Medicare Claims Processing Manual
Chapter 17 - Drugs and Biologicals

Table of Contents
(Rev. 2424, 03-169-12)

10 - Payment Rules for Drugs and Biologicals

(Rev. 1445, Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates, except for hemophilia clotting factors for hospital inpatients under Part A.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different methodology. Non pass-through drugs with estimated per day costs less than or equal to the applicable drug packaging threshold that are furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) group payment for the service with which they are billed. Non pass-through drugs with estimated per day costs greater than the applicable drug packaging threshold are paid separately.

Drugs that are granted "pass through" payment status are required by law to be paid at either the amount paid under the physician fee schedule, or, if the drug is included in the Part B drug competitive acquisition program (CAP), at the Part B drug CAP rate. Drugs that have pass-through status may have coinsurance amounts that are less than 20 percent of the OPPS payment amount. This is because pass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise applicable OPPS payment rate to be the pass-through payment amount. Thus, in situations where the pass-through payment rate exceeds the otherwise applicable OPPS payment rate, the coinsurance is based on a portion of the total drug payment rate, not the full payment rate.

Hospitals must report all appropriate HCPCS codes and charges for separately payable drugs, in addition to reporting the applicable drug administration codes. Hospitals should also report the HCPCS codes and charges for drugs that are packaged into payments for the corresponding drug administration or other separately payable services. Historical hospital cost data may assist with future payment packaging decisions for such drugs. Drugs are billed in multiples of the dosage specified in the HCPCS code long descriptor. If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided.

If the full dosage provided is less than the dosage for the HCPCS code descriptor specifying the minimum dosage for the drug, the provider reports one unit of the HCPCS code for the minimum dosage amount.

OPPS Pricer includes a table of drugs and prices and provides the contractor with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries

who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians' services.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines a Specified Covered Outpatient Drug (SCOD) as a covered outpatient drug for which a separate APC has been established and that is either a radiopharmaceutical agent, or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002. Payment for SCODs is set, by law, at the average acquisition cost. Under the OPPS, a single payment is made for SCODs that represents payment for both the acquisition cost of the drug and any associated pharmacy overhead or nuclear medicine handling costs.

Drugs or biologicals must meet the coverage requirements in Chapter 15 of the Medicare Benefit Policy Manual. Additionally, for end stage renal disease (ESRD) patients, see the Medicare Benefit Policy Manual, Chapter 11. For ESRD patient billing for drugs and claims processing, see Chapter 8 of this manual.

The following chart describes the payment provisions for drugs.

Table - Drug Payment Methodology

(Rev. 1445, Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

In the table below, if the item does not have an asterisk ("*") the bill is submitted to the contractor. An asterisk ("*") indicates the bill is submitted to the local carrier or DMERC, as applicable.

Key to the following Table:

* Bills carrier; no asterisk means bill the hospital's contractor or RHHI **NOTE:** DMERCs do not process claims for blood clotting factors.

† - Drugs & biologicals outside the composite rate are paid as described in 2 below. Those inside the composite rate are paid as described in 1.

1 - Included in PPS rate, or other provider-type all inclusive encounter rate

2 – Price taken from CMS drug/biological pricing file effective on the specific date of service.

3 - Reasonable cost

4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS

5 - OPPS-APC, whether pass-thru drug or not

6 - Can not furnish as that "provider" type;

7 - $10.00 per 1000 units (Payment rate for EPO set in statute)

8 - May get carrier billing number if qualified and bill carrier

++ Except in the State of Washington, where CMS permits the RDF to bill immunosuppressives due to the unique State assistance to the beneficiary provided only via the RDF.

Provider/Drug	Hepatitis B Vaccine	Pneumococcal & Flu Vaccines	Hemophilia Clotting Factors	Immuno - Suppressive	Erythro- (EPO)	Self Admin Anti-Cancer Anti-Emetic	Other

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & Flu Vaccines**	**Hemophilia Clotting Factors**	**Immuno - Suppressive**	**Erythro- (EPO)**	**Self Admin Anti-Cancer Anti-Emetic**	**Other**
Hospital Inpatient (IP) A - Prospective Payment System (IPPS)	1	1	4	1	1	1	1
Hospital IP A - not IPPS	3	3	3	3	3	3	3
Hospital IP B Outpatient Prospective Payment System (OPPS)	5	3	5	5	5	5	5
Hospital IP B - not OPPS	3	3	3	3	3	3	3
Hospital Outpatient (OP) - OPPS	5	3	5	5 (30 day supply)	5	5	5
Hospital OP - not OPPS hospital	3	3	3	3	3	3	5
Skilled Nursing Facility (SNF)	1	1	1	1	1	1	1
SNF IP B	3	3	3	3	6	6	6
SNF OP	3	3	3	3	6	6	6
Independent Renal Dialysis Facility (RDF)	3	3	6	6++	7	6	1/2†
Hospital based RDF	5	5	5	6	7	6	3
Comprehensive Outpatient	5	2	6	2 *	2	6	2

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & Flu Vaccines**	**Hemophilia Clotting Factors**	**Immuno - Suppressive**	**Erythro- (EPO)**	**Self Admin Anti-Cancer Anti-Emetic**	**Other**
Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)							
Community Mental Health Clinic (CMHC)	6	6	6	6	6	6	6
Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) -hospital based	1	1	5	5	5	5	5
RHC/FQHC-independent	1	1	8,2*	8,2*	8,2*	8,2*	8,2*
Home Health Agencies (HHA)	5	3	5	5	5	5	5
Hospice	6 1	6 1	6 1	6 1	6 1	6 1	6 1
Physicians	2*	2 *	2 *	2 *	2 *	2 *	2 *
Pharmacy	2*	2 *	2 *	2 *	7 *	2 *	2 *
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier	2*	2 *	2 *	2 *	7 *	2	2 *
Critical Access Hospital (CAH) Outpt-Method I	3	3	3	3	3	3	3
CAH Outpt-Method II	3	3	3	3	3	3	3

Provider/Drug	Hepatitis B Vaccine	Pneumococcal & Flu Vaccines	Hemophilia Clotting Factors	Immuno - Suppressive	Erythro- (EPO)	Self Admin Anti-Cancer Anti-Emetic	Other
CAH Inpt	3	3	3	3	3	3	3

NOTE: RHCs do not bill for vaccines. These are paid on the cost report. Vaccine payment to FQHCs is bundled into the encounter rate.

Hepatitis B vaccine is paid on a reasonable cost basis in a hospital outpatient department. Deductible and coinsurance apply.

Influenza and pneumococcal vaccines are also paid on a reasonable cost basis in a hospital outpatient department. Neither deductible nor coinsurance apply.

HHAs cannot bill for vaccines, except on TOB 34X, since vaccines are not part of the HH benefit and cannot be paid under HH PPS.

Pneumococcal and influenza are paid once for the vaccine and once for the administration of the vaccine. The provider or supplier (including physician) must enter each of the HCPCS on separate lines of the claim.

A Part B blood clotting factor claim from a Part B supplier is processed by the Local Part B Carrier.

A Part A blood clotting factor claim from a Part A provider, including a hospital-based hemophilia center, is processed by the hospital's Medicare contractor.

20 - Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

(Rev. 131, 03-26-04)
AB-02-075, AB-02-174, PRM 2711.2 B.2, B3-5202, R1799B3

Prior to January 1, 2004, drugs and biologicals not paid on cost or prospective payment are paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that are paid on this basis include, but are not limited to, drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. For January 1, 2004, through December 31, 2004, such drugs or biologicals are paid as described below:

- The payment limits for blood clotting factors will be 95 percent of the AWP.

- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1,2003. A drug would not be considered new if: the brand or manufacturer of the drug changed; a new formulation of the vial size is developed; or the drug received a new indication.

- The payment limits for pneumococcal and hepatitis B drugs and biologicals will be 95 percent of the AWP.

- The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWPs specified on Table 1 below.

- The payment limits for infusion drugs furnished through an item of implanted durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.

- Drugs and biologicals not described above are paid at 85 percent of the April 1, 2003 AWP.

Payment limits determined under this instruction shall not be updated during 2004.

