOS%20Com petitive%20Bidding%20Areas%20Zip%20Codes?opendocument](http://dmecompetitivebid.com/Palmetto/Cbic.nsf/docsCat/DMEPOS%20Com petitive%20Bidding%20Areas%20Zip%20Codes?opendocument) on the Internet.

**Payment**

Payment for contract DMEPOS items will be the single payment amounts that were announced by CMS on March 20, 2008 (versus the current fee schedule determination of payment) for:

- Contract Suppliers, and
- Noncontract Suppliers that provide item to traveling beneficiaries.

**Additional Information**

DMEPOS suppliers should note that previous articles have explained the program in more detail as it relates to DMEPOS suppliers. MLN Matters article SE0714, “Pre-Bidding Activities for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program,” is available at [http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0714.pdf](http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0714.pdf)

In addition, all providers may find more detailed information at http://www.dmecompetitivebid.com on the Internet and at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/ on the CMS Web site.

As this is the first in a series of MLN Matters articles on this issue, further articles will be released in the very near future.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Grandfathering, Repair and Replacement, Mail Order Diabetic Supplies and Advanced Beneficiary Notices (ABNs): The Second in a Series of Articles on the New DMEPOS Competitive Bidding Program

MLN Matters Number: SE0806
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
Any Medicare Fee-for-Service (FFS) provider supplying DMEPOS to a Medicare beneficiary. This article also contains information of interest to those who order DMEPOS and to referral agents as defined in MLN Matters article SE0805.

Provider Action Needed
The first article (SE0805) in this series on the DMEPOS Competitive Bidding Program being instituted by the Centers for Medicare & Medicaid Services (CMS) presented an overview of how the program may affect your patients. There are also some key provisions of the program about which your patients may raise questions. While the competitive bidding program only affects ten areas of the country as of July 1, 2008, it will expand to 70 additional geographic areas in 2009. Thus, it is important for you to be familiar with this program.

Background
MLN Matters article SE0805, entitled “Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS),” which is available at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0805.pdf on the CMS Web site, summarizes information on competitive bidding that may impact your patients. Article SE0805 contains the list of competitive bidding areas for the first phase of competitive bidding as well as a list of the DMEPOS product categories that are included in the program’s initial implementation.

In using this series of DMEPOS articles, it is important to remember that in most instances, beneficiaries maintaining a permanent residence in one of the Competitive Bidding Areas (CBAs) must obtain competitive bidding items from a contract supplier. There are also program requirements that apply to beneficiaries who reside in CBAs but travel outside of those CBAs and to beneficiaries who do not live in CBAs but travel to them.

Grandfathered Suppliers
The Medicare DMEPOS Competitive Bidding Program requires Medicare beneficiaries to obtain competitive bidding items from a contract supplier, unless an exception applies. Therefore, in some instances, your patient may be required to change from a non-contract supplier to a contract supplier. However, the program does allow for certain suppliers to be “grandfathered.” Grandfathered suppliers are allowed to continue to provide certain rented DME items and services even though they are not contract suppliers.

Grandfathering only applies when the patient is renting DME or oxygen equipment at the time the competitive bidding program becomes effective and the rental period for the item began before the start of the competitive bidding program.

Beneficiaries who are receiving oxygen, oxygen equipment or rented DME at the time the competitive bidding program becomes effective may elect to continue to receive these items from a non-contract supplier, if the supplier is willing to continue furnishing these items. If a non-contract supplier chooses not to be “grandfathered” or if a beneficiary wants to change to a contract supplier, the non-contract supplier must pick up the rental equipment and oxygen equipment. Unless a beneficiary relocates outside of the CBA and the supplier service area, the supplier cannot discontinue services by picking up a medically necessary item prior to the end of a rental month for which the supplier was eligible to receive a rental payment, even if the last day of a rental month is after the start date of the program.
If the date of the beginning of a monthly rental period is prior to the start of the competitive bidding program, the supplier must submit a claim for that month. Note that the grandfathering provision also applies to Medicare beneficiaries who transition from a Medicare Advantage Plan to the Fee-for-Service program.

If the beneficiary stays with a "grandfathered" supplier, he or she may elect to change to a contract supplier at any time, and the contract supplier would be required to accept the beneficiary as a customer. For more details on the grandfathering provision, visit http://www.dmecompetitivebid.com on the CMS Web site.

**Repair and Replacement of Beneficiary-Owned Items**

**Repair ONLY**
A beneficiary who owns a competitively bid item that needs to be repaired may have the repairs performed by either a contract supplier or by a non-contract supplier. In these cases, Medicare pays for reasonable and necessary labor not otherwise covered under a manufacturer's or supplier's warranty.

**Repair and Replacement**
If a part needs to be replaced in order to make the beneficiary-owned equipment serviceable, and the replacement part is also a competitively bid item for the CBA in which the beneficiary maintains a permanent residence, the part may be obtained from either a contract supplier or a non-contract supplier. In either case, Medicare pays the single payment amount provided under the Competitive Bidding Program for the replacement part.

**Replacement ONLY**
Beneficiaries maintaining permanent residences in a CBA are required to obtain replacement of all items subject to competitive bidding from a contract supplier. This includes replacement of base equipment and replacement of parts or accessories for base equipment that are being replaced for reasons other than servicing of the base equipment.

Beneficiaries who are not permanent residents of a CBA but require a replacement of a competitively bid item while visiting a CBA, must obtain the replacement item from a contract supplier. The supplier will be paid the fee schedule amount for the state where the beneficiary is a permanent resident.

**Mail Order Diabetic Supplies under the Program**
Medicare beneficiaries who permanently reside in a CBA may purchase their diabetic testing supplies from:

★ A mail order contract supplier for the area in which the beneficiary maintains a permanent residence; or

★ A non-contract supplier in cases where the supplies are not furnished on a mail order basis.

The mail order contract period covers diabetic testing supplies furnished from July 1, 2008 through March 31, 2010. The term "mail order" refers to items ordered remotely (i.e., by phone, email, internet, or mail) and delivered to the beneficiary's residence by common carriers (e.g., U.S. Postal Service, Federal Express, United Parcel Service) and does not include items obtained by beneficiaries from local supplier storefronts.

Mail order contract suppliers will be reimbursed at the single payment amount for the CBA where the beneficiary maintains a permanent residence.

For diabetic supplies that are not furnished through mail order, suppliers will be paid the fee schedule amount.

Medicare payment will not be made to non-contract suppliers that furnish mail order diabetic testing supplies to Medicare beneficiaries residing in a CBA. A special modifier, KL, will be used on each claim to indicate that the item was furnished on a mail order basis.

---

**NOTE** - Suppliers that furnish diabetic testing supplies on a mail order basis and do not attach the mail order modifier could be subject to significant penalties under the False Claims Act.

Both the Medicare program and beneficiaries will save money each time a mail order contract supplier is used; however, it is solely up to the beneficiaries to decide whether or not they wish to obtain their diabetic testing supplies on a mail order basis.

All mail order contract suppliers are required to report the manufacturer or make and model number of products they furnish and must update this list on a quarterly basis. This information will be made available to the public once the contract suppliers have been announced and will be updated on a routine basis. Contract suppliers will be required to make available the same range of products to Medicare beneficiaries that they make available to non-Medicare customers.

**Advance Beneficiary Notice (ABN) Information**
In general, if a non-contract supplier in a CBA furnishes a competitively bid item to any Medicare beneficiary regardless of whether that beneficiary maintains a permanent residence in the CBA or another area, and no applicable exceptions apply, Medicare will not make payment. In addition, the beneficiary is not liable for payment unless the non-contract supplier in a CBA obtains an ABN signed by the beneficiary.

receiving the item that there would be no Medicare coverage due to the supplier's contract status, and that the beneficiary understands that he/she will be liable for
all costs that the non-contract supplier may charge the beneficiary for the item.

If a non-contract supplier furnishes a competitively bid item to a beneficiary and the beneficiary signs an ABN, the supplier must use the “GA” modifier on their claim. If the “GA” modifier is not present on the claim, the supplier may not hold the beneficiary liable for the cost of the item.

Additional Information


If you have concerns, questions, or complaints about the quality of an item or the service that a patient received from a contract supplier, please call the Competitive Bidding Program helpline at 1.877.577.5331.


HCPCS Updates

Nebulizers - HCPCS Code Changes

The following codes will be valid for claims with dates of service on or after April 1, 2008:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7611</td>
<td>Albuterol, inhalation solution, FDA-approved final product, non-compounded, administered through DME, concentrated form, 1 mg</td>
</tr>
<tr>
<td>J7612</td>
<td>Levalbuterol, inhalation solution, FDA-approved final product, non-compounded, administered through DME, non-compounded, administered through DME, concentrated form, 0.5 mg</td>
</tr>
<tr>
<td>J7613</td>
<td>Albuterol, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, 1 mg</td>
</tr>
<tr>
<td>J7614</td>
<td>Levalbuterol, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, 0.5 mg</td>
</tr>
<tr>
<td>Q4099</td>
<td>Formoterol fumarate, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, 20 micrograms</td>
</tr>
</tbody>
</table>

The following codes, which became valid for claims with dates of service on or after January 1, 2008 will be discontinued. These codes will be invalid for claims with dates of service on or after April 1, 2008.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7602</td>
<td>Albuterol, all formulations including separated isomers, inhalation solution, FDA-approved final product, non-compounded, administered through DME, concentrated form, per 1 mg (albuterol) or per 0.5 mg (levalbuterol)</td>
</tr>
<tr>
<td>J7603</td>
<td>Albuterol, all formulations including separated isomers, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, per 1 mg (albuterol) or per 0.5 mg (levalbuterol)</td>
</tr>
</tbody>
</table>

The new codes will be included in a future revision of the Nebulizers LCD and Policy Article.

Nebulizers: Brovana and Perforomist - Instructions for New HCPCS Codes, April 2008

New HCPCS codes have been created for Perforomist (formoterol, Q4099), effective April 1, 2008, and Brovana (arformoterol, J7605), effective January 1, 2008.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7605</td>
<td>Arformoterol, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, 15 micrograms</td>
</tr>
<tr>
<td>Q4099</td>
<td>Formoterol fumarate, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, 20 micrograms</td>
</tr>
</tbody>
</table>

In August 2007, an article, *Nebulizers – Perforomist and Brovana – Coverage Criteria and Billing Instructions*, was published providing guidance on coverage and coding of these drugs. The updated article below includes instructions for each new product.

Coverage Criteria

FDA-approved inhalation solutions of formoterol (Q4099) or arformoterol (J7605) are covered when the following criteria are met:

1. It is medically necessary for the management of chronic obstructive pulmonary disease (ICD-9 diagnosis codes 491.0-492.8, 496); and
2. The patient has a documented history of routine use of at least four doses per day of an FDA-approved albuterol or metaproterenol inhalation solution or at least three doses per day of an FDA-approved levalbuterol inhalation solution.

If the above coverage criteria are not met, formoterol and arformoterol will be denied as not medically necessary.
Formoterol and arformoterol are administered using a pneumatic compressor (E0570, E0571) and a small volume nebulizer (A7003, A7004, A7005).

A maximum of two vials of formoterol (20 micrograms each) or two vials of arformoterol (15 micrograms each) are covered per day.

Short-acting beta-adrenergic agonists (SABAs) may be covered as rescue/supplemental medication in addition to formoterol or arformoterol. However, when formoterol or arformoterol is used, the maximum amount of SABA inhalation solutions that will be covered is an average of one dose per day (31 doses per month).

**Coding and Billing Guidelines**

When submitting claims for formoterol or arformoterol, use the following codes:

- **Q4099** for Perforomist (formoterol), effective April 1, 2008
- **J7605** for Brovana (arformoterol), effective January 1, 2008
- Append the KO modifier, when submitting claims for formoterol or arformoterol.
- A KX modifier must be appended to these codes, only when the coverage criteria stated above have been met.
- When billing for Perforomist, 1 unit of service = 1 vial (20 micrograms).
- When billing for Brovana, 1 unit of service = 1 vial (15 micrograms).
- Also, remember that the LCD requires that an ICD-9 code, describing the condition, which necessitates nebulizer therapy, must be included on each claim for equipment, accessories, and/or drugs.
- Refer to the Nebulizers LCD and Policy Article for additional information on coverage, coding, and billing of inhalation solutions.
- The Nebulizers policy has been revised to incorporate this information.

To view the Future Dated LCD, please click on the following link: [http://www.cms.hhs.gov/MCD/viewlcd.asp?lcd_id=5007&lcd_version=53&basket=lcd%3A5007%3A53%3ANebulizers%3ADME%3ACIGNA+Government+Services+%2818003%29%3A](http://www.cms.hhs.gov/MCD/viewlcd.asp?lcd_id=5007&lcd_version=53&basket=lcd%3A5007%3A53%3ANebulizers%3ADME%3ACIGNA+Government+Services+%2818003%29%3A)

**New HCPCS Codes for the April 2008 Update**

**MLN Matters Number:** MM5981  
**Related Change Request (CR) #:** 5981  
**Related CR Release Date:** April 18, 2008  
**Effective Date:** April 1, 2008  
**Related CR Transmittal #:** R1492CP  
**Implementation Date:** April 7, 2008  

**Provider Types Affected**

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, DME Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), Part A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.

**Provider Action Needed**

This article is based on Change Request (CR) 5981, which instructs Medicare Contractors to implement Healthcare Common Procedure Coding System (HCPCS) code changes effective April 1, 2008. Make sure that your billing staffs are aware of these changes.

**Background**

The Centers for Medicare & Medicaid Services (CMS) updates the Healthcare Common Procedure Coding System (HCPCS) code set on a quarterly basis.

Effective for claims with dates of service on or after April 1, 2008, the following HCPCS codes will no longer be payable for Medicare:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Description</th>
<th>Long Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7602</td>
<td>Albuterol inh non-comp con</td>
<td>Albuterol, all formulations including, separated Isomers, Inhalation Solution, FDA-Approved final product, non-compounded, administered through DME, concentrated form, per 1 MG (Albuterol) or per R 0.5 MG (Levalbuterol)</td>
</tr>
<tr>
<td>J7603</td>
<td>Albuterol inh non-comp u d</td>
<td>Albuterol, all formulations including separated Isomers, Inhalation Solution, FDA-Approved final product, non-compounded, administered through DME, unit dose, per 1 MG (Albuterol) or per R 0.5 MG (Levalbuterol)</td>
</tr>
<tr>
<td>J1751</td>
<td>Iron dextran 165 injection</td>
<td>Injection, Iron Dextran 165, 50 MG</td>
</tr>
<tr>
<td>J1752</td>
<td>Iron dextran 267 injection</td>
<td>Injection, Iron Dextran 267, 50 MG</td>
</tr>
</tbody>
</table>
Effective for claims with dates of service on or after April 1, 2008, the following HCPCS codes will be payable for Medicare:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Description</th>
<th>Long Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7611</td>
<td>Albuterol non-comp con</td>
<td>Albuterol, Inhalation Solution, FDA-Approved final product, Non-compounded, administered through DME, concentrated form, 1 MG</td>
</tr>
<tr>
<td>J7612</td>
<td>Levalbuterol non-comp con</td>
<td>Levalbuterol, Inhalation Solution, FDA-Approved Final Product, non-compounded, administered through DME, concentrated form, 0.5 MG</td>
</tr>
<tr>
<td>J7613</td>
<td>Albuterol non-comp unit</td>
<td>Albuterol, Inhalation Solution, FDA-Approved Final Product, non-compounded, administered through DME, unit dose, 1 MG</td>
</tr>
<tr>
<td>J7614</td>
<td>Levalbuterol non-comp unit</td>
<td>Levalbuterol, Inhalation Solution, FDA-Approved Final Product, non-compounded, administered through DME, unit dose, 0.5 MG</td>
</tr>
<tr>
<td>Q4096</td>
<td>VWF complex, NOS</td>
<td>Injection, Von Willebrand Factor Complex, Human, Ristocetin Cofactor (not otherwise specified), per I.U. VWF:RCO</td>
</tr>
<tr>
<td>Q4097</td>
<td>Inj IVIG Privigen 500 mg</td>
<td>Injection, Immune Globulin (Privigen), Intravenous, Non-Lyophilized (e.g., liquid), 500 MG</td>
</tr>
<tr>
<td>Q4098</td>
<td>Inj iron dextran</td>
<td>Injection, Iron Dextran, 50MG</td>
</tr>
<tr>
<td>Q4099</td>
<td>Formoterol fumarate, inh</td>
<td>Formoterol Fumarate, Inhalation Solution, FDA-Approved final product, non-compounded, administered through DME, unit dose form, 20 MICROGRAMS</td>
</tr>
</tbody>
</table>

Currently, Alphanate® is the only product that should be billed using code Q4096. J7190 should continue to be billed when Alphanate® is furnished for purposes of administering Factor VIII. The blood clotting furnishing fee is payable when payment is allowed for Q4096. When a payment allowance limit for Q4096 is included on the quarterly Part B drug pricing files, the payment allowance limit will include payment for the blood clotting furnishing fee.

Effective for dates of service on or after April 1, 2008, the requirements under CR 5713 (See the MLN Matters article for CR5713, which is at [http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5713.pdf](http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5713.pdf) on the CMS Web site) are being updated by CR 5981 to apply to claims that bill Intravenous Immunoglobulins (IVIG) using Q4097 as follows:

- Effective for dates of service on or after April 1, 2008, Medicare Contractors will:
  - Only pay a claim for preadministration-related services (G0332) associated with IVIG administration if G0332, the drug (IVIG, HCPCS codes: J1566, J1568, J1569, J1561, J1572 and/or Q4097), and the drug administration service are all billed on the same claim for the same date of service;
  - Return institutional claims for G0332 to the provider if J1566, J1568, J1569, J1561, J1572 and/or Q4097 and a drug administration service are not also billed for the same date of service on the same claim;
  - Reject professional claims as unprocessable for G0332 if J1566, J1568, J1569, J1561, J1572 and/or Q4097 and a drug administration service are not billed for the same date of service on the same claim; and
  - Use the appropriate reason/remark messages such as: M67 “Missing other procedure codes” and/or 16 “Claim/service lacks information” which are needed for adjudication when claims are returned/rejected.

**Additional Information**


If you have any questions, please contact your carrier, FI, RHHI, A/B MAC, or DME MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.
New Healthcare Common Procedure Coding System (HCPCS) Modifiers when Billing for Patient Care in Clinical Research Studies

**MLN Matters Number:** MM5805  
**Related Change Request (CR) #:** 5805  
**Related CR Release Date:** January 18, 2008  
**Effective Date:** January 1, 2008  
**Related CR Transmittal #:** R1418CP  
**Implementation Date:** April 7, 2008

**Provider Types Affected**
Physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), including Regional Home Health Intermediaries (RHHIs), Medicare Administrative Contractors (A/B MACs) and Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for services provided to Medicare beneficiaries in clinical research studies.

**What Providers Need to Know**
This article is based on Change Request (CR) 5805. The Centers for Medicare & Medicaid Services (CMS) is discontinuing the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007, and creating two new modifiers that will be used solely to differentiate between routine and investigational clinical services.

These new modifiers will be included in the 2008 Annual HCPCS Update and are effective for dates of service on and after January 1, 2008:

- **Q0** - Investigational clinical service provided in a clinical research study that is in an approved clinical research study. Q0 replaces QA and QR.
- **Q1** - Routine clinical service provided in a clinical research study that is in an approved clinical research study. Q1 replaces QV.

**Use these two new modifiers as follows:**
Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent), clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers), and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

Medicare contractors will not search their files to adjust affected claims processed prior to implementation of this change, but they will adjust such claims that you bring to their attention.

**Additional Information**
If you have questions, please contact your Medicare A/B MAC, FI, DMERC, DME/MAC, RHHI or carrier at their toll-free number which may be found at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

You may see the official instruction (CR5805) issued to your Medicare A/B MAC, FI, DMERC, DME/MAC, RHHI or carrier by going to [http://www.cms.hhs.gov/Transmittals/downloads/R1418CP.pdf](http://www.cms.hhs.gov/Transmittals/downloads/R1418CP.pdf) on the CMS Web site.

New “K” Code for Replacement Interface Material

**MLN Matters Number:** MM5900  
**Related Change Request (CR) #:** 5900  
**Related CR Release Date:** February 7, 2008  
**Effective Date:** April 1, 2008  
**Related CR Transmittal #:** R1441CP  
**Implementation Date:** April 7, 2008

**Provider Types Affected**
Suppliers who bill Durable Medical Equipment Medicare Administrative Contractors (DME MAC) for orthosis services for Medicare beneficiaries.

**What You Need to Know**
CR 5900, from which this article is taken, announces that (effective April 1, 2008) a new “K” code (K0672 – Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each) will be established.
for replacement interface material. You should make sure that your billing staffs are aware of this new "K" code.

Additional Information

If you have any questions, please contact your DME MAC at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Appeals

Requesting Individual Redeterminations for Each Different Line on a Claim Form

Background:
Over the past several months, we have identified situations to where suppliers are billing several items on a claim. An example would be B4154, B4035, and B9002. The items deny and the supplier requests individual appeals for each item.

Results
We receive the first appeal and adjust item B4154 to pay. Another specialist receives the second request for B4035 and has to wait for the first adjustment to complete in order to complete the second adjustment and move forward.

Recommendation:
As a best practice pertaining to the scenario above, in your request, please include all three items that were processed on the same claim control number within one redetermination request. This will eliminate additional steps and time and will allow CIGNA Government Services to more efficiently process your Redetermination request.

You may request a redetermination by submitting a completed Medicare DME MAC Jurisdiction C Redetermination Request Form (http://www.cignagovernmentservices.com/jc/forms/pdf/JC_redetermination_form.pdf) or a CMS-20027 (05/05) form, which may be obtained online at http://www.cms.hhs.gov/forms/CMS20027.pdf. (A supply of the CMS-20027 form can be ordered by writing to Superintendent of Documents, United States Government Printing Office, Washington, DC, 20402.) Additional information that the supplier wishes to be considered during the redetermination should be mailed with the written redetermination request. Redetermination requests should be mailed to:

CIGNA Government Services
DME MAC Jurisdiction C
PO Box 20009, Nashville, TN 37202

Modification to the Model Medicare Redetermination Notice (for partly or fully unfavorable redeterminations)

MLN Matters Number: MM5836
Related Change Request (CR) #: 5836
Related CR Release Date: January 11, 2008
Effective Date: January 1, 2008
Related CR Transmittal #: R1408CP
Implementation Date: February 11, 2008

Provider Types Affected
All physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FI), regional home health intermediaries (RHHI), Medicare Administrative Contractors (A/B MAC), or Durable Medical Equipment Medicare Administrative Contractors (DME MAC)) for services provided or supplied to Medicare beneficiaries.