Table 1: Percentages of April 1, 2003 AWP for Selected Drugs

HCPCS	Applicable Percentage
J0640	80
J1100	86
J1260	80
J1440	81
J1441	81
J1561/J1563	80
J1626	80
J1642	80
J2405	87
J2430	85
J2820	80
J7320	82
J7517	86
J7608	80
J7619	80
J7631	80
J7644	80
J8520/J8521*	90
J9000	80
J9045	81
J9170	80
J9201	80
J9202	80

HCPCS	Applicable Percentage
J9206	80
J9217	81
J9265	81
J9310	81
J9350	84
J9390	81
Q0136	87

* Use the following NDC numbers when processing claims:

  00004-1100-20 150 mg

  00004-1100-51 150 mg

  00004-1101-16 500mg

  00004-1101-50 500mg

20.1 – MMA Drug Pricing – Average Sales Price

(Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08)

In general, CMS establishes a single, national payment limit for FI, carrier, DME MAC, and A/B MAC payment for each Medicare-covered drug whose payment is determined based on the methodology described above. Drugs billed to DME MACs are still priced locally, albeit under the new statutory formula, as applicable. The four DME MACs jointly establish drug payment limits for drugs that are billed to DME MACs.

The CMS provides an ASP file to each FI, carrier, DME MAC, and A/B MAC for pricing drugs. Each FI, carrier, DME MAC, and A/B MAC must accept the ASP files made available by CMS for pricing bills/claims for any drug identified on the price files.

The ASP drug pricing file shall contain 3 places after the decimal point in the currency field for the ASP file and contractors shall load the ASP file including 3 places after the decimal point. Contractors shall carry 3 places after the decimal point for the calculation of the amount due for a line item for each covered drug, then follow standard rounding procedures in determining the final allowance for that line item. The final allowed amounts will continue to carry 2 places after the decimal point.

The payment limits included in the revised ASP and Not Otherwise Classified (NOC) payment files supersede the payment limits for these codes in any publication published prior to this document.

20.1.1 – Online Pricing Files for Average Sales Price

(Rev. 509, Issued: 03-18-05; Effective: 07-01-05; Implementation: 07-05-05)

Beginning July1, 2005, the standard for the number of online pricing files maintained by DMERCs for determining the applicable allowed amount for paying drug claims is eight fee screens/pricing files for Part B drugs billed to DMERCs for payment on a fee-for-service basis.

20.1.2 – Average Sales Price (ASP) Payment Methodology

(Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08)

Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, the vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. Additionally, beginning in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Contractors will be notified of the availability of this file via a Recurring Update Notification. Please click here to see these notifications.

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 shall make these determinations.

Beginning January 1, 2005, in general, 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. Beginning January 1, 2006, in general, the payment allowance limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. CMS will update the payment allowance limits quarterly.

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 this effort, we have also reviewed how we

have operationalized the terms “single source drug,” “multiple source drug,” and “biological product” in the context of payment under Section 1847A. For the purposes of identifying “single source drugs” and “biological products” subject to payment under Section 1847A, generally CMS (and its contractors) will utilize a multi-step process. We will consider:

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

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are 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, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of “not otherwise classified” HCPCS codes.

20.1.3 – Exceptions to Average Sales Price (ASP) Payment Methodology

(Rev. 2424, Issued: 03- 16-12, Effective: 08-01-12; Implementation: 08-01-12)

The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or prospective payment basis, are determined in the same manner the payment allowance limits were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits will be 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 Classification (APC) to which the product is assigned.

The 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 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 compendia except 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. CMS will supply contractors with the payment allowance limits annually to be effective on *August* 1 of each year. Contractors will be notified of the availability of *payment allowance limits* via a Recurring Update Notification.

The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, 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 Publication. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is *106* percent of the lesser of the lowest-priced brand or median generic WAC.

Carriers, DME MACs, and A/B MACs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. At the contractors discretion, contractors may contact CMS to obtain payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.

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 Food and Drug Administration, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (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 that were first sold on or after January 1, 2005. At the contractors discretion, contractors may contact CMS to obtain payment limits for new drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.

The payment allowance limits for radiopharmaceuticals are not subject to ASP. Carriers should 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. Refer to Chapter 17, §90.2 of the manual regarding radiopharmaceuticals furnished in the hospital outpatient department.

20.2 - Single Drug Pricer (SDP)
(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Effective January 1, 2003, contractors pay drug claims on the basis of the prices shown on the SDP files, if present.

On a quarterly basis, CMS furnishes three SDP files to all FIs, carriers, and ROs except regional home health intermediaries (RHHIs) and durable medical equipment regional carriers (DMERCs), as follows:

1. "HCPCS" Drug Pricing File

    a. CMS furnishes a SDP file that contains drugs identified by a code established by the Health Care Procedure Code System (HCPCS). This HCPCS drug-pricing file (HDPF) contains:

        - Every HCPCS drug code for every drug for which claims are submitted to local carriers (excluding DMERCs);
        - With respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;
        - With respect to each HCPCS code and unit of measure, the Medicare allowed amount;
        - With respect to each HCPCS code for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
        - With respect to each new HCPCS code, an indicator to that effect; and
        - With respect to each deleted HCPCS code, an indicator to that effect.

    b. The filename convention is as follows: (1) "hdpf" in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., hdpf0301.xls).

    c. An HDPF will be made available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

2. "Not otherwise classified" (NOC) Drug Pricing File

    a. CMS furnishes a NOC SDP file for drugs "not otherwise classified." This NOC drug pricing file (NDPF) contains:

- With respect to every drug NOC under the HCPCS for which claims are submitted to local carriers (excluding DMERCs), the NDC code and drug name;

- With respect to each such NDC code, the unit of measure by which such drug is covered;

- With respect to each NOC drug, the Medicare allowed amount;

- With respect to each NOC drug for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;

- With respect to each new NOC drug, an indicator to that effect; and

- With respect to each deleted NOC drug, an indicator to that effect.

b. The filename convention is as follows: (1) "ndpf" in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., the initial NOC file's filename was "ndpf0301.xls").

c. The CMS makes a revised NDPF available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

NOTE TO FIs: The NOC file does not necessarily contain all NOC drugs. FIs must contact local carriers to determine if there are other drugs the carrier has priced separately and request the prices for those drugs as needed.

3. The CMS furnishes a pricing documentation file (PDF) that contains only new drugs and biologicals for which a Medicare price has been established since the previous quarter:

a. The data in the drug pricing file, i.e., each HCPCS code and its Medicare allowed amount;

b. With respect to each HCPCS drug code, every product, as identified by its NDC code, that contains the same active ingredient as specified in the definition of the HCPCS code;

c. With respect to those NDC codes used to determine the Medicare-allowed amount, an indicator to that effect;

d. With respect to each such NDC, the price or prices used to determine the average wholesale price (AWP) of the product;

e. With respect to each such price, an identification of the source(s) of the price; and

f. With respect to each such source, the date, edition, and other information necessary and sufficient to enable CMS to verify the price.

Except as specifically noted, each FI and carrier will:

- Upon receiving the quarterly update files, execute its normal update process using the SDP files. If necessary, the contractor shall process manually to implement SDP file prices effective with the beginning of the following quarter.

- Compare the prices it paid previously with the prices shown on the prior SDP file; taking note of the unit pricing quantity shown on the applicable SDP file and comparing it to the unit pricing quantity to ensure that any apparent price changes are real.

    - Carriers must notify physicians of price changes.

    - FIs must notify ESRD facilities (with respect to ESRD drugs not included in the composite rate) and hospitals (with respect to clotting factors) of price changes to the extent and in the manner you have done previously.

- Advise the RO of any price on a SDP file it believes is not correct.

- Not substitute its price for the price shown on an SDP file unless authorized to do so by a joint memorandum from CMS.

- If updated prices, in whole or in part, are not made available on a timely basis, use the prices from the prior quarter's SDP files to the extent necessary.

- Carriers continue to price drugs as outlined in §20.2 with respect to any drug that is not listed on the SDP files and with respect to any compounded drug that is not identified by a single NDC.

    - Report to the RO, on or before March 1 of each year, whether any drugs are being priced separately, including but not limited to NOC drugs. If one or more drugs are being priced separately, then the name of the drug, its NDC, the price determined, and the source used to price drug must also be included in the report.

- Carriers and FIs: Publish current SDP prices on their Web site immediately upon receipt of the file from CMS.

- FIs: As needed on a quarterly basis and within seven days of receipt of the SDP files, request, from carriers, prices of drugs that carriers may price separately.

- Carriers: Upon request, on a quarterly basis and within seven days of any such request, furnish to FIs within jurisdiction, free of charge, the subset of files, which includes drugs that are priced separately.

- FIs and Carriers: Respond to questions about price changes and the implementation of AWP pricing as done previously. Contractors respond to questions about the SDP on the basis of these instructions. Questions that cannot be answered should be referred to the RO.

- The MCS Carrier shared systems shall maintain eight fee screens/pricing files (a current period and seven prior periods) for Part B "incident to" drugs billed to carriers for payment on a fee-for-service basis. (**NOTE:** VIPS is waived and will continue to carry 5 pricing periods)

- Since they post the updated SDP file to their Web site upon receipt from CMS, carriers are waived from the requirement to give 30 days advance notice for fee schedule changes with respect to drugs.

- SDP does not preclude the use of inherent reasonableness or the establishment of local medical review policies, including the use of a least costly alternative.

    - If a least costly alternative is determined and a process for the least costly alternative exists on the SDP, the SDP price for the least costly alternative must be used.

- Medicare coverage determinations are independent of the SDP. The presence or absence of a price for a particular drug in the SDP is irrelevant to Medicare coverage determinations.

- EPO=Q codes are included in the SDP, applicable to physician claims. The statutory limit for EPO applies to nonphysician claims.

- "Unit Measurement" means the amount of whatever measurement is used in the code description (e.g., milligrams (mg)).

ROs:

1. Advise carriers concerning the implementation of the SDP.

2. Respond to questions about drug price changes.

3. Respond to questions about the implementation of the AWP pricing methodology.

4. Respond to questions about the SDP on the basis of these instructions.

5. Refer any questions that cannot be answered to central office (CO) per item 6, below.

6. Advise CO of matters that require CO attention.

20.3 – Calculation of the Payment Allowance Limit for DMERC Drugs
(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Payments for drugs billed to the DMERCs will be based on the implementation of the MPDIMA, beginning January 1, 2004, and will be paid at 85 percent of the AWP for HCPCS payment amounts based on the April 1, 2003 fee schedule. Exceptions to this calculation are as follows:

The payment limits for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.

- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1,2003. A drug would not be considered new if: The brand or manufacturer of the drug changed; a new formulation of the vial size is developed; or the drug received a new indication.

The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWPs specified on Table 1 in §20.

Payment limits determined under this instruction shall not be updated during 2004.

20.4 - Calculation of the AWP
(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

See Business Requirements and Excel Spreadsheets at
http://www.medicaid.com/manuals/pm_trans/R54CP.pdf

http://www.medicaid.com/manuals/pm_trans/R55CP.pdf

Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately.

A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources, or there may be no source.

- For a single-source drug or biological, the AWP equals the AWP of the single product.

- For a multi-source drug or biological, the AWP is equal to the lesser of;

- The median AWP of all generic forms of the drug or biological; or

- The lowest brand name product AWP.

A "brand name" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

NOTE: Repackagers make the status of the drug a multi-source.

After determining the AWP, carriers multiply it by 0.85 or 0.95, or other percentage, as applicable, and round to the nearest penny. This is the drug payment allowance limit. Carriers round it in accordance with standard rounding procedure. Part B coinsurance and deductible requirements apply.

In applying this procedure, carriers use the package sizes that are most commonly used for the most frequently administered dosage of the drug.

Intermediaries get drug prices from the carrier for drugs not listed on the Single Drug Pricer.

20.5 - Detailed Procedures for Determining AWPs and the Drug Payment Allowance Limits

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

20.5.1 - Background

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Payment for drugs and biologicals under Medicare is determined by a standard methodology. Law and regulations require that a drug payment allowance limit be used as described in §20.1. (See 42 CFR 405.517 and MPDIMA, Section 303(b).)
The earliest drug payment allowance limit effective in 2004 will not be subsequently updated during 2004. When limits are initially established, carriers inform FIs and the provider community as described in paragraph §30 below.

20.5.2 - Review of Sources for Medicare Covered Drugs and Biologicals

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Carriers check updates for Medicare covered services or procedures for new codes or code description changes before updating files.

For new codes, the Carrier Medical Staff determines coverage in accordance with the coverage rules in Chapter 15 of the Medicare Benefit Policy Manual.

Carriers refer to common sources for drug pricing information. Examples are the various Redbook products, "Drug Facts and Comparisons," the FDA publication Approved Drug

Products with Therapeutic Equivalence (the Orange Book), or the "Hospital Formulary Pricing Guide" by MediSpan, Inc. If a price cannot be located in the available sources, they contact the manufacturer of the drug.

If a code has a description change, carriers adjust formulas to account for any changes in the strength or dosage of the drug. For example, if a code is listed as 50 mg, and changed to100 mg. the drug payment allowance limit is adjusted to compensate for the difference in the dosage.

20.5.3 - Use of Generics

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Carriers identify the generic name of the drug from the code description. They always rely on the CMS HCPCS tape file or an official HCPCS publication.

Carriers locate generic sources in the Drug Topics Redbook or other source based on the HCPCS description of the drug. They use entries that match the strength of the drug described by the HCPCS code, e.g., 50 mg, 100 mg, etc.

To determine if a drug is generic or brand, carriers compare the name of the drug in the HCPCS code (generic) with the name of the drug being identified. If they are the same, the drug is generic. If they are different, the drug is a brand. For example, the description for J3360 is injection, diazepam, up to 5 mg. Diazepam is the generic name. The HCPCS code for Valium is listed as J3360. Valium is a brand name.

If there is a question as to whether a drug is brand or generic, carriers consult the PDR Generics, or telephone the drug company.

20.5.4 - Find the Strength and Dosage

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Carriers use ampules, single dose and multiple dose vials and repacks to compare the strength and dosage. If multiple dose vials are used, carriers must determine how they are used, based on the strength indicator compared with the HCPCS code description (i.e., if the strength on the vial matches the HCPCS description, multi-dose vials should be used).

Carriers must determine which of the following conditions are true before pricing the drug:

1. The strength and dosage of the drugs in the price source match the HCPCS code and description.

Carriers calculate allowable reimbursements for drugs using "all" the NDCs for a given active drug ingredient and calculate a unit price that is associated with the HCPCS descriptor. If, for example, the HCPCS code descriptor specifies 50 ml and there is a 50 ml size shown in the Redbook or other source material, they may use only the 50 ml size (and not use 10-5 ml vials) or may use all products that meet the strength based on

strength and volume of the drug. In the latter case price per unit is calculated and then converted to the HCPCS units definition.

2. The strength and dosage from the HCPCS code description are not found in the price source.

Carriers use the closest dosage to the HCPCS definition without exceeding the dosage.

3. The strength and dosage in the price source do not include a generic form but do include a brand form.

Carriers use the lowest brand price.

20.5.5 - Restrictions

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

To determine AWPs and Payment Allowance Limits, carriers:

- Exclude special sized packaging, e.g., Institutional Use.
- Do not use flip top vial, carpu-ject, tubes, cartridge, rapi-ject, lure lock syringe, blunt point abu-ject, rapi-ject, leurlock, advantage, min-i-jet, unless it is the only source available. These items are considered convenience and tend to inflate the price.
- Do not use drugs marked preservative free, sulfite free, piggy back, or sterile unless the HCPCS description specifies otherwise.
- Do not use drugs with an Orange Book Code (OBC) other than "A" if more than one source exists. This restriction applies to SADMERC only (reference CMS Memorandum PUB 60 AB.94-2, 60 dated March 1994).

20.5.6 - Inherent Reasonableness for Drugs and Biologicals

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Section 4316 of the Balanced Budget Act of 1997 permits Medicare carriers to establish realistic and equitable payment amounts for drugs when the existing payment amounts are inherently unreasonable because they are either grossly excessive or deficient. Refer to chapter 23, for a complete description of Inherent Reasonableness rules.

Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to the following:

1. Payment amounts for drugs or biologicals are grossly higher or lower than acquisition or production costs for the category of items or services.

2. There have been increases in payment amounts that cannot be explained by inflation or technology.

In some instances, the calculation of the AWP may lead to a payment limit that is not reasonable for the purpose of paying for drugs and biologicals. Carriers can apply the principal of inherent reasonableness in selecting the drugs to be included in the calculation. For instance in situations where there are some drugs in a HCPCS grouping that are significantly more expensive due to having preservatives added, there is no effect on the quality of the drug whether or not there are preservatives. Therefore, leave the drugs with preservatives out of the calculation.

While carriers and FIs may determine under their inherent reasonableness authority that a greater than 15 percent increase or decrease in payment amounts is warranted, they may not increase or decrease the payment amounts for any item by greater than 15 percent in any given year. However, a contractor may determine that a 25 percent reduction is warranted, and accomplish the adjustment over 2 years, e.g., 15 percent applied the first year, and 10 percent applied the following year.

In addition, a contractor must inform CMS of any inherent reasonableness determinations. The CMS will then acknowledge receipt of the notification. The payment adjustment may not take effect until the contractor has notified CMS and received CMS's acknowledgment of the notification.

Notification should be sent to CMS Central Office (CO) at the following address:

Centers for Medicare & Medicaid Services
Center for Medicare Management
Provider Billing Group
C4-10-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

20.5.7 – Injection Services

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Where the sole purpose of an office visit was for the patient to receive an injection, payment may be made only for the injection service (if it is covered). Conversely, injection services (codes 90782, 90783, 90784, 90788, and 90799) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time. Pay separately for those injection services only if no other physician fee schedule service is being paid. However, pay separately for cancer chemotherapy injections (CPT codes 96400-96549) in addition to the visit furnished on the same day. In either case, the drug is separately payable. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables you to pay for the services.