What You Need to Know
CR 5836, from which this article is taken, modifies the Reconsideration Request Form that is included with the model Medicare Redetermination Notice (for partly or fully unfavorable redeterminations), to clarify the minimum set of elements on the form that you must complete in order for the request to be considered valid for reconsideration.

You should make sure that your billing staffs are aware that they must complete items 1, 2a, 6, 7, 11 & 12 on this Reconsideration Request Form.

Background
The Reconsideration Request Form modification that CR 5836 requires is necessary because the current Medicare manual instructions do not clearly identify all of the elements required for a reconsideration request to be considered valid in accordance with Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) Section 405.964(b).

The modification to the form is as follows:
Directions: If you wish to appeal this decision, please fill out the required information below and mail this form to the address shown below. At a minimum, you must complete/include information for items 1, 2a, 6, 7, 11 & 12 but to help us serve you better, please include a copy of the redetermination notice with your request.

Those elements that, as a minimum, you must complete in the form are:

1. Name of Beneficiary
2a. Medicare Number
6. Item or service you wish to appeal
7. Date of the service (From and To dates)
11. Name of Person Appealing
12. Signature of Person Appealing/Date

Additional Information
You can find more information about the modification to the model Medicare Redetermination Notice (for partly or fully unfavorable redeterminations) by going to CR S836, located at http://www.cms.hhs.gov/Transmittals/downloads/R1408CP.pdf on the CMS Web site. The updated Medicare Claims Processing Manual, Chapter 29, Section 320.7 (Medicare Redetermination Notice (for partly or fully unfavorable redeterminations)) is an attachment to that CR. The Reconsideration Request Form is also attached to CR5836.

If you have any questions, please contact your contractor at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Change in the Amount in Controversy Requirement for Administrative Law Judge Hearings and Federal District Court Appeals

MLN Matters Number: MMS897
Related Change Request (CR) #: S897
Related CR Release Date: February 5, 2008
Effective Date: January 1, 2008
Related CR Transmittal #: R1437CP
Implementation Date: May 5, 2008

Impact on Providers
This article is based on Change Request (CR) S897 which notifies Medicare contractors of an increase in the Amount in Controversy (AIC) required to sustain Administrative Law Judge (ALJ) and Federal District Court appeal rights beginning January 1, 2008. The amount remaining in controversy requirement for ALJ hearing requests made before January 1, 2008 is $110. The amount remaining in controversy requirement for requests made on or after January 1, 2008 is $120. For Federal District Court review, the amount remaining in controversy goes from $1,130 for requests prior to January 1, 2008 to $1,180 for requests on or after that date.

Background
The Medicare claims appeal process was amended by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides for annual reevaluation (beginning in 2005) of the dollar amount in controversy required for an Administrative Law Judge (ALJ) hearing and Federal District Court review.

Change Request (CR) S897 revises the Medicare Claims Processing Manual (Publication 100-4, Chapter 29, Section 330.1 and Section 345.1) to update the Amount In Controversy (AIC) required for an ALJ hearing or Federal District Court review. As of January 1, 2008, the amount remaining in controversy must be at least $120 for an ALJ hearing or at least $1,180 for a Federal District Court review requested on or after January 1, 2008.

Additional Information

If you have any questions, please contact your carrier, FI, RHHI, A/B MAC, DMERC, or DME MAC at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Provider Types Affected
Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, DME Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), Part A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.
EDI

Vendor and Trading Partner Frequently Asked Questions

National Government Services, Inc. was awarded the Durable Medical Equipment (DME) Common Electronic Data Interchange (CEDI) front end contract by the Centers for Medicare & Medicaid Services (CMS). With this contract, CEDI will provide a single front end solution for the submission and retrieval of electronic transactions.

With this change, DME MAC Trading Partners (Electronic Submitters) will send all electronic claims (X12 837 and NCPDP) and 276 Claim Status Inquiry transactions to CEDI. CEDI will return all electronic front end reports directly to the submitter.

CEDI will also receive the X12N 835 Electronic Remittance Advice (ERA) and 277 Claims Status Response transactions from the DME MACs and deliver them to the Trading Partner's (Electronic Submitters) CEDI mailbox.

CEDI will be working with DME suppliers, clearinghouses, billing services and vendors to minimize any disruption to the current EDI processes. Listed below are some key dates and important information to facilitate the transition to the CEDI system. NOTE: Trading Partners (Electronic Submitters) can move fully into production with CEDI before their final cutover date listed below.

Key Dates

<table>
<thead>
<tr>
<th>Date</th>
<th>Jurisdiction A and Jurisdiction D are no longer processing new requests for submitter IDs or changes to an existing ID. All new setups and changes will be done by the CEDI Enrollment Team.</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.01.08</td>
<td>Infrastructure B and Jurisdiction C will no longer process new requests for submitter IDs or changes to an existing ID. All new setups and changes will be done by the CEDI Enrollment Team.</td>
</tr>
<tr>
<td>04.30.08</td>
<td>Last day for Jurisdiction A and Jurisdiction D to process EDI transactions.</td>
</tr>
<tr>
<td>05.01.08</td>
<td>All Jurisdiction A and Jurisdiction D EDI transactions will be processed by CEDI.</td>
</tr>
<tr>
<td>05.31.08</td>
<td>All Jurisdiction B and Jurisdiction C to process EDI transactions.</td>
</tr>
<tr>
<td>06.01.08</td>
<td>All Jurisdiction B and Jurisdiction C EDI transactions will be processed by CEDI.</td>
</tr>
</tbody>
</table>

CEDI Help Desk

The CEDI Help Desk is available from 9:00 a.m. – 9:00 p.m. (ET) Monday through Friday.

Email: NGS.CEDIHelpdesk@wellpoint.com

The CEDI Help Desk will provide support for electronic transactions exchanged with CEDI including claims, ERA, 276/277. The DME MAC Jurisdictions will continue to provide support for the online Claim Status Inquiry (referred to as CSI, VPIQ, or PINQ) and Electronic Funds Transfer (EFT).

CEDI Web Site

The CEDI Web site is located at http://www.ngscedi.com with the following information:

- CEDI Enrollment Forms
- Help Desk Contact Information including the Email address and phone number.
- Implementation Schedule for the CEDI transition.
- ListServ Registration to be notified of important CEDI information.
- Outreach Materials including Listserv messages and the listing of vendors, billing services and clearinghouses who have passed testing with CEDI.
- Software Downloads including the Express Plus upgrade for Jurisdiction A, Jurisdiction B and Jurisdiction Express Plus users. The upgrade had updated communications software for exchanging transactions with CEDI. Also included are instructions on installing the upgrade, making the necessary changes to the communications program, and how to login, send and receive transactions with CEDI.
- Telecommunications has the guides for setting up and using asynchronous and FTP connections for CEDI.
- Trading Partner Agreements provide information for vendors to exchange transactions with CEDI.

Frequently Asked Questions

Communications

- Files can come in zipped. We must be informed prior to sending a file to update our system. All zipped files must come in Binary mode.
- File names cannot be longer than 57 characters.
- Production cutoff time for claim submission is 3:00 p.m. (ET).
- If you find that you are having consistent trouble connecting to CEDI, you may want to consider one of the Network Service Vendors that provide a continuous connection to our gateway.
- IVANS can be contacted at 1.800.548.2675, select option 1, and enter extension 3742.
- Nebo can be contacted at 1.630.916.8818, x: 261.
- VisionShare can be contacted at 1.888.895.2649 or via e-mail at info@visionshareinc.com.
- MedXpress can be contacted via their Web site: http://www.icssoftware.net/MedXpress

Enrollment

- Do I need to re-enroll with CEDI?

No. CEDI has received all EDI enrollment information from the DME MAC Jurisdictions. Your Trading Partner/Submitter ID will remain the same.

CEDI will perform validation that the Trading Partner/Submitter is authorized to submit claims for the
supplier in the transmitted file. You can confirm the Supplier to Trading Partner relationship is established by sending an email to the CEDI Help Desk at ngs.cedihelpdesk@wellpoint.com. Be sure to include your Trading Partner/Submitter ID and the supplier numbers that should be linked to that ID.

**I have multiple Trading Partner/Submitter IDs. Can I combine these into one to exchange transaction with CEDI?**
Yes. If you have multiple Trading Partner/Submitter IDs and you wish to combine them into one ID, you can contact the CEDI Help Desk at ngs.cedihelpdesk@wellpoint.com to obtain the form to submit to CEDI.

**Will there be one standardized EDI form for all 4 regions?**
Yes. CEDI will maintain the EDI setup forms and they will be located on the CEDI Web page (http://www.ngscedi.com). You will be able to submit them electronically for EDI setups. We will also have you fax and efax the EDI enrollment Form so we have the actual signature on file.

You will only need to submit one set of forms and CEDI will process them for all four DME MAC Jurisdictions.

**What will happen to EDI’s that are already in the process of being set-up when CEDI goes into production?**
The current DME MAC EDI setup areas will discontinue new EDI setups or changes to existing EDI setups one month prior to cutover (see the Key Dates above). Any new setups or changes done by the Jurisdictions before the freeze dates will be sent to and processed by CEDI.

For those submitters running in dual mode until 4/30/08 and 5/31/08 - Files last submitted to a Jurisdiction will receive front end edit reports and remits from that Jurisdiction. Only files sent directly to CEDI will be sent back from CEDI.

**What is the turnaround time for CEDI to process enrollment requests?**
CEDI will process new EDI enrollment requests within 10 business days of receipt.

Requests to combine data for multiple Trading Partners IDs into one ID may take longer depending on the size of the request.

**Testing Process**
We are working vendors, clearinghouses and billing services to test connectivity and verify they are ready to send production files. CEDI will assign a representative as the contact for the transition. The contact will work one on one to assist vendors, clearinghouses and billing services with changes to the phone number, scripting changes, and testing the new CEDI.

Vendors, clearinghouses and billing services will be assigned a specific Trading Partner/Submitter ID to be used for testing. This ID will be in the format “V089#####”. **This V089 ID cannot be used to submit production claims.**

The CEDI Communications Manual for Async and FTP as well as a Gen Response Reports Document that will show you what the Gen Response report format will look like is available on the CEDI Web site (http://www.ngscedi.com)

This testing process is end-to-end that we want each vendor to perform. Once you have successfully connected to us, sent in a file and received a front end edit report back, we can consider you passed. You may continue to send in test files until you are comfortable migration over to Production keeping in mind the transition time frames. The sooner testing begins, the longer you will have to test.
Once you have passed testing with CEDI, your customers can begin to move fully into production to send claims (837), receive remits (835), send NCPDP files or 276's and receive reports and remittances prior to the final cutover dates.

Please notify your customers that they can use their existing Trading Partner/Submitter ID. There is no need for them to obtain a new one. You also need to let them know what phone number they need to switch to as well as the temporary password.

If a sender begins to send to us in production and then begins to have problems, they would need to contact the Jurisdiction they used to submit claims files to and see if they could begin submitting back to them. We do not anticipate that any submitters will have problems once they begin submitting to CEDI.

The process CEDI has with the Jurisdictions is that once we have a production sender, we will notify the Jurisdictions and they will determine how long to keep the submitter connected to their Jurisdiction. If the submitter has been deleted from the Jurisdiction, they will need to contact CEDI for support in resolving their communications issue.

We will update the Passed CEDI Vendor list posted to the CEDI Web site to reflect which vendors have passed their testing with CEDI. This will be updated daily, posted at least once a week.