20.5.8 - Injections Furnished to ESRD Beneficiaries
(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

When an ESRD beneficiary is given a renal related injection outside the ESRD facility or provider-setting, it should be administered by the beneficiary's monthly capitation payment (MCP) physician or his/her staff as "incident to" such physician's services.

There is no additional allowance for the physician or his staff, e.g., an office nurse. This is because payment for the administration of a renal-related injection to a dialysis patient is included in the physicians' monthly capitation payment (MCP).

The regulations governing Medicare payment for physicians' ESRD services (42 CFR 405.542) require that all physicians' outpatient ESRD-related services except declotting shunts be paid under the MCP. If a physician, other than the patient's MCP physician, administers a renal-related injection, the other physician must look to the MCP physician for compensation for the services.

Although an additional allowance for the administration of a renal-related injection to a dialysis patient may not be made, the patient's MCP physician or a physician other than the MCP physician may submit claims and be paid for the drug itself as well as supplies, e.g., needles and syringes, used to administer the drug.

EXAMPLE: Dr. Jones is Mr. White's MCP physician. Dr. Jones is unable to furnish the regular EPO injections his patient needs three times a week. It is Dr. Jones' responsibility to compensate the physician who administers the injections. The administering physician submits claims for the injectable and necessary supplies. In this case, the carrier makes a reasonable monthly allowance, e.g., $3 for the cost of supplies (i.e., syringes and needles).

20.5.9 - Annual Update of AWP Payment Allowance Limit for Vaccines
(Rev. 1357, Issued: 10-26-07, Effective: 09-01-07, Implementation: 11-26-07)

The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except 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. Medicare contractors will be receiving subsequent annual updates of the vaccine payment allowance limits for influenza and pneumococcal vaccines communicated by a Recurring Update Notification.

30 - Carrier Distribution of Limit Amounts
(Rev. 1, 10-01-03)

B3-5202.1

The FIs get drug prices from the carrier for drugs not listed on the SDP.

Carriers prepare a list of the drug payment allowance limits updates (or new file depending upon local requirements) to the claims system.

Carriers distribute, free of charge, the updated limits in an agreed upon format directly to the FIs in their jurisdiction.

Carriers should contact each FI to determine the preferred method of transmission. Carriers are to send this information to all FIs they routinely deal with. If this method of obtaining payment allowance updates does not work for any FI, the carrier must contact the appropriate RO office.

40 - Discarded Drugs and Biologicals

(Rev. 1962, Issued: 04-30-10, Effective: 07-30-10, Implementation: 07-30-10)

The CMS encourages physicians, hospitals and other providers and suppliers to care for and administer to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

When a physician, hospital or other provider or supplier must discard the remainder of a single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

When processing claims for drugs and biologicals (except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP)), local 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, billed on a separate line, will provide payment for the amount of discarded drug or biological. For example, a single use vial that is labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. The 95 unit dose is billed on one line, while the discarded 5 units may be billed on another line by using the JW modifier. Both line items would be processed for payment.

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a patient while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted.

The JW modifier is not used on claims for CAP drugs. For CAP drugs, see subsection 100.2.9 - Submission of Claims With the Modifier JW, "Drug or Biological Amount Discarded/Not Administered to Any Patient", for additional discussion of the discarded remainder of a vial or other packaged drug or biological in the CAP.

NOTE: Multi-use vials are not subject to payment for discarded amounts of drug or biological.

40.1 – Discarded Erythropoietin Stimulating Agents for Home Dialysis
(Rev. 1581; Issued: 08-29-08; Effective/Implementation Date: 12-01-08)

Multiuse vials are not subject to payment for discarded amounts of drug or biological, with the exception of self administered erythropoietin stimulating agents (ESAs) by Method I home dialysis patients. The renal facility must bill the program using the modifier JW for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient's plan of care, or unused ESAs on hand after a patient's death. Specific instructions are found in chapter 8 of this manual, §60.4.4.1 "Self Administered EPO Supply", and §60.7.4 "Darbepoetin Alfa (Aranesp) Furnished to Home Patients".

This applies only to home dialysis patients who meet the Method I conditions described in Pub 100-2 Benefits Policy Manual, chapter 11, §90 "Epoetin (EPO)", and does not apply to Method II home dialysis patients.

Supplies of ESAs for self administration are billed according to the pre-determined plan of care schedule provided to home dialysis patients that meet the criteria for self administered ESAs discussed in chapter 8 of this manual, §60.4 "Epoetin Alfa (EPO) For ESRD Patients" and §60.7 "Darbepoetin Alfa (Aranesp) for ESRD Patients". The renal facility, through the amounts prescribed in the plan of care, shall ensure the patient's ESA on hand at any time does not exceed a 2-month supply. CMS expects the facility to minimize excess dispensing of the ESAs for self administration based on the patient's plan of care.

50 - Assignment Required for Drugs and Biologicals
(Rev. 1, 10-01-03)

PM B-01-15, B3-5247

A. Local Carriers

Under §114 of the Benefits Improvement Act of 2000, effective for claims with dates of service on or after February 1, 2001, payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis. Therefore, no charge or bill may be rendered to anyone for these drugs and biologicals for any amount except for any applicable unmet Medicare Part B deductible and coinsurance amounts.

All entities (including physicians, nonphysicians practitioners, pharmacies and suppliers) that bill Medicare for drugs and biologicals must take assignment on all claims for drugs and biologicals furnished to any beneficiary enrolled in Medicare Part B. Contractors apply this policy to all items paid based on the lower of the actual charge on the claim or 95 percent of the AWP. See §§20 for a description of the AWP.

Mandatory assignment does not apply to HCPCS code E0590, which represents the dispensing fee for nebulizer drugs.

Carriers process all claims for drugs and biologicals with a date of service on or after February 1, 2001, as though the physician or nonphysician practitioner had taken assignment. If only drugs and biologicals are billed on the claim, and the claim was submitted as unassigned, contractors change the claim to assigned and process as an assigned claim. If a physician or nonphysician practitioner submits an unassigned claim that contains both codes for drugs or biologicals and codes for other services, carriers split the claim into two claims. The first claim will be an unassigned claim for services other than drugs or biologicals, and the second will be an assigned claim for drugs or biologicals furnished on or after February 1, 2001. The following messages apply when a carrier has changed the claim to assigned status (regardless of whether the contractor had to split the claim):

- Remittance advice remark code N71, "Your unassigned claim for a drug or biological, clinical diagnostic laboratory services or ambulance service was processed as an assigned claim. You are required by law to accept assignment for these types of claims."

- MSN 16.50 English, "The doctor or supplier may not bill more than the Medicare approved amount," **or** MSN 16.50 Spanish, "El doctor o suplidor no podrá facturar más que la cantidad aprobada por Medicare."

- Remark Code MA 72, "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total amount shown as patient responsibility and as paid to the beneficiary on this notice."

Additional appropriate message for physicians, suppliers, and beneficiaries should be added as necessary.

B. DMERCs

Under §114 of BIPA, DMEPOS suppliers must accept assignment on all claims for drugs and biologicals that they bill to the DMERCs. A supplier may not render a charge or bill to anyone for these drugs and biologicals for any amount other than the Medicare Part B deductible and coinsurance amounts.

Mandatory assignment does not apply to HCPCS code E0590, which represents the dispensing fee for nebulizer drugs.

The DMERCs must inform suppliers on their Web sites and in their next bulletins that they must accept assignment on claims for drugs and biologicals furnished on or after February 1, 2001.

The DMERCs must deny any claims a beneficiary submits for drugs and biologicals with dates of service on or after February 1, 2001. The DMERCs must notify beneficiaries that suppliers must accept assignment on claims for drugs and biologicals, and therefore, the beneficiaries may not submit claims for drugs and biologicals. When denying beneficiary-submitted claims, DMERCs use the following Medicare Summary Notice (MSN) messages:

> MSN 16.6 (English): "This item or service cannot be paid unless the provider accepts assignment."
>
> MSN 16.6 (Spanish): "Este artículo o servicio no se pagará a menos de que el proveedor acepte asignación."
>
> MSN 16.7 (English): "Your provider must complete and submit your claim."
>
> MSN 16.7 (Spanish): "Su proveedor debe completar y someter su reclamación."
>
> MSN 16.34 (English): "You should not be billed for this service. You do not have to pay this amount."
>
> MSN 16.34 (Spanish): "Usted no debería ser facturado por este servicio. Usted no tiene que pagar esta cantidad."
>
> MSN 16.36 (English): "If you have already paid it, you are entitled to a refund from this provider."
>
> MSN 16.36 (Spanish): "Si usted ya lo ha pagado, tiene derecho a un reembolso de su proveedor."