File formats

- 837 Claim Files will be translated by CEDI and CEDI will perform Level 1 Standard Editing to verify the structure of the file. 837 claims can be submitted with any one of the four DME MAC Jurisdiction’s contractor code. CEDI will route all 837 claims to the appropriate DME MAC Jurisdiction based on the beneficiary address on each claim.
  - DME MAC Contractor Codes
    - Jurisdiction A – 16003
    - Jurisdiction B – 17003
    - Jurisdiction C – 18003
    - Jurisdiction D – 19003

- NCPDP Claim Files will be delivered to the DME MAC Jurisdiction based on the contractor code in the header record of the NCPDP file. CEDI will not perform any editing on the NCPDP claim files at this time. CEDI will simply pass these through to the DME MAC as indicated on the header record. The DME MAC will perform all editing, translation and reporting. These reports will be delivered back to you through CEDI. The DME MAC will also perform the routing to the appropriate DME MAC based on the beneficiary address on the claims within the file.

- 835 ERA Files will have an 835 prefix but the Jurisdiction’s contractor code will not be in the file name. The ISA06 will have the contractor code for the DME MAC that produced the ERA.
  - DME MAC Contractor Codes
    - Jurisdiction A – 16003
    - Jurisdiction B – 17003
    - Jurisdiction C – 18003
    - Jurisdiction D – 19003

- Pre-process reports returned from the DME MAC Jurisdictions will have a .RPT in the file name. Report formats should not be any different than what are received currently. CEDI will create a GenResponse report that will indicate the DME MAC Jurisdiction contractor code where the claims were delivered.
  - DME MAC Contractor Codes
    - Jurisdiction A – 16003
    - Jurisdiction B – 17003
    - Jurisdiction C – 18003
    - Jurisdiction D – 19003

PCAce Pro32 Software Users

All PC-Ace Pro32 Users must complete the following instructions to communicate with CEDI.

2. Contact the CEDI Help Desk at 866-311-9184 or via e-mail at NGS.CEDIHelpdesk@wellpoint.com to obtain the CEDI phone number and your password.
3. Follow the instructions in the Asynchronous Communication Manual to change the dial-in phone number to the CEDI phone number obtained from the CEDI Help Desk.
4. Follow the instructions in the manual to dial, login, connect and begin sending and receiving files with CEDI.
5. PCAce Pro32 users can continue to use the January release as the most current version. CEDI will notify PCAce Pro32 users when the next upgrade is available to download from the CEDI Web site.

Express Plus Software Users

National Government Services has upgraded the Express Plus software program to connect and exchange transactions with CEDI. Jurisdiction A, Jurisdiction B, and Jurisdiction D offer the Express Plus software as their low cost electronic billing software.

All Express Plus users must download the upgrade (Version 4.3.8) and follow the instructions below to communicate with CEDI. To download and begin using the new Version 4.3.8 of Express Plus, you need to:
1. Access the CEDI Web site at:
http://www.ngscedi.com

2. Select “Software Downloads”

3. On the “Software Downloads” page, print ALL of the following documents:
   - Express Plus Upgrade Instructions - These instructions will guide you through the process of running the Express Plus upgrade program.
   - Express Plus CEDI Script - These instructions will guide you through the procedures to create the communications’ scripts to connect to and send/receive files with CEDI.
   - Express Plus CEDI Connection and Login - These instructions will assist you in logging into CEDI and sending/receiving files with CEDI.

4. Follow the instruction documents listed in the order above.

Healthcare Provider Taxonomy Codes (HPTC) Update April 2008

Under HIPAA, code sets that characterize a general administrative situation, rather than a medical condition or service, are referred to as non-clinical or non-medical code sets. The Healthcare Provider Taxonomy Codes (HPTC) is an external non-medical data code set designed for use in classifying health care providers according to provider type or practitioner specialty in an electronic environment, specifically within the American National Standards Institute (ANSI) Accredited Standards Committee (ASC) health care transaction.

The HPTC is maintained by the National Uniform Claim Committee (NUCC) or standardized classification of health care providers. The NUCC updates the code set twice a year with changes effective April 1 and October 1. Visit the Washington Publishing Company Web site (http://www.wpc-edi.com/codes/taxonomy) for additional HPTC information and the HPTC code list, which is available in two forms:

- A free Adobe PDF download or
- An electronic representation of the list which will facilitate automatic loading of the code set. This version is available for purchase.

The HPTC is not required. However, if a HPTC is submitted it must be valid data from that code set. The HPTC is a named code set in the 837 professional implementation guide, thus carriers must validate the inbound taxonomy codes against their internal HPTC tables.

Terminated HPTC are not approved for use after a specific date and newly approved codes are not approved for use prior to the effective date of the code set update in which each new code first appears.

Specialty and/or provider type codes issued by any entity other than the NUCC are not valid and Medicare would be guilty of non-compliance with HIPAA if Medicare contractors accepted claims that contain invalid HPTC. Taxonomy code changes are applied to claims processed on and after the effective date of the code set.

Although the NUCC generally posts their updates on the WPC Web page 3 months prior to the effective date, changes are not effective until April 1 or October 1 as indicated in each update.

Code changes that are effective April 1, 2008 are noted in the table below:

<table>
<thead>
<tr>
<th>Type of Change</th>
<th>Provider Taxonomy Value Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additions</td>
<td></td>
</tr>
<tr>
<td>111NP0017X</td>
<td>1835P00118X</td>
</tr>
<tr>
<td>173C00000X</td>
<td>253000000X</td>
</tr>
<tr>
<td>173F00000X</td>
<td></td>
</tr>
<tr>
<td>1835P0018X</td>
<td></td>
</tr>
<tr>
<td>253J00000X</td>
<td></td>
</tr>
<tr>
<td>Revisions</td>
<td></td>
</tr>
<tr>
<td>207ND0101X</td>
<td>208X0206X</td>
</tr>
<tr>
<td>207NS0135X</td>
<td>208X05127X</td>
</tr>
<tr>
<td>2084A0401X</td>
<td></td>
</tr>
</tbody>
</table>

Overpayment Recovery

Offset Request Form

CIGNA Government Services is driven to provide our customers with a high level of service. In this and upcoming publications, the Overpayment Recovery Department will address topics about the overpayment recovery process.

This publication will provide guidelines for completion of the Offset Request form utilized by the Overpayment Recovery Department. This form, when completed properly, assists the Overpayment Recovery analyst with processing the request more efficiently and provides the supplier a means to reconcile their records. When submitting this form:

- It must be received within 20 days from the demand letter to ensure proper handling and to possibly avoid the interest penalty.
- Include all documentation relevant to the overpayment with the Offset Request form submission.
- Include a copy of the first page of the demand letter.
- Complete all requested information on form.
- Submit and attach a separate form for each overpayment to be offset.
Fax request to: 1.615.782.4477.

Remember that the total receivable amount will be placed in immediate offset. You may not request partial amounts to be placed in offset. Offset details can be tracked with the information provided on the Medicare Remittance Notice (MRN).

## Miscellaneous

### Support Income Tax Reporting

**MLN Matters Number:** MMS816  
**Related Change Request (CR) #:** 5816  
**Related CR Release Date:** January 25, 2008  
**Effective Date:** January 1, 2007 (date of payment)  
**Related CR Transmittal #:** R311OTN  
**Implementation Date:** January 30, 2008

### Provider Types Affected

Suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

### Provider Action Needed

This article is based on Change Request (CR) 5816, which notifies all DME MACs of the requirements to issue Internal Revenue Service (IRS) Form 1099-MISC to every supplier paid under contract and/or any other forms required for income tax and reporting purposes. Thus, your DME MAC will issue appropriate 1099 forms to you, when you receive $600 or more in Medicare payments in a calendar year, beginning with January 1, 2007.

### Background

The reporting requirements of the Internal Revenue Code (Section 6041A) state that any service-recipient engaged in a trade or business that pays in the course of such trade or business during any calendar year remuneration for such services in the aggregate of $600 or more must file an information return with the Internal Revenue Service (IRS). Internal Revenue Code section 6041A(d)(3) provides that payments made for services performed by a corporation are subject to information reporting requirements when the remuneration has been paid to the corporation by a Federal executive agency. The $600 or more paid by a Federal executive agency to a corporation is subject to information reporting per section 6041A(d)(3) of the Internal Revenue Code.

Further, the IRS has determined that payments to Durable Medical Equipment companies paid from Medicare trust fund monies are subject to Form 1099 MISC reporting requirements. IRS has also ruled that payments to persons providing health care services, including proprietary hospitals, physicians and dentists, often include charges for injections, drugs, dentures, and similar items. In such cases, the entire payment is subject to information reporting.

IRS instructions for completing form 1099-MISC states in part that Form 1099-MISC (Miscellaneous Income) should be filed for each person to whom one has paid during the year:

- At least $600 in rents, services (including parts and materials), prizes and awards, other income payments, medical and health care payments.


Note that "services" as defined by Medicare means "medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, Critical Access Hospital (CAH), or Skilled Nursing Facility (SNF)."

### In summary, CR5816 instructs that DME MACs should:

- Issue to every supplier paid under contract a 1099 and/or any other forms required for income tax and reporting purpose;
- Report all payments made to suppliers during the previous year.

### Additional Information


If you have any questions, please contact your DME MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.
Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

MLN Matters Number: MM5870
Related Change Request (CR) #: 5870
Related CR Release Date: February 7, 2008
Effective Date: January 1, 2008
Related CR Transmittal #: R81BP
Implementation Date: March 7, 2008

Provider Types Affected
Providers who bill Medicare carriers and Medicare Administrative Contractors (A/B MAC) for drugs and biologicals used in anti-cancer chemotherapeutic regimens.

What You Need to Know
CR 5870, from which this article is taken, announces that the 2008 Physician Fee Schedule contains a new rule for revising the compendia list used to determine medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

Background
A compendium (a comprehensive listing of either FDA-approved drugs and biologicals, or of a specific subset of drugs and biologicals -- for example, a compendium of anti-cancer treatment):

- Is indexed by the drug or biological, rather than by disease; and
- Includes a summary of the pharmacologic characteristics of each drug or biological's pharmacologic characteristics, and may include information on dosage, as well as recommended or endorsed uses in specific diseases.

Section 1861(t)(2)(B)(ii)(I) of the Social Security Act lists three drug compendia (American Hospital Formulary Service-Drug Information (AHFS–DI), American Medical Association Drug Evaluations (AMA–DE), and United States Pharmacopoeia-Drug Information (USP–DI)) that may be used to determine the medically accepted indications for drugs and biologicals used in an anti-cancer chemotherapeutic regimen. (The list is available on the Centers for Medicare & Medicaid (CMS) Web site at http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp#TopOfPage on the CMS Web site.)

But changes in the pharmaceutical reference industry limit the availability of some of these statutorily named compendia for CMS reference.

Therefore, per Section 1861(t)(2) of the Act that provides the Secretary of the Department of Health and Human Services the authority to revise the list of compendia for determining medically-accepted indications for drugs. CR 5870 announces that the 2008 Physician Fee Schedule contains a new rule for revising the compendia list used to determine medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

Process for Changing List of Compendia
Starting January 15, 2008, and each following January 15th, CMS will provide an annual 30-day open request period for the public to submit requests for additions or deletions to the compendia list that is on the CMS Web site.

By March 15th, CMS will post complete requests to its Web site for public notice and comment. Requests considered complete (and therefore accepted for review) must include the following information:

- The requestor’s full name and contact information (including the mailing address, e-mail address, and telephone number);

  **NOTE** - If the requestor is not an individual person, the information will identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.

- Full identification of the requested compendium, including name, publisher, edition (if applicable) date of publication, and any other information needed for its accurate and precise identification;

- A complete copy (written, electronic, or available online at no cost to the Government) of the requested compendium;

- The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium;

- Detailed, specific documentation that the requested compendium does or does not comply with the conditions of this rule.

  **NOTE** - Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed; therefore, will not be accepted.

CMS will accept these public comments for a 30-day period beginning on the day the request is posted on the Web site.

Finally, in addition to this annual process, CMS may also generate a request for changes to the list at any time an
urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

**Request Submission Instructions**

You should note that a request may have only a single compendium as its subject (to provide greater clarity on the scope of the agency's review of a given request), though a requestor may submit multiple requests, each requesting a different action.

Requests must be in writing and submitted in either one (but not both) of the following two ways:

- In order to facilitate administrative efficiency, electronic requests are preferred. Each solicitation will include the electronic address for submissions.
- Hard copy requests can be sent to:
  Centers for Medicare & Medicaid Services
  Coverage and Analysis Group
  Mailstop C1–09–06
  7500 Security Boulevard
  Baltimore, MD 21244

**NOTE** - Make sure that you allow sufficient time for hard copies to be received prior to the close of the open request period.

**Request Review**

Compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy should have these desirable characteristics:

- Extensive breadth of listings;
- Quick processing from application for inclusion to listing;
- Detailed description of the evidence reviewed for every individual listing;
- Use of pre-specified published criteria for weighing evidence;
- Use of prescribed published process for making recommendations;
- Publicly transparent process for evaluating therapies;
- Explicit "Not recommended" listing when validated evidence is appropriate;
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies;
- Explicit "Equivocal" listing when validated evidence is equivocal; and
- A process for public identification and notification of potential conflicts of interest of the compendia's parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

When reviewing requests, CMS may consider:

- A compendium's attainment of these listed characteristics;
- Additional reasonable factors (For example, factors that are likely to impact the compendium's suitability for this use, such as a change in ownership or affiliation, the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest; and that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians or both in choosing among treatment options); and
- The process by which the compendium grades the evidence used in making recommendations regarding off-label uses, as well as the grades themselves. Further, to facilitate administrative efficiency in the review of requests, CMS (at its discretion) may combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions.

**Publishing Review Results**

CMS will publish decisions on the CMS Web site within 90 days after the close of the public comment period.

**Additional Information**

You can find more information about the official instruction to your Medicare contractor about the new rule for revising the compendia list used to determine medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen by going to CR 5870, located at [http://www.cms.hhs.gov/Transmittals/downloads/R81BP.pdf](http://www.cms.hhs.gov/Transmittals/downloads/R81BP.pdf) on the CMS Web site. The amended Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services, Section 50.4.8 (Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen) as an attachment to that CR.

If you have questions, please contact your Medicare DME MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.
Items and Special Services Having Special DME Review Considerations

MLN Matters Number: MM5909
Related Change Request (CR) #: 5909
Related CR Release Date: February 22, 2008
Effective Date: March 1, 2008
Related CR Transmittal #: R242PI
Implementation Date: March 1, 2008

Provider Types Affected
Suppliers who submit claims to durable medical equipment Medicare Administrative Contractors (DME MACs) for DME items and services furnished to Medicare beneficiaries.

What Suppliers Need to Know
This article is informational for suppliers and is based on Change Request (CR) 5909 that alerts suppliers that the medical review (MR) function (Chapter 5 of the Program Integrity Manual (PIM) - Items and Services Having Special DME Review Considerations) that was the responsibility of the DME Program Safeguard Contractors (PSCs) is being transitioned to the DME MACs.

CR 5909 rescinds and replaces CR 5765 of the same title. This replacement also renames the DME PSCs to be Zone Program Integrity Contractors (ZPICS).

Additional Information
To see the official instruction (CR5909) issued to your Medicare DME MAC visit http://www.cms.hhs.gov/Transmittals/downloads/R242PI.pdf on the CMS Web site.

If you have questions, please contact your Medicare DME MAC at their toll-free number which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Update

MLN Matters Number: MM5942
Related Change Request (CR) #: 5942
Related CR Release Date: March 7, 2008
Effective Date: April 1, 2008
Related CR Transmittal #: R1475CP
Implementation Date: April 7, 2008

Provider Types Affected
Physicians, providers, and suppliers who submit claims to Medicare contractors (carriers, fiscal intermediaries (FIs), regional home health intermediaries (RHHIs), Part A/B Medicare Administrative Contractors (A/B MACs), durable medical equipment Medicare Administrative Contractors (DME MACs)) for services.

Provider Action Needed
CR 5942, from which this article is taken, announces the latest update of Remittance Advice Remark Codes (RARCs) and Claim Adjustment Reason Codes (CARCs), effective April 1, 2008. Be sure billing staff are aware of these changes.

Background
Two code sets—the reason and remark code sets—must be used to report payment adjustments in remittance advice transactions. The reason codes are also used in some coordination-of-benefits (COB) transactions. The RARC list is maintained by the Centers for Medicare & Medicaid Services (CMS), and used by all payers; and additions, deactivations, and modifications to it may be initiated by any health care organization. The CARC list is maintained by a national Code Maintenance committee that meets when X12 meets for their trimester meetings to make decisions about additions, modifications, and retirement of existing reason codes.

Both code lists are updated three times a year, and are posted at http://www.wpc-edi.com/Codes on the Internet. The lists at the end of this article summarize the latest changes to these lists, as announced in CR 5942.

CMS has also developed a new tool to help you search for a specific category of code and that tool is available at http://www.cmsremarkcodes.info on the Internet. Note that this Web site does not replace the WPC site and, should there be any discrepancies in what is posted at this site and the WPC site, consider the WPC site to be correct.

Additional Information
To see the official instruction (CR5942) issued to your Medicare Carrier, RHHI, DME/MAC, FI and/or A/B MAC refer to http://www.cms.hhs.gov/Transmittals/downloads/R1475CP.pdf on the CMS Web site.


If you have questions, please contact your Medicare Carrier, RHHI, DME/MAC, FI and/or A/B MAC at their toll-free number which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.
Claim Status Category Code and Claim Status Code Update

MLN Matters Number: MM5947  
Related Change Request (CR) #: 5947  
Related CR Release Date: February 29, 2008  
Effective Date: April 1, 2008  
Related CR Transmittal #: R1468CP  
Implementation Date: April 7, 2008

Provider Types Affected
Physicians, providers, and suppliers who submit Health Care Claim Status Transactions to Medicare contractors (carriers, Medicare Administrative Contractors (A/B MACs), Durable Medical Equipment Medicare Administrative Contractors (DME MACs), fiscal intermediaries (FIs), and Regional Home Health Intermediaries (RHHIs)).

Provider Action Needed

STOP – Impact to You
This article is based on Change Request (CR) 5947 which indicates there have been updates to the Claim Status Category Codes and Claim Status Codes.

CAUTION – What You Need to Know
All code changes approved during the October 2007 meeting of the national Code Maintenance Committee have been posted at http://www.wpc-edi.com/content/view/180/223/ and will become effective April 1, 2008.

GO – What You Need to Do
See the Background section of this article for further details.

Background
The Health Insurance Portability and Accountability Act (HIPPA) requires all health care benefit payers, including Medicare, to use only Claim Status Category Codes and Claim Status Codes approved by the national Code Maintenance Committee. These codes are used in the X12 276/277 Health Care Claim Status Request and Response format to explain the status of submitted claim(s).

The decisions about additions, modifications, and retirement of existing Claim Status Category and Claim Status codes made at the October 2007 meeting of the national Code Maintenance Committee were posted at http://www.wpc-edi.com/content/view/180/223/ on November 5, 2007. These updates are effective April 1, 2008 and are to be used in editing of all X12 276 transactions processed by Medicare contractors on or after April 7, 2008.

Additional Information
To see the official instruction (CR5947) issued to your Medicare FI, carrier, DME MAC, or A/B MAC, refer to http://www.cms.hhs.gov/Transmittals/downloads/R1468CP.pdf on the CMS Web site.

If you have questions, please contact your Medicare Carrier, A/B MAC, DME MAC, FI or RHHI at their toll-free number which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Personally Identifiable Information on Written Correspondence
To avoid displaying the Medicare beneficiary’s personally identifiable information on written correspondence, CIGNA Government Services will be replacing the first 5 digits of the HICN with XXX-XX. Be aware, this does not eliminate the need to provide the beneficiary’s HICN when prompted by Customer Service or the IVR.

April 2008 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

MLN Matters Number: MM5982  
Related Change Request (CR) #: 5982  
Related CR Release Date: March 26, 2008  
Effective Date: April 1, 2008  
Related CR Transmittal #: R1484CP  
Implementation Date: April 7, 2008

Provider Types Affected
All physicians, providers and suppliers who submit claims to Medicare contractors (Medicare Administrative Contractors (A/B MACs), Fiscal Intermediaries (FIs), carriers, Durable Medical Equipment Medicare Administrative Contractors (DME MACs) or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.

What You Need to Know
CR 5982, from which this article is taken, instructs Medicare contractors to download and implement the April 2008 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs; and if released by CMS, also the revised January 2008, January 2007, April 2007, July 2007, October 2007, and October 2006 files.

Background
Section 303(c) of the Medicare Modernization Act of 2003 revised the payment methodology for Part B covered
Drugs and biologicals that are not paid on a cost or prospective payment basis. Beginning January 1, 2005, the vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology, and pricing for compounded drugs has been performed by the local contractor.

Additionally, beginning in 2006, all end-stage renal disease (ESRD) drugs (that both independent and hospital-based ESRD facilities furnish), as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), are paid based on the ASP methodology.

The ASP methodology is based on quarterly data that drug manufacturers submit to the Centers for Medicare & Medicaid Services (CMS), which CMS then provides (quarterly) to Medicare contractors (carriers, DME MACs, FIs, A/B MACs, and/or RHHIs) through the ASP drug pricing files for Medicare Part B drugs.

As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of the effort to ensure compliance with this requirement, CMS has also reviewed how the terms “single source drug,” “multiple source drug,” and “biological product” have been operationalized in the context of payment under section 1847A.

For the purpose of identifying “single source drugs” and “biological products” subject to payment under section 1847A, CMS (and its contractors) will generally utilize a multi-step process that will consider:

- The FDA approval,
- Therapeutic equivalents as determined by the FDA, and
- The date of first sale in the United States.

The payment limit for the following will be based on the pricing information for products marketed or sold under the applicable FDA approval:

- A biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval), first sold in the United States after October 1, 2003; or
- A single source drug (a drug for which there are not two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book), first sold in the United States after October 1, 2003.

As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of “not otherwise classified, (NOC)” HCPCS codes.

**ASP Methodology**

Beginning January 1, 2005, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Further, beginning January 1, 2006, payment allowance limits are paid based on 106 percent of the ASP for the following:

- ESRD drugs (when separately billed by freestanding and hospital-based ESRD facilities); and
- Specified covered outpatient drugs and drugs and biologicals with pass-through status under the OPPS.

Beginning January 1, 2008, under the OPPS, payment allowance limits for specified covered outpatient drugs are paid based on 105 percent of the ASP. Drugs and biologicals with pass-through status under the OPPS continue to have a payment allowance limit of 106 percent of the ASP. CMS will update the payment allowance limits quarterly.

Exceptions are summarized as follows:

- The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a prospective payment basis are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits are updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPPS at the amount specified for the Ambulatory Payment Class (APC) to which the product is assigned.
- Payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2005, will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits will not be updated in 2008. The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service.
- The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published
compounded where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost.