If a supplier submits an unassigned claim with a date of service on or after February 1, 2001, to the DMERC for a drug or biological, the DMERC must process the claim as though the supplier accepted assignment. It is possible that a supplier may bill drugs and other items on the same claim, which would result in a claim with some assigned and some nonassigned items.

In the event that a supplier bills an unassigned claim to a DMERC that contains both codes for drugs or biologicals and codes for other items, the DMERCs must replicate the claim. This will result in two claims in the DMERC system: an unassigned claim for items other than drugs or biologicals, and an assigned claim for drugs and biologicals

furnished on or after February 1, 2001. When a DMERC changes an unassigned drug claim to an assigned claim, it must use the following messages on the supplier remittance advice (RA):

> Remark code MA72: "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total of the amount shown as patient responsibility and as paid to the beneficiary on this notice." (VMS shared system maintainer must use remark code MA72 on the claim level on the remittance advice for drugs and biologicals when the incoming claim indicated that the patient had already paid for the billed services.)
>
> Remark code N71: "Your unassigned claim for a drug or biological was processed as an assigned claim. The law requires that you must take assignment on all claims for drugs and biologicals."

The VMS Shared System Maintainer must hard-code RA message MA72 and RA message N71 into its system.

Suppliers that bill the DMERCs for drugs for use with DMEPOS must have a pharmacy license to dispense drugs. When a DMERC denies a claim for a drug because the National Supplier Clearing House (NSC) records do not show that the supplier has a pharmacy license, the DMERC must also deny any equipment, accessories, and supplies related to the drug, when the supplier bills the drug on the same claim as the equipment. (Suppliers should bill drugs for use with DMEPOS on the same claim as the equipment itself, if they are also providing and billing for the equipment.) In situations when a supplier bills unassigned drugs and equipment, accessories, or supplies on the same claim, the DMERC and VMS Shared System Maintainer must ensure that they apply nonlicensed pharmacy equipment, accessory and supply edits and denials before they replicate the claim. Even if the system denies a line due to the nonlicensed pharmacy edit prior to replicating the claim, the system must still replicate any unassigned claims for drugs and biologicals and change the assignment indicator. DMERCs use the following messages to suppliers, as appropriate:

> RA Remark code MA72: "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total of the amount shown as patient responsibility and as paid to the beneficiary on this notice." (VMS shared system maintainer must use remark code MA72 on the claim level on the remittance advice for drugs and biologicals when the incoming claim indicated that the patient had already paid for the billed services.)
>
> RA Remark code N71: "Your unassigned claim for a drug or biological was processed as an assigned claim. The law requires that you must take assignment on all claims for drugs and biologicals."

RA Adjustment reason code B6: "This service/procedure is denied/reduced when performed/billed by this type of provider, by this type of provider in this type of facility, or by a provider of this specialty."

RA Adjustment reason code #107: "Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim."

RA Remark code M143: "We have no record that you are licensed to dispense drugs by the state in which you are located."

The DMERCs must work together to create and maintain a list of HCPCS drug codes that suppliers must bill on an assigned basis. This will enable VMS shared system maintainer and the DMERCs to implement the necessary edits in their systems. Finally, the four DMERCs must work together to create a list of drug and equipment codes to which the nonlicensed pharmacy edit would apply in this situation. For this second list, the DMERCs need add only drugs that are used with equipment, and the equipment, and related supplies and accessories, that use those drugs, as opposed to all drugs that are subjected to the licensure edit. The DMERCs must share these lists with VMS shared system maintainer and CMS Central Office.

60 – DMEPOS Suppliers Require a License to Dispense Drugs
(Rev. 1, 10-01-03)

PM B-01-02

Regulations at 42 CFR 424.57(b)(4) (supplier standards) state that a "supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs. (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)"

Therefore, suppliers may not bill the durable medical equipment regional carriers (DMERCs) for any Medicare-covered drugs unless they have a State license to dispense the drugs, regardless of whether or not the drugs require a prescription. Similarly, a physician may not dispense Medicare-covered prescription or nonprescription drugs unless he or she is authorized by the State to dispense such drugs as part of his or her physician's license.

The DMERCs must deny claims for prescription drugs, and related equipment when billed on the same claim, if the National Supplier Clearinghouse's (NSC) records show the supplier was not licensed to dispense the drug on the DOS (date of service).

In effect, for DOS on or after December 11, 2000, the DMERCs must deny claims for all Medicare- covered drugs dispensed by a supplier or physician who is not licensed to dispense the drug. If the DMERCs feel that it is necessary, they may coordinate to

develop a list of drugs and related equipment that should be subjected to the licensure edit.

Note that these provisions do not apply to EPO. Method I beneficiaries must obtain their EPO through their dialysis facilities, and Method II beneficiaries must receive EPO from the same supplier that provides all their other dialysis supplies.

60.1 - Prescription Drugs Billed by Suppliers Not Licensed to Dispense Them

(Rev. 1, 10-01-03)

B3-4118

Medicare does not cover a drug used as a supply with DME or a prosthetic device if the drug is dispensed by an entity that is not licensed to dispense the drug. The drug is not considered to be reasonable and necessary because CMS cannot be assured of its safety and effectiveness unless it is dispensed by an entity that has a State license that qualifies it to dispense the drug. The equipment used with the drugs dispensed by a nonlicensed entity is also considered to be not reasonable and necessary because of the related safety and efficacy concerns. Physicians are considered to have been "deemed" the right to dispense prescription drugs, and therefore do not require a pharmacy license.

The DMERCs should deny claims for a prescription drug (and related equipment when billed on the same claim as the drug) when the National Supplier Clearinghouse's (NSC's) files show the supplier is or was not licensed to dispense the drugs on the date of service (DOS).

An exception to this general policy is oxygen claims.

Messages for Assigned Claims:

> "Medicare cannot pay for this drug/equipment because our records do not show your supplier is licensed to dispense prescription drugs, and, therefore, cannot assure the safety and effectiveness of the drug/equipment. You are not financially liable for any amount for this drug/equipment unless your supplier gave you a written notice in advance that Medicare would not pay for it and you agreed to pay." (MSN #8.50.)
>
> Remittance for Drugs: "This service/procedure is denied/reduced when performed/billed by this type of provider, in this type of facility, or by a provider of this specialty." (Remittance advice code B6, with group code CO - the provider may not bill the beneficiary.)
>
> Additionally, the following remark code should appear on the remittance notices: Remark code M143: "We have no record that you are licensed to dispense drugs by the State in which you are located."

Messages for Nonassigned Claims:

> MSN: "This item or service is not covered when performed or ordered by this provider." (MSN #12.18)

Appeals should be addressed according to the instructions in Chapter 29.

70 - Claims Processing Requirements - General

(Rev. 1281; Issued: 07-06-07; Effective: 04-04-05; Implementation: 01-07-08)

No cross reference - CMS Staff developed

Carriers are billed with the Form CMS-1500 data set and FIs with the Form CMS-1450 data set (paper or approved EDI data set).

See chapters 25 and 26 for detailed claims processing requirements, including forms, data elements, and formats; and chapters 21 and 22 for MSN and remittance record requirements.

In addition to requirements applicable to all claims the following apply to drug claims.

- On claims to FIs the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 0636 unless specific instruction states otherwise;

- On claims to carriers the drug is identified by HCPCS code;

- All drugs, including Prodrugs, are reported to DMERCS by National Drug Code (see §80.1.2);

- Where HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4; See examples below.

- Where the NDC is required units are entered in multiples of the units shown in the NDC label description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;

- If the units provided exceed the size of the units field, or require more characters to report than spaces available in the format, repeat the HCPCS or NDC code on multiple lines until all units can be reported;

- Covered administration codes for injections may be billed to the carrier and FI in addition to billing for the drug. The drug maximum payment allowance is for the

drug alone. However, if payment is under a PPS, such as OPPS, the injection would be included in the APC rate.

The examples below include the HCPCS code and indicate the dosage amount specified in the descriptor of that code. Facilities use the units field as a multiplier to arrive at the total dosage amount.

EXAMPLE 1

HCPCS	Drug	Dosage
J7189	Factor VIIa	1 mcg

Actual dosage: 13,365 mcg

On the bill, the facility shows J7189 and 13,365 in the units field (13,365 mcg divided by 1 mcg = 13,365 units).

NOTE: The process for dealing with one international unit (IU) is the same as the process of dealing with one microgram.