- The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or NOC Pricing File, other than new drugs and biologicals that are produced or distributed under a new drug application (or other application) approved by the FDA, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Pub. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC. For 2006, the blood clotting furnishing factor of $0.146 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2007, the blood clotting furnishing factor of $0.152 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2008, the blood clotting furnishing factor of $0.158 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file.

- The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the FDA and that are not included in the ASP Medicare Part B Drug Pricing File or NOC Pricing File are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs and biologicals that were first sold on or after January 1, 2005.

- The payment allowance limits for radiopharmaceuticals are not subject to the ASP payment methodology. Medicare contractors determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Radiopharmaceuticals furnished in the hospital outpatient department are paid charges reduced to cost by the hospital's overall cost to charge ratio.

On or after March 18, 2008, the April 2008 ASP file will be available for download along with revisions to prior ASP payment files, if CMS determines that revisions to these prior files are necessary. On or after March 18, 2008, the April 2008 ASP NOC files will be available for retrieval from the CMS ASP webpage along with revisions to prior ASP NOC files, if CMS determines that revisions to these prior files are necessary. The payment limits included in revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document.

The payment files will be applied to claims processed or reprocessed on or after the implementation date of CRS982 for the dates of service noted in the following table:

<table>
<thead>
<tr>
<th>Payment Allowance Limit Revision Date</th>
<th>Applicable Dates of Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2008 ASP and ASP NOC files</td>
<td>April 1, 2008, through June 30, 2008</td>
</tr>
<tr>
<td>October 2007 ASP and ASP NOC files</td>
<td>October 1, 2007, through December 31, 2007</td>
</tr>
<tr>
<td>April 2007 ASP and ASP NOC files</td>
<td>April 1, 2007, through June 30, 2007</td>
</tr>
<tr>
<td>October 2006 ASP and ASP NOC files</td>
<td>October 1, 2006, through December 31, 2006</td>
</tr>
</tbody>
</table>

**NOTE** - The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The local Medicare contractor processing the claim makes these determinations.

**Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir**

Physicians may be paid for filling or refilling an implantable pump or reservoir when it is medically necessary for the physician (or other practitioner) to perform the service. Medicare contractors must find the use of the implantable pump or reservoir medically reasonable and necessary in order to allow payment for the professional service to fill or refill the implantable pump or reservoir and to allow payment for drugs furnished incident to the professional service.

If a physician (or other practitioner) is prescribing medication for a patient with an implantable pump, a nurse may refill the pump if the medication administered is accepted as a safe and effective treatment of the patient’s illness or injury; there is a medical reason that the medication cannot be taken orally; and the skills of the nurse are needed to infuse the medication safely and effectively. Payment for drugs furnished incident to the filling or refilling of an implantable pump or reservoir is determined under the ASP methodology as described above. Note that pricing for compounded drugs is done by your local Medicare contractor.
Additional Information

To see the official instruction (CR5982) issued to your Medicare contractor visit http://www.cms.hhs.gov/Transmittals/downloads/R1484CP.pdf on the CMS Web site.

If you have questions, please contact your Medicare contractor at their toll-free number which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS Web site.

Individuals Authorized Access to CMS Computer Services - Provider Community (IACS-PC): THE SECOND IN A SERIES OF ARTICLES ON THE IACS

MLN Matters Number: SE0753 Revised
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

**NOTE** - This article was revised on January 15, 2008, to add another question and answer to emphasize that potential users should only register once in IACS.

This article contains:
- ★ 4 questions and answers about the registration process for provider organizations. (See NOTE below.)
- ★ Links to the Quick Reference Guides for completing the registration process for provider organizations. (See NOTE below.)

**NOTE** - This article was revised on January 15, 2008, to add another question and answer to emphasize that potential users should only register once in IACS.

Provider Types Affected

Physicians, providers, and suppliers (collectively referred to as providers) who submit fee-for-service claims to Medicare contractors (carriers, fiscal intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and Medicare Administrative Contractors (A/B MACs)).

Special Note for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. Do not register for IACS-PC at this time. DMEPOS suppliers may want to review the first MLN Matters article in this new series on IACS-PC, which can be found at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0747.pdf on the Centers for Medicare & Medicaid Services (CMS) Web site.

Provider Action Needed

Even though these new Internet applications are not yet available, CMS recommends that providers take the time now to set up their online account so they can access these applications as soon as they are available. The first step is for the provider and/or appropriate staff to register for access through a new CMS security system known as the Individuals Authorized Access to CMS Computer Services - Provider Community (IACS-PC).

What Providers Need to Know

In the near future, the CMS will be announcing new online enterprise applications that will allow Medicare fee-for-service providers to access, update, and submit information over the Internet. CMS enterprise applications are those hosted and managed by CMS and do not include FI/Carrier/MAC Internet applications. Details of these provider applications will be announced as they become available.

Registering in IACS-PC

The provider community is the first in a series of IACS communities which are the front-door to protecting and allowing access to CMS enterprise applications. Communities are comprised of groups of users who provide a similar service to CMS and who need access to similar applications (ex. Providers need access to provider-related CMS applications). The next community which will become available in early 2008 is the FI/Carrier/MAC community. It will be comprised of users who work within Medicare contracting organizations (FIs, Carriers and MACs). Since many IACS communities will be added in the future, the IACS community’s user instructions are generic to allow use by multiple communities. The rules and concepts across communities are very similar.

When given a choice in IACS to select your community, please select the “Provider Community”.

The first MLN Matters article in this series provided an overview of the IACS-PC registration process as well as registration instructions for Security Officials (SOs) and individual practitioners using IACS-PC personally. This article can be found at http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0747.pdf on the CMS Web site.

Four Questions and Answers about the Provider Organization Registration Process

1. **How can I get registered in IACS-PC? Can I just figure it out by myself?**

   We recommend that you use the reference guides as they contain detailed explanations of the role responsibilities, acceptable data formats and
interpretations of error messages. To directly access IACS-PC, go to [https://applications.cms.hhs.gov](https://applications.cms.hhs.gov) and then click on Enter CMS Applications Portal.

2. I want to register as an SO. I do not have my organization's IRS CP-575. What else can I send?
In addition to the CP-575, SOs may also submit copies of other official IRS documentation. An official IRS document should have the following information:

**Required:**
- IRS letterhead;
- Legal Business Name (not handwritten); and
- TIN/EIN (not handwritten).

**Optional:**
- Form Number in upper right; and
- Reference to a letter or form number in body of text.

**Examples of acceptable IRS documents include, but are not limited to:**
- Copy of IRS CP-575;
- Copy of IRS 147C Letter; or
- Copy of Federal Tax Deposit Coupon.

**All documents received must be legible.**

3. I will work for more than one provider, or serve in multiple roles in the same organization. Do I need to register in IACS separately for each organization or role?
No. Each user will receive only one IACS-PC User ID and password. If you will work for more than one provider, or have multiple roles in the same provider, register in IACS for one role. Once you receive approval and your user ID and password, you can add additional roles to your account.

Instructions for modifying your IACS profile will be released shortly. In the meantime, questions may be directed to the help desk as shown in the “Additional Help” section at the end of this article.

4. My organization is too small to fill all these roles. What should I do?
As few as 2 staff can be registered in IACS-PC for a provider organization to access CMS enterprise applications. The first person must register as a Security Official (SO), the second registers as a User Group Administrator (UGA). The UGA may access CMS applications as approved by the SO.

The Backup Security Official is an optional role. End users are only required for provider organizations with 10 or more IACS-PC users.

If you are an individual practitioner who will be using IACS-PC personally, please refer to the first MLN article which may be found at [http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0747.pdf](http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0747.pdf) on the CMS Web site.

**Quick Reference Guides for Completing the Provider Organization Registration Process**

1. **Backup Security Official (BSO) Guide**

2. **User Group Administrator (UGA) Guide**
UGAs are the first user type able to request access to CMS web-based applications. Their task, during the registration process, is to create a provider or surrogate user group, or associate with an existing provider or surrogate user group. A provider user group is a group that can be created by a UGA within an existing provider organization.

Once the user group is created and approved by the SO/BSO, end users can then submit a request to register in IACS-PC and join that user group. The UGA will either approve or deny their request to join their user group. This is a way for users within an organization to form groups that align with business needs or any other logical grouping that is appropriate for that organization and ensure that the UGA appropriately approves each end user into their user group. The important thing to keep in mind is that the UGA will need to approve the end users in the user group for which s/he is responsible, so they should know everyone in their user group.

Special note for UGAs of Surrogate User Groups
A surrogate user group is established by individuals or a company outside of the provider organization which performs Medicare work on behalf of the provider organization (a contractor for a provider organization, billing company, etc.). If you will be creating a surrogate user group, the UGA of the surrogate user group must be approved by the SO or BSO in the provider organization on whose behalf it performs work. For example: Surrogate Billing Company ABC will work on behalf of Provider Organization XYZ. Once the Provider Organization XYZ is approved in IACS-PC, the Surrogate Billing Company ABC can register in IACS-PC and request to create a surrogate user group under the Provider Organization XYZ. Once approved, the UGA of a surrogate user group is issued an IACS user ID that enables the UGA to associate with other provider organizations for which it performs work without registering again.

At this time, a new surrogate user group must be created for each provider organization with which a UGA wishes to associate. If a surrogate user group performs work on behalf of 3 different provider organizations, the UGA for the surrogate user group will need to make 3 different requests to create 3 different surrogate user groups, one for each provider with which the UGA needs to associate. If a provider organization does not appear in IACS-PC, they have not yet registered/been approved and you should contact them. You will not be able to associate with them until the provider appears in IACS-PC.

If the provider organization does appear in IACS-PC, each provider’s SO or BSO must approve the request to associate that surrogate user group with their organization. Remember, as a surrogate user group, you will only be able to associate with provider organizations after those respective provider organizations and SOs have been approved in IACS-PC.

In the future, CMS will explore options for simplifying this process for contractors which perform work on behalf of more than one provider organization and also to allow surrogate user groups to associate to Individual Practitioners within IACS-PC.


4. Approver Quick Reference Guide

Next Steps in Accessing a CMS Enterprise Application
A third MLN article discussing the final steps in accessing CMS enterprise applications has been released on this issue, and may be found at [http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0754.pdf](http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0754.pdf) on the CMS Web site.

Additional Help
The CMS has established an External User Services (EUS) Help Desk to assist with your access to IACS-PC. The EUS Help Desk may be reached by E-mail at EUSSupport@cgi.com or by phone on 1.866.484.8049 or TTY/TDD on 1.866.523.4759.


Upcoming Critical Dates for Medicare’s Fee-for-Service (FFS) Implementation of the National Provider Identifier (NPI)

MLN Matters Number: SE0802
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
This article is primarily for physicians and providers who submit Medicare claims using the Medicare Fee-for-Service (FFS) 837P and the CMS-1500 form.
Provider Action Needed
This special edition article, SE0802, is being provided by the Centers for Medicare & Medicaid Services (CMS) in order to clear up some confusion that providers are experiencing regarding the March 1, 2008 implementation of the NPI on professional claims, and the May 23, 2008 requirement for ONLY the NPI on all Health Insurance Portability & Accountability Act (HIPAA) electronic transactions and their paper versions.

The following charts illustrate expected claim results for different identifiers, or combinations of identifiers, submitted in the primary provider fields on the Medicare FFS 837P and CMS-1500. Note that when the chart indicates that claims will be paid, this would only be if no other errors (non-NPI) exist.