EXAMPLE 2

HCPCS	Drug	Dosage
J9355	Trastuzumab	10 mg

Actual dosage: 140 mg

On the bill, the facility shows J9355 and 14 in the units field (140 mg divided by 10mg = 14 units).

When the dosage amount is greater than the amount indicated for the HCPCS code, the facility rounds up to determine units. When the dosage amount is less than the amount indicated for the HCPCS code, use 1 as the unit of measure.

EXAMPLE 3

HCPCS	Drug	Dosage
J3100	Tenecteplase	50 mg

Actual Dosage: 40 mg

The provider would bill for 1 unit, even though less than 1 full unit was furnished.

See §10 for a description of drug payment rules.

70.1 – Billing Drugs Electronically - NCPDP
(Rev. 867, Issued: 02-17-06, Effective: 04-01-06, Implementation: 04-03-06)

The National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard Version 5.1 and Batch Standard 1.1 is the HIPAA standard for electronic retail pharmacy drug claims and coordination of benefits (COB).

The CMS has issued a companion document for NCPDP in PM-B-03-041

DMERCs that process retail pharmacy drug transactions require their retail pharmacy claimants to use this standard. Retail pharmacies must use the American National Standards Institute (ANSI) Accredited Standards Committee (ASC) ANSI X12N 837P HIPAA version Health Care Claim format to submit claims other than retail pharmacy claims to the DMERCs.

DMERCs and VIPS shall accommodate quarterly and monthly NDC crosswalk updates as needed. DMERCs shall reject NDC codes that have been deactivated/end dated.

A - Requirements for Implementing the NCPDP Standard

Retail pharmacies will be identified by a value of A5 in the specialty code as received by the National Supplier Clearinghouse. Only DMERC suppliers with an A5 specialty code may use the NCPDP standard. The DMERCs, their EDI submitters, and their other trading partners are required to transmit the NDCs in the NCPDP standards for identification of prescription drugs dispensed through a retail pharmacy. NDCs replace the drug HCPCS codes for retail pharmacy drug transactions billed to DMERCs via the NCPDP standards.

B - Certificate of Medical Necessity (CMN)

The CMN for Parenteral Nutrition (Form CMS-852) is required. The DMERC Information Form for Immunosuppressive Drugs (Form DMERC-08.02) is not required when billing for immunosuppressive drugs with dates of service on or after April 1, 2006. As with other electronic formats, CMN data must be submitted within the valid transaction.

For claims submitted on the Form CMS-1500, retail pharmacies will continue to supply hard copy CMNs when required.

C - NCPDP Companion Document

DMERCs are to provide the NCPDP companion document, found at: http://cms.hhs.gov/manuals/pm_trans/B03041.pdf to retail pharmacy drug claim submitters (either provider, billing agent, or clearinghouse) that will submit retail pharmacy drug claims to Medicare electronically.

70.1.1 – Reporting Modifiers in the Compound Drug Segment
(Rev. 1, 10-01-03)

B-03-057

Certain informational modifiers are required on compound ingredients. The NCPDP format does not currently support reporting modifiers in the compound segment. Therefore, the narrative portion in the prior authorization segment must be used to report these modifiers. The following must be entered in positions 001-003 of the narrative (Example, MMN or MNF). Starting at position 355, indicate the two-byte ingredient number followed by the two-position modifier:

MMN - Indicates that the Supporting documentation that follows is Medicare modifier information and CMN information or DIF information

MNA - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information and narrative information

MFA - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information and Facility Name and Address

MNF - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information, narrative information and Facility Name and Address

MAC - Indicates that the Supporting documentation that follows is Medicare modifier information and Facility Name and Address

MAN - Indicates that the Supporting documentation that follows is Medicare modifier information, narrative information and Facility Name and Address

MAR - Indicates that the Supporting documentation that follows is Medicare modifier information and narrative information

70.1.2 – Coordination of Benefits (COB)
(Rev. 1, 10-01-03)

The NCPDP has approved the following use of qualifiers for reporting Medicare COB amounts:

07 Medicare Allowed Amount
08 Medicare Paid Amount
99 1st Occurrence – Deductible Amount
99 2nd Occurrence – Coinsurance Amount
99 3rd Occurrence – Co-Payment Amount

70.1.3 – Inbound NCPDP Claim
(Rev. 1, 10-01-03)

The DMERC needs to be able to determine whether a beneficiary has Medicaid coverage and in which state. In order to determine this, the provider must enter the two position state alpha code followed by the word "MEDICAID" in the Group ID field (Example, NYMEDICAID or FLMEDICAID). Therefore, "XXMEDICAID" must be accepted in the Group ID field (301-C1) in order to allow DMERC's to determine that a beneficiary has Medicaid coverage in that specific state.

80 - Claims Processing for Special Drug Categories
(Rev. 1, 10-01-03)

NOTE: Preventive vaccines, influenza, pneumococcal and hepatitis B, are covered in Chapter 18 of this manual.

NOTE: The definition of Off-Label and its uses are described in the Medicare Benefit Policy Manual, Chapter 15.

80.1 - Oral Cancer Drugs
(Rev. 1, 10-01-03)

A3 3660.13, SNF 536.1

Effective January 1, 1994, oral self administered versions of covered injectable cancer drugs furnished may be paid if other coverage requirements are met. To be covered the drug must have had the same active ingredient as the injectable drug. Effective January 1, 1999, this coverage was expanded to include FDA approved Prodrugs used as anti-cancer drugs. A Prodrug may have a different chemical composition than the injectable drug but body metabolizing of the Prodrug results in the same chemical composition in the body.

80.1.1 - HCPCS Service Coding for Oral Cancer Drugs
(Rev. 1, 10-01-03)

The following codes may be used for drugs other than Prodrugs, when covered:

Generic/Chemical Name	How Supplied	HCPCS
Busulfan	2 mg/ORAL	J8510
Capecitabine	150mg/ORAL	J8520
Capecitabine	500mg/ORAL	J8521

Generic/Chemical Name	How Supplied	HCPCS
Methotrexate	2.5 mg/ORAL	J8610
Cyclophosphamide *	25 mg/ORAL	J8530
Cyclophosphamide * (Treat 50 mg. as 2 units	50 mg/ORAL	J8530
Etoposide	50 mg/ORAL	J8560
Melphalan	2 mg/ORAL	J8600
Prescription Drug chemotherapeutic NOC	ORAL	J8999

Each tablet or capsule is equal to one unit, except for 50 mg./ORAL of cyclophosphamide (J8530), which is shown as 2 units. The 25m and 50 mg share the same code.

NOTE: HIPAA requires that drug claims submitted to DMERCs be identified by NDC.

80.1.2 - HCPCS and NDC Reporting for Prodrugs
(Rev. 136, 04-09-04)

FI claims

For oral anti-cancer Prodrugs HCPCS code J8999 is reported with revenue code 0636.

DMERC claims

The supplier reports the NDC code on the claim. The DMERC converts the NDC code to a "WW" HCPCS code for CWF. As new "WW" codes are established for oral anti-cancer drugs they will be communicated in a Recurring Update Notification.

80.1.3 - Other Claims Processing Issues for Oral Cancer Drugs
(Rev. 1, 10-01-03)

Deductible and coinsurance apply.

A cancer diagnosis code must be reported when billing for these HCPCS codes. If there is no cancer diagnosis the claims is denied.

The number of tablets or capsules is reported as units.

80.1.4 - MSN/ANSI X12N Message Codes for Oral Cancer Drug Denials
(Rev. 1, 10-01-03)

If the claim for an oral cancer drug is denied because it was not approved by FDA, is not considered to be a medically accepted treatment for cancer, or is not the chemical equivalent of a covered injectable cancer drug (or a covered Prodrug), use the appropriate message on the MSN:

> 6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (ANSI X12 Adjustment Code 114)
>
> 6.3 - Payment cannot be made for oral drugs that do not have the same active ingredients as they would have if given by injection. (ANSI X12 Group Code-PR 46)

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen
(Rev. 1599, Issued: 09-19-08, Effective: 10-01-08, Implementation: 10-06-08)

See the Medicare Benefits Policy Manual, Chapter 15, for detailed coverage requirements.

Effective for dates of service on or after January 1, 1998, FIs and carriers pay for oral anti-emetic drugs when used as full therapeutic replacement for intravenous dosage forms as part of a cancer chemotherapeutic regimen when the drug(s) is administered or prescribed by a physician for use immediately before, at, or within 48 hours after the time of administration of the chemotherapeutic agent.

The allowable period of covered therapy includes day one, the date of service of the chemotherapy drug (beginning of the time of treatment), plus a period not to exceed two additional calendar days, or a maximum period up to 48 hours. Some drugs are limited to 24 hours; some to 48 hours. The hour limit is included in the narrative description of the HCPCS code.