Prior to March 1, 2008 – 837P and 1500 Claims, Primary Provider Fields

<table>
<thead>
<tr>
<th>Legacy Medicare Identifier</th>
<th>NPI</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td>Claim will be paid.</td>
</tr>
<tr>
<td>X X</td>
<td></td>
<td>Claim will be paid as long as there is an NPI/legacy match on the NPI Crosswalk*.</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>Claim will be paid as long as there is an NPI/legacy match on the NPI Crosswalk.</td>
</tr>
</tbody>
</table>

As of March 1, 2008 – 837P and 1500 Claims, Primary Provider Fields

<table>
<thead>
<tr>
<th>Legacy Medicare Identifier</th>
<th>NPI</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td>Claim will be rejected</td>
</tr>
<tr>
<td>X X</td>
<td></td>
<td>Claim will be paid as long as there is an NPI/legacy match on the NPI Crosswalk*.</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>Claim will be paid as long as there is an NPI/legacy match on the NPI Crosswalk*.</td>
</tr>
</tbody>
</table>

May 23, 2008 and Beyond – All Providers, All Transactions**, Both Primary and Secondary Provider Fields

<table>
<thead>
<tr>
<th>Legacy Medicare Identifier</th>
<th>NPI</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td>Claim/transaction will reject</td>
</tr>
<tr>
<td>X X</td>
<td></td>
<td>Claim/transaction will reject</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>Claim/transaction will be paid/processed as long as there is an NPI/legacy match on the NPI Crosswalk*.</td>
</tr>
</tbody>
</table>

* Claims will reject when there is not a match on the Medicare NPI Crosswalk. You must correct any data which may be preventing an NPI/legacy match on the NPI crosswalk. The correction might require that you file a CMS-855 Medicare Provider Enrollment form with your Medicare carrier, A/B MAC, or DME MAC a process which can take a number of months to accomplish.

** HIPAA electronic transactions (837I, 837P, 837COB, NCPDP, 276/277, 270/271, and 835), paper claims and SPR remittance advice.

TEST NPI-Only NOW
If you have been submitting claims with both an NPI and a Medicare legacy number and those claims have been paid, you need to test your ability to get paid using only your NPI (i.e., no Medicare legacy number) by submitting one or two claims today for each NPI you’ve been assigned. If the Medicare NPI Crosswalk cannot match your NPI to your Medicare legacy number, the claim with an NPI-only will reject. You can and should do this test now! If the claim is processed and you are paid, continue to increase the volume of claims sent with only your NPI. If the claims reject, validate that the National Plan and Provider Enumeration System (NPPES) has the correct Medicare Legacy number. If your NPPES information is correct, contact your Medicare carrier or A/B MAC enrollment staff for advice right away.

Additional Information
As of January 1, 2008, FFS Medicare required an NPI in the primary provider fields on the 837I and UB-04 claim types. Providers billing with these claim forms must continue to include an NPI in the primary provider field until May 23rd at which time an NPI-only is required in all fields.

For more information on correcting NPPES errors and how to use the NPI on Medicare claims, visit http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0725.pdf on the CMS Web site.

If you do not have an NPI, you need to obtain one as soon as possible. Providers can apply for an NPI online at https://nppes.cms.hhs.gov or can call the NPI enumerator to request a paper application at 1.800.465.3203.

A table of Medicare’s key dates relative to the NPI is available at the CMS NPI page http://www.cms.hhs.gov/NationalProvIdentStand/02_WhatsNew.asp on the CMS Web site. More information and education on the NPI can be found through the CMS NPI page http://www.cms.hhs.gov/NationalProvIdentStand on the CMS Web site.
Opportunity to Participate in Third Annual Medicare Contractor Provider Satisfaction Survey (MCPSS) Ends in April

MLN Matters Number: SE0804
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
All Medicare physicians, providers, and suppliers billing the Medicare fee-for-service (FFS) program who were selected to participate in the MCPSS for 2008.

Provider Action Needed
Those Medicare providers who were selected by the Centers for Medicare & Medicaid Services (CMS) to participate in the MCPSS are asked to please take the time to complete the survey or respond to the survey contractor, Westat, follow-up calls. The survey is designed so that it can be completed in 15 minutes and responses may be submitted via a secure Web site, mail, fax or over the telephone. Currently the average response rate is 32%; CMS' goal is to reach a 65% response rate. Data collection ends in April.

Background
The MCPSS offers providers the opportunity to contribute directly to CMS’ understanding of contractor performance as well as aid future process improvement efforts of Medicare contractors (carriers, fiscal intermediaries, Medicare Administrative Contractors, (A/B MACs), and Durable Medical Equipment Medicare Administrative Contractors (DME MACs). Specifically, the survey is used by CMS as an additional measure to evaluate contractor performance. In fact, all Medicare Administrative Contractors (MACs) will be required to achieve performance targets on the MCPSS as part of their contract requirements by 2009.

The MCPSS is designed to gather quantifiable data on provider satisfaction levels with the key services that comprise the provider-contractor relationship. The survey focuses on seven major parts of the relationship: provider inquiries, provider outreach and education, claims processing, appeals, provider enrollment, medical review, and provider audit and reimbursement.

Respondents are asked to rate their experience working with contractors using a scale of 1 to 6 with “1” representing “not at all satisfied” and “6” representing “completely satisfied.” The results of the second MCPSS showed that 85 percent of respondents rated their contractors between 4 and 6.

The 2007 MCPSS results indicate that the provider inquiry function has the greatest influence on whether providers are satisfied with their contractors. This indicated a shift from 2006, when the claims processing function was the strongest predictor of a provider’s overall satisfaction.

“CMS and the Medicare contractor community are committed to high quality relationships with the provider community,” CMS Acting Administrator Kerry Weems said in a recent CMS press release. “The MCPSS provides contractors with greater insight into their provider communities, and allows them to make process improvements based on provider feedback.”

“The shift from claims processing to provider inquiries as the top predictor of satisfaction is a perfect example of the type of trend data the MCPSS will reveal,” Weems said. “Contractors are able to factor this insight into how they prioritize their provider-focused efforts.”

Additional Information

Announcing the Release of the Revised CMS-855 Medicare Enrollment Applications

MLN Matters Number: SE0810
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
All Medicare physicians, providers, and suppliers.

Background
The Centers for Medicare & Medicaid Services (CMS) issued revised CMS-855 Medicare enrollment applications in March 2008. With the exception of providers enrolling as a
specialty hospital on the CMS-855A, Medicare contractors will continue to accept the 2006 version of the Medicare enrollment application through June 2008. Providers and suppliers should begin to use the new Medicare enrollment applications immediately. Initially, these applications will be available only from the CMS provider enrollment Web site. The link for that CMS Web site is listed in the Additional Information section of this article.

Over the last year, CMS has received numerous comments and suggestions regarding the proposed revisions to the Medicare enrollment applications. CMS reviewed the comments and adopted many of the suggested revisions. Also, CMS incorporated a number of enhancements and changes (see Key Points below) to clarify the enrollment process and to reduce the burden imposed on the provider and supplier communities.

Key Points
This Special Edition outlines the significant revisions to the Medicare enrollment applications and they are as follows:

Application-Specific Changes for Physicians and Non-Physician Practitioners (CMS-855I)
- Removed the requirement in Section 17 that providers attach their National Provider Identifier notification that is received from the National Plan and Provider Enumeration System.

Application-Specific Changes for Clinics/Group Practices and Certain Other Suppliers (CMS-855B)
- Removed the supplier type "Voluntary Health/ Charitable Agency" from Section 2A.
- Clarified reporting timeframes throughout the CMS-855B.
- Added additional information about the National Provider Identifier (NPI)-legacy association and expanded the number of NPI – legacy combinations that a provider may enter in Section 4A from one to five.
- Removed the data element "Medicare Year-End Cost Report Date" from Section 2.
- Removed the requirement in Section 17 that providers attach their National Provider Identifier notification that is received from the National Plan and Provider Enumeration System.

Application-Specific Changes for Institutional Providers (CMS-855A)
- Revised Section 2A2 to include a specific box that specialty hospitals must check when completing the application. Instructions explaining the definition of a "specialty hospital" were also added to the form.
- Clarified the term "primary practice location"in the instructions in Section 4. (The clarification did not change any data elements on the form.)
- Added additional information about the National Provider Identifier (NPI)-legacy association and expanded the number of NPI – legacy combinations that a provider may enter in Section 4A from one to five.

Additional Information
For additional information regarding the Medicare enrollment process, including the mailing address and telephone number for the carrier or FI serving your area, visit http://www.cms.hhs.gov/MedicareProviderSupEnroll on the CMS Web site.


Pre-Bidding Activities for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program

MLN Matters Number: SE0811
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
Suppliers of Durable Medical Equipment (DME) that wish to participate in the upcoming Medicare DMEPOS competitive bidding program.
Provider Action Needed

In order to participate in the second round of the DMEPOS Competitive Bidding Program, suppliers will be required to register in the Centers for Medicare & Medicaid Services (CMS) security system known as the Individuals Authorized Access to CMS Computer Services (IACS). This includes suppliers that bid in the first round of competition last year and are interested in competing in the second round. Although the bidding window for the second round of competition may not be announced before the issue date of this article, CMS urges suppliers planning to bid in the 2008 bidding cycle to make sure their provider enrollment record is current. Specifically, suppliers should verify their supplier number(s) and Authorized Official(s) information associated with that supplier number(s) on file with the National Supplier Clearinghouse (NSC). The accuracy of this data is critical for successful bid registration.

Background

In this year’s bid cycle, suppliers who wish to bid will need to first register in IACS, before the bidding window opens. There will be three user roles available, which are described as follows:

- **Authorized Official (AO)** – Each supplier’s organization will be allowed one AO. The AO role can approve all other users associated with their organization who are requesting access to the bidding system. The AO will be able to input bid data, approve Form A and certify Form B in the bidding system.
- **Backup Authorized Official (BAO)** - Each supplier organization will be allowed to designate one or more Backup Authorized Officials (BAOs). In this role, the BAO can approve the supplier’s End User registration for access to the bidding system. Like the AO, the BAO can also input bid data, approve Form A and certify Form B in the bidding system.
- **End User** - Each supplier organization will be allowed one or more End User(s). The End User can input bid data, but cannot approve Form A or certify Form B.

Save Time and Delay by Verifying NSC Information Prior to Registering to Bid

Only those AOs listed on the CMS-855S (Medicare Enrollment Application) as an AO can register in IACS to approve and certify as described above. As part of the CMS-855S, a supplier designates one or more AO(s). The AO is an appointed official to whom the organization has granted the legal authority to enroll it in the Medicare program and to commit the organization to fully abide by the statutes, regulations and program instructions of the Medicare program.

End Users do not need to be listed on the CMS-855S. However, the AO or BAO will need to approve an End User’s request for access to the bidding system.

Take Action Now

Be sure that the data you are submitting is current and in accordance with that submitted to the NSC. In particular, this concerns the AO’s name, date of birth, Social Security Number (SSN), and mailing address. If any of these data elements have changed since your last submission to the NSC, then you should PROMPTLY complete a change of information on the CMS-855-S.

CMS urges that suppliers do it now. The NSC processing time to complete a change of information on the CMS-855S is approximately 45 days and all submissions are processed in the order in which they are received.

Overview of AO IACS Registration Process

For an AO, the verification of his/her last name, date of birth, and SSN must be validated against the data maintained by NSC. The NSC received this AO data when the supplier completed their most recent CMS-855S Medicare Enrollment Application. The AO’s last name is listed in Section 15 and the AO’s date of birth and SSN in Section 6A of the CMS-855S. If the data does not match, the registration will be rejected.