The oral three drug combination is aprepitant, a 5-HT_3 antagonist, e.g. granisetron, ondansetron, or dolasetron, and dexamethasone, a cortico-steroid.

The oral anti-emetic drug(s) should be prescribed only on a per chemotherapy treatment basis. For example, only enough of the oral anti-emetic(s) for one 24- or 48-hour dosage regimen (depending upon the drug) should be prescribed/supplied for each incidence of chemotherapy treatment. The three drug combination protocol requires the first dose to be administered before, during, or immediately after the anti-cancer chemotherapy administration. The second day is defined as “within 24 hours” and the third day is defined as “within 48 hours” of the chemotherapy administration. These drugs may be

supplied by the physician in the office, by an inpatient or outpatient provider (e.g., hospital, CAH, SNF), or through a supplier (e.g., a pharmacy).

The physician must indicate on the prescription that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen. Where the drug is provided by a facility, the beneficiary's medical record maintained by the facility must be documented to reflect that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.

Payment for these drugs is made under Part B. Beginning 1/1/05, the payment allowance limit for these Part B drugs (the term "drugs" includes biologicals) will be based on the Average Sales Price (ASP) plus 6%. Hospital outpatient department providers may either:

(1) Bill the entire Tri-Pak to the FI (three days of aprepitant, 57 units of J8501), or (2) Bill the first day's drug to their local FI or A/B MAC, and give a prescription for the second and third days' supply of aprepitant.

If billed to the FI, all three drugs in the combination oral anti-emetic must be on the same claim. Providers subject to the hospital outpatient PPS will be paid on the basis of an APC. If the hospital outpatient department dispenses the aprepitant for days two and three to the beneficiary and bills the DME MAC for the take home drugs, the hospital's billing department should review all instructions for billing oral anti-emetics. Follow this link to reach the LCD for oral anti-emetics:

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5058&lcd_version=27&show=all

In the case of IV Emend provided on day 1, payment for days 2 and 3 would not be made under Part B.

Payment allowances for these drugs dispensed in physician offices will be based on the lower of the submitted charge or the ASP file price. These drugs continue to be priced based on the date of service. The drug payment allowance limit pricing file is distributed to contractors by CMS on a quarterly basis.

The HCPCS codes shown in section 80.2.1 are used.

The CWF edits claims with these codes to assure that the beneficiary is receiving the oral anti-emetic(s) as part of a cancer chemotherapeutic regimen by requiring a diagnosis of cancer.

Most drugs furnished as an outpatient hospital service are packaged under OPPS. However, chemotherapeutic agents and the supportive and adjunctive drugs used with them are paid separately.

Effective for dates of service on or after April 4, 2005, coverage for the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT_3 antagonist, and dexamethasone is considered reasonable and necessary for only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine
- Mechlorethamine
- Streptozocin
- Doxorubicin
- Epirubicin

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

(Rev. 590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

The physician/supplier bills for these drugs on Form CMS-1500 or its electronic equivalent. The facility bills for these drugs on Form CMS-1450 or its electronic equivalent. The following HCPCS codes are assigned:

J8501 APREPITANT, 5mg, Oral (Code is Effective 1/1/05 but coverage is effective 4/4/05, Note: Aprepitant is only covered in combination with a 5-HT_3 antagonist, and dexamethasone for beneficiaries who have received one or more of the specified anti-cancer chemotherapeutic agents.

Q0163 DIPHENHYDRAMINE HYDROCHLORIDE 50mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at time of chemotherapy treatment not to exceed a 48-hour dosage regimen.

Q0164 PROCHLORPERAZINE MALEATE 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0165 PROCHLORPERAZINE MALEATE 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0166 GRANISETRON HYDROCHLORIDE 1mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.

Q0167 DRONABINOL 2.5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0168 DRONABINOL 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0169 PROMETHAZINE HYDROCHLORIDE 12.5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0170 PROMETHAZINE HYDROCHLORIDE 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0171 CHLORPROMAZINE HYDROCHLORIDE 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0172 CHLORPROMAZINE HYDROCHLORIDE 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0173 TRIMETHOBENZAMIDE HYDROCHLORIDE 250mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0174 THIETHYLPERAZINE MALEATE 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0175 PERPHENAZINE 4mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0176 PERPHENAZINE 8mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hours dosage regimen.

Q0177 HYDROXYZINE PAMOATE 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0178 HYDROXYZINE PAMOATE 50mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0179 ONDANSETRON HYDROCHLORIDE 8mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Q0180 DOLASETRON MESYLATE 100mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.

Q0181 UNSPECIFIED ORAL DOSAGE FORM, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

NOTE: The 24-hour maximum drug supply limitation on dispensing, for HCPCS Codes Q0166 and Q0180, has been established to bring the Medicare benefit as it applies to these two therapeutic entities in conformity with the "Indications and Usage" section of currently FDA-approved product labeling for each affected drug product.

80.2.2 - Claims Processing Jurisdiction for Oral Anti-Emetic Drugs

(Rev. 882, Issued: 03-03-06; Effective: 07-01-06; Implementation: 07-03-06)

The following chart shows which drugs are billed to the local carrier or FI and which to the DMERC.

Per the BBA '97, effective for claims with dates of service on or after January 1, 1998, the claims processing jurisdiction rules in Chart 1 apply. Effective July 1, 2006, claims from institutional (hospital) pharmacies are also billed as shown in this chart.

CHART 1

COMBINATION	JURISDICTION
Oral anti-cancer chemotherapy drug with oral anti-emetic drug	DMERC maintains processing responsibility for the NDC oral anti-cancer chemotherapy drug and the K0415 oral anti-emetic drug code combinations. DMERC processes the NDC oral anti-cancer chemotherapy drug and Q code oral anti-emetic drug(s) when provided in the physician's office. DMERC processes the NDC oral anti-cancer chemotherapy drug and/or Q code oral anti-emetic drug(s) when supplied by a pharmacy, including a hospital pharmacy.
Oral anti-cancer chemotherapy drug with rectal anti-emetic drug	DMERC maintains responsibility for processing both the NDC oral anti-cancer chemotherapy drug and the K0416 rectal anti-emetic drug.
Oral anti-cancer chemotherapy drug with intravenous anti-emetic drug	DMERC maintains responsibility for processing the NDC oral anti-cancer chemotherapy drug and the local carrier or FI for processing the intravenous anti-emetic J code drug(s).
Intravenous anti-cancer chemotherapy drug with oral anti-emetic drug	Local carrier or FI processes the intravenous J code anti-cancer chemotherapy drug. The oral anti-emetic Q code drug(s) is processed by the DMERC when provided in the physician's office, hospital, or when provided by a supplier.
Intravenous anti-cancer chemotherapy drug with intravenous anti-emetic drug	Local carrier or FI processes both intravenous anti-cancer chemotherapy J code drug and intravenous anti-emetic J code drug(s).

For claims with dates of service prior to January 1, 1998, per OBRA '93, the claims processing jurisdiction rules in Chart 2 apply.

CHART 2

COMBINATION	UNDER OBRA '93
Oral anti-cancer chemotherapy drug with oral anti-emetic drug	DMERC processes both oral anti-cancer chemotherapy drug (NDC) [1] and the oral anti-emetic drug (HCPCS code J8498) [2].

Oral anti-cancer chemotherapy drug with rectal anti-emetic drug	DMERC processes both the oral anti-cancer chemotherapy drug (NDC) [1] and the anti-emetic drug (HCPCS code J8498) [2].
Oral anti-cancer chemotherapy drug with intravenous anti-emetic drug	DMERC processes the oral anti-cancer chemotherapy drug (NDC) [1] and the local carrier or FI processes the intravenous anti-emetic drug (NDC) [3].
Intravenous anti-cancer chemotherapy drug with oral anti-emetic drug	Local carrier or FI processes intravenous anti-cancer chemotherapy drug (NDC) [3] and self-administered oral anti-emetic drug is noncovered.
Intravenous anti-cancer chemotherapy drug with intravenous anti-emetic drug	Local carrier or FI processes both intravenous anti-cancer chemotherapy drug (NDC) [3] and intravenous anti-emetic drug (NDC) [3].

Key: 1 = OBRA '93 Legislation (Coverage for Oral Anti-Cancer Drugs)

2 = Carrier Manual Transmittal No. 1528 (November 1995) (Adds oral/rectal anti-emetic)

3 = "Incident to" a physician service

Providers (HIPAA definition) that bill the DMERC require a supplier number issued by the NSC in order to submit claims. Medicare Carriers and Fiscal Intermediaries (FIs) should instruct providers without a supplier number to contact the National Supplier Clearinghouse (NSC) service center at 1-866-238-9652 to request an enrollment package for a supplier number. Alternatively, providers may go to the CMS Web site, cms.hhs.gov/providers/enrollment/default.asp, and download the Form CMS-855-S in Adobe Acrobat format. The application can be completed hard copy and submitted to the NSC.