Following successful registration, as an added measure of security, the AO’s User ID and password is then mailed in a separate correspondence to the mailing address listed in Section 2A2 of the CMS-855S Medicare Enrollment Application.

The BAO goes through a similar process and an AO for the organization must approve a BAO’s request for access before a User ID and password will be emailed to the BAO.

Do I need a BAO role?

The establishment of a BAO is highly recommended to avoid any disruption in the bidding process. The AO’s role is instrumental to bidding, as the AO’s role must be active to avoid all other users of the organization from losing access to the bidding system. If the AO leaves the organization, the BAO role can be changed to an AO role by the Competitive Bidding Implementation Contractor (CBIC).

You will want to verify that the CMS-855S Medicare Enrollment Application for your organization has two or more AOs listed.

Additional Information

Have You Called Our IVR Lately?

CIGNA Government Services Jurisdiction C DME MAC continually strives to improve the services we provide our customers. One example of this is the recent additions to our Interactive Voice Response (IVR) System. Not only is Claim status, outstanding checks, beneficiary Medicare eligibility, deductible, offset and pricing information available on our IVR, you may also receive Pending claim information, Redetermination status, CMN status, the last 5 checks issued, and EFT application status. Our pending claim option includes pending claims on the payment floor, pending claims at CWF and other pending claims information.

You may reach the CIGNA Government Services Jurisdiction C DME MAC C IVR at 1.866.238.9650. The IVR menu options that require system access are available 6:00 AM – 6:00 PM (CT) Monday – Friday and Saturday 6:00 AM – 4:00 PM (CT) with the exception of system upgrades, and routine maintenance. General information through the IVR is available 24 hours a day, 7 days a week. Our customer service representatives are available at 1.866.270.4909 Monday - Friday from 8:00 AM – 4:00 PM, in the time zones of the states we service. Customer service representatives can assist you with inquiries that cannot be handled through the IVR. Based on the CMS requirements, if a provider contacts a customer service representative with a question that can be handled by the IVR, the provider will be referred back to the IVR.

To assist you in navigating our IVR, a complete Supplier Interactive Voice Response (IVR) System script and IVR Summary Flow Chart is available on our Web site at http://www.cignagovernmentservices.com.

Appendix

Revised ABN Frequently Asked Questions (FAQs)

Q1. What changes have been made to the current ABN?
A1. Some key features of the revised ABN are that it:
   » Has a new official title, the “Advance Beneficiary Notice of Noncoverage (ABN)” in order to more clearly convey the purpose of the notice;
   » Replaces both the existing ABN-G and ABN-L;
   » May also be used for voluntary notifications, in place of the Notice of Exclusion from Medicare Benefits (NEMB);
   » Has a mandatory field for cost estimates of the items/services at issue; and
   » Includes a new beneficiary option, under which an individual may choose to receive an item/service, and pay for it out-of-pocket, rather than have a claim submitted to Medicare.

Q2. How long will the transition period be for use of the revised form?
A2. Providers and suppliers may begin using the new ABN on March 3, 2008. CMS will allow a 6-month transition period from the date of implementation for use of the revised form and instructions. Thus, all providers and suppliers must begin using the new ABN (CMS-R-131) no later than September 1, 2008.

Q3. Where can we access the revised ABN and instructions?
A3. The revised ABN and form instructions can be accessed online at http://www.cms.hhs.gov/bni.

Q4. May we translate the revised ABN into other languages?
A4. The ABN is an OMB-approved form and cannot be altered except as permitted by the accompanying instructions. The ABN is available in English and will soon be available in Spanish. Notifiers should choose the appropriate version of the ABN based on the language the beneficiary best understands.

When Spanish-language ABNs are used, the notifier should make insertions on the notice in Spanish. For beneficiaries who speak languages other than English or Spanish, verbal assistance in other languages may be provided to help beneficiaries understand the notice. Notifiers should document any translation assistance that they provide in the “Additional Information” section of the notice.

Q5. Are there manual instructions for the revised form?
A5. We will post detailed manual instructions for the revised form to the Medicare Online Claims Processing Manual in the near future. Please check the BNI webpage for updates at http://www.cms.hhs.gov/bni.

Q6. Where can we send questions regarding the revised ABN?
A6. Questions regarding the revised ABN can be sent to RevisedABN_OIDF@cms.hhs.gov.

Q7. Will SNFs be required to use the revised ABN?
A7. No, the revised SNFABN will cover all Part B items/services delivered in a SNF and will be available before September 1, 2008. Therefore, SNFs may continue using the current ABN-G for Part B items/services until the revised SNFABN is implemented.
Announcement of the Implementation of the Revised ABN

MARCH 3, 2008

On Monday, March 3, 2008, CMS will implement use of the revised Advance Beneficiary Notice of Noncoverage (ABN) (CMS-R-131). This form replaces the General Use ABN (CMS-R-131-G), and the Lab ABN (CMS-R-131-L) for physician-ordered laboratory tests. The form and notice instructions will be posted on the Beneficiary Notice Initiative web page (http://www.cms.hhs.gov/bni). We will post updated manual instructions and the Spanish version of the form on the BNI web page in the near future.

Some key features of the new form are that it:

- Has a new official title, the “Advance Beneficiary Notice of Noncoverage (ABN),” in order to more clearly convey the purpose of the notice;
- Replaces both the existing ABN-G and ABN-L;
- May also be used for voluntary notifications, in place of the Notice of Exclusion from Medicare Benefits (NEMB);
- Has a mandatory field for cost estimates of the items/services at issue; and
- Includes a new beneficiary option, under which an individual may choose to receive an item/service, and pay for it out-of-pocket, rather than have a claim submitted to Medicare.

CMS will allow a 6-month transition period from the date of implementation for use of the revised form and instructions. Thus, all providers and suppliers must begin using the new ABN (CMS-R-131) no later than September 1, 2008. Questions about the new ABN may be sent to RevisedABN_ODF@cms.hhs.gov.

News Flash Items

- The Hospice Payment System Fact Sheet, which offers providers information about the Medicare hospice benefit, is now available from the Centers for Medicare & Medicaid Services Medicare Learning Network in downloadable format at http://www.cms.hhs.gov/MLNProducts/downloads/hospice_pay_sys_fs.pdf on the CMS Web site.
- A New MLN Feature – the Quarterly Journal Ad – Each calendar quarter, the Medicare Learning Network will create a journal advertisement based on an initiative or new product of particular importance during that time frame. National, state and local associations are encouraged to use this journal ad in their publications and/or newsletters and Web sites, as appropriate. This quarter’s journal ad features a basic message about the Medicare Learning Network and where to go on the CMS Web site to get more information. The ad is designed to fit the requirements for most journals’ print specifications. The files for this quarter’s ad, as well as future ads, can be found at http://www.cms.hhs.gov/MLNGenInfo/downloads/MLNQuarterly_Journal.zip on the CMS Web site.
- Effective March 1, 2008, Medicare fee-for-service 837P and CMS-1500 claims must include an NPI in the primary fields on the claim (i.e., the billing, pay-to, and rendering fields). You may continue to submit NPI/legacy pairs in these fields or submit only your NPI on the claim. You may not submit claims containing only a legacy identifier in the primary fields. Failure to submit an NPI in the primary fields will result in your claim being rejected or returned as unprocessable beginning March 1, 2008. Until further notice, you may continue to include legacy identifiers only for the secondary fields.
- Test Your Medicare Claims Now! After you have submitted claims containing both National Provider Identifiers (NPIs) and legacy identifiers and those claims have been paid, Medicare urges you to send a small batch of claims now with only the NPI in the primary provider fields. If the results are positive, begin increasing the number of claims in the batch. (Reminder: For institutional claims, the primary provider fields are the Billing and Pay-to Provider fields. For professional claims, the primary provider fields are the Billing, Pay-to, and Rendering Provider fields. If the Pay-to Provider is the same as the Billing Provider, the Pay-to Provider does not need to be identified.)
- It’s Not Too Late to Get the Flu Shot. We are in the midst of flu season and a flu vaccine is still the best way to prevent infection and the complications associated with the flu. But re-vaccination is necessary each year because flu viruses change every year. Please encourage your Medicare patients who haven’t already done so to get their annual flu shot. – And don’t forget to immunize yourself and your staff. Protect yourself, your patients, and your family and friends. Get Your Flu Shot – Not the Flu! Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. Health care professionals and their

- **Medicare Remit Easy Print (MREP)** software allows professional providers and suppliers to view and print the Health Insurance Portability and Accountability Act (HIPAA) compliant 835. This software, which is available for free can be used to access and print RA information, including special reports, from the HIPAA 835. Please go to your Carrier or DME MAC’s Web site to download the MREP software. To find your carrier or DME MAC’s web address, see [http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS Web site.

### DME MAC Jurisdiction C Contact Information

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<th>Contact for:</th>
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| EDI – Electronic Claim Submission; Electronic Remittance Notices | Jurisdiction C CEDI (toll-free): 1.866.311.9184  
Support hours: 9:00 a.m. – 9:00 p.m. Eastern, Monday – Friday  
Jurisdiction C CEDI Web site: [http://www.ngsedi.com](http://www.ngsedi.com)  
E-mail Address: ngs.CEDIHelpdesk@wellpoint.com |
| Paper Claim Submission | Address: CIGNA Government Services  
PO Box 20010, Nashville, TN 37202 |
| Provider Customer Service Calls | IVR (Interactive Voice Response): 1.866.238.9650  
Hours: 24/7 (with allowances for normal IVR and system maintenance)  
Customer Service: 1.866.270.4909 (Hours: 8:00 a.m. to 6:00 p.m. EST)  
Hearing Impaired: 1.888.204.3771 (Hours: 8:00 a.m. to 6:00 p.m. EST) |
| Beneficiary Customer Service Calls | Phone: 1.800.Medicare |
| Written Inquiries | Address: CIGNA Government Services  
PO Box 20010, Nashville, TN 37202 |
| Claim Reopenings (Adjustments) | Address: CIGNA Government Services  
PO Box 20010, Nashville, TN 37202  
Fax: 1.615.782.4649  
Telephone requests for Reopenings: 1.866.813.7878  
Hours: 8:00 a.m. - 10:30 a.m. and 12:00 p.m. – 3:30 p.m. Central |
| Appeals – Redetermination Requests | Address: CIGNA Government Services  
PO Box 20010, Nashville, TN 37202 |
| Electronic Funds Transfer | Address: CIGNA Government Services  
Attn: EFT-DME  
PO Box 20010, Nashville, TN 37202 |
| Refunds | Address: CIGNA Government Services  
Jurisdiction C DME MAC  
PO Box 30629, New York, NY 10087-0629 |
| Overnight or Special Shipping | Address: CIGNA Government Services  
DME MAC Jurisdiction C  
Two Vantage Way, Nashville, TN 37228 |
| DME MAC Jurisdiction C Web site | Web site: [http://www.cignagovernmentservices.com](http://www.cignagovernmentservices.com) |
| Advance Determination of Medicare Coverage (ADMC) - Requests | Address: CIGNA Government Services  
Attn: ADMC  
PO Box 20010, Nashville, TN 37202  
Fax: 1.615.782.4647 |
| Requests for Additional Information from TrustSolutions, LLC | Address: TrustSolutions, LLC  
PO Box 50218, Indianapolis, IN 46250  
Fax: 1.317.863.0054 |
| Supplier Enrollment | Address: National Supplier Clearinghouse  
Palmetto GBA * AG-495  
PO Box 100142, Columbia, SC 29202-3142  
Phone: 1.866.238.9652 |