80.2.3 - MSN /ANSI X12N Denial Messages for Anti-Emetic Drugs

(Rev. 684, Issued: 09-23-05; Effective and Implementation Dates: 12-23-05)

If the claim for an anti-emetic drug is denied because FDA did not approve it or because the drug is not being used as part of an anticancer chemotherapeutic regimen, the contractor uses one of the following appropriate messages on the MSN:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (ANSI X12 Adjustment Code 114)

6.4 - Medicare does not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours after administration of a Medicare covered chemotherapy drug. (ANSI X12 Group Code PR 96 with Remark Code M100)

80.2.4 - Billing and Payment Instructions for FIs
(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Claims for the initial dose of the oral anti-emetic drug aprepitant must be billed to the FI on the ASC 837I or on hard copy Form CMS-1450 with the appropriate cancer diagnosis and HCPCS code or CPT code. The following payment methodologies apply when furnished to hospital and SNF outpatients:

- Based on APC for hospitals subject to OPPS;
- Under current payment methodologies for hospitals not subject to OPPS; or
- On a reasonable cost basis for SNFs.

Institutional providers bill for aprepitant under Revenue Code 0636 (Drugs requiring detailed coding).

Medicare contractors shall pay claims submitted for services provided by a CAH as follows: Method I technical services are paid at 101% of reasonable cost; Method II technical services are paid at 101% of reasonable cost, and, Professional services are paid at 115% of the Medicare Physician Fee Schedule Data Base.

NOTE: Inpatient claims submitted for oral anti-emetic drugs are processed under the current payment methodologies.

80.3 - Billing for Immunosuppressive Drugs
(Rev. 1448; Issued: 02-15-08; Effective: 07-01-08; Implementation: 07-07-08)

Beginning January 1, 1987, Medicare pays for FDA approved immunosuppressive drugs and for drugs used in immunosuppressive therapy. (See the Medicare Benefit Policy Manual, Chapter 15 for detailed coverage requirements.) Generally, contractors pay for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. This benefit is subject to the Part B deductible and coinsurance provision.

Contractors are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and notify providers. Prescriptions for immunosuppressive drugs generally should be nonrefillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription from one drug to another. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, contractors will not consider a supply of drugs in excess of 30 days to be reasonable and necessary and should deny payment accordingly.

Entities that normally bill the carrier bill the DME **MAC**. Entities that normally bill the FI continue to bill the FI, except for hospitals subject to OPPS, which must bill the DME MAC.

Prior to December 21, 2000 coverage was limited to immunosuppressive drugs received within 36 months of a transplant. ESRD beneficiaries continue to be limited to 36 months of coverage after a Medicare covered kidney transplant. For all other beneficiaries, BBA '97 increased the length of time a beneficiary could receive immunosuppressives by a sliding method. So for the period 8/97 thru 12/00 a longer period of time MAY apply for a transplant. Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no time limit, but an organ transplant must have occurred for which immunosuppressive therapy is appropriate. That is, the time limit for immunosuppressive drugs was eliminated for transplant beneficiaries that will continue Medicare coverage after 36 months based on disability or age. The date of transplant is reported to the FI with occurrence code 36.

CWF will edit claim records to determine if a history of a transplant is on record. If not an error will be returned. See Chapter 27 for edit codes and resolution.

For claims filed on and after July 1, 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary, when such drug has been prescribed due to the beneficiary having undergone an organ transplant, shall: 1) secure from the prescriber the date of such organ transplant, 2) retain documentation of such transplant date in its files, and 3) annotate the Medicare claim for such drug with the "KX" modifier to signify both that the supplier retains such documentation of the beneficiary's transplant date and that such transplant date precedes the Date of Service (DOS) for furnishing the drug.

For claims received on and after July 1, 2008, contractors shall accept claims for immunosuppressive drugs without a KX modifier but shall deny such claims unless a query of the Master Beneficiary Record (MBR) shows that Medicare has made payment for an organ transplant on a date that precedes the DOS of the immunosuppressive drug claim.

In the context of a claim for an immunosuppressive drug that is submitted to Medicare in order to receive payment, the use of the KX modifier signifies that the supplier has documentation on file to the effect that the beneficiary has undergone an organ transplant on a date certain and that the immunosuppressive drug has been prescribed incident to such transplant.

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

80.3.1 - Requirements for Billing FI for Immunosuppressive Drugs
(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Hospitals not subject to OPPS bill on a Form CMS-1450 with bill type 12x (hospital inpatient Part B) or l3x (hospital outpatient) as appropriate. For claims with dates of service prior to April 1, 2000, providers report the following entries:

- Occurrence code 36 and date;
- Revenue code 0250; and
- Narrative description.

NOTE: Information regarding the claim form locators that correspond with these fields and a table to crosswalk the CMS-1450 form locators to the 837 transaction is found in Chapter 25.

For claims with dates of service on or after April 1, 2000, hospitals report

- Occurrence code 36 and date;
- Revenue code 0636;
- HCPCS code of the immunosuppressive drug; and
- Number of units (the number of units billed must accurately reflect the definition of one unit of service in each code narrative. E.g.,: If fifty 10-mg. Prednisone tablets are dispensed, the hospital bills J7506, 100 units (1 unit of J7506 = 5 mg.).

NOTE: Information regarding the claim form locators that correspond with these fields and a table to crosswalk the CMS-1450 form locators to the 837 transaction is found in Chapter 25.

The hospital completes the remaining items in accordance with regular billing instructions.

80.3.2 - MSN/Remittance Messages for Immunosuppressive Drugs
(Rev. 1, 10-01-03)

A. MSN

MSN messages for denied Immunosuppressive Drugs are as follows:

If no transplant use:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered.

If the claim for an immunosuppressive drug is partially denied because of the 30-day supply limitation, use the following message:

4.3 - Prescriptions for immunosuppressive drugs are limited to a 30-day supply.

B. Remittance

Remittance codes/messages for denied Immunosuppressive Drugs are as follows:

If the claim is denied because the immunosuppressive drug is not approved by the FDA, the FI uses existing American National Standard Institute (ANSI) X-12-835 claim adjustment reason code/message 114, Procedure/product not approved by the Food and Drug Administration.

If the claim is denied because the benefit period has expired or because of the 30 day limitation, the FI uses existing ANSI X12N 835 claim adjustment reason code/message 35, Benefit maximum has been reached.

If the claim is denied for the immunosuppressive drug because a transplant was not covered, the FI uses existing ANSI X12N 835 claim adjustment reason code/message 107, Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

80.4 - Billing for Hemophilia Clotting Factors

(Rev. 1564, Issued: 07-25-08, Effective: 04-01-08, Implementation: 01-05-09)

Blood clotting factors not paid on a cost or prospective payment system basis are priced as a drug/biological under the drug pricing fee schedule effective for the specific date of service. As of January 1, 2005, the average sales price (ASP) plus 6 percent shall be used.

If a beneficiary is in a covered part A stay in a PPS hospital, the clotting factors are paid in addition to the DRG/HIPPS payment. For FY 2005, this payment is based on 95 percent of AWP. For FY 2006, the add-on payment for blood clotting factor administered to hemophilia inpatients is based on average sales price (ASP) + 6 percent and a furnishing fee. The furnishing fee is updated each calendar year. For a SNF subject to SNF/PPS, the payment is bundled into the SNF/PPS rate.

For hospitals subject to OPPS, the clotting factors, when paid under Part B, are paid the APC. For SNFs the clotting factors, when paid under Part B, are paid based on cost.

Local carriers and Part B MACs shall process non-institutional blood clotting factor claims.

The FIs and Part A MACs shall process institutional blood clotting factor claims (Part A and Part B institutional).

80.4.1 - Clotting Factor Furnishing Fee

(Rev. 2279, Issued: 08-19-11, Effective: 01-01-12, Implementation: 01-03-12)

The Medicare Modernization Act section 303(e)(1) added section 1842(o)(5)(C) of the Social Security Act which requires that, beginning January 1, 2005, a furnishing fee will be paid for items and services associated with clotting factor.

Beginning January 1, 2005, a clotting factor furnishing fee is separately payable to entities that furnish clotting factor unless the costs associated with furnishing the clotting factor is paid through another payment system.

The clotting factor furnishing fee is updated each calendar year based on the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending with June of the previous year. The clotting factor furnishing fees applicable for dates of service in each calendar year (CY) are listed below:

CY 2005 - $0.140 per unit
CY 2006 - $0.146 per unit
CY 2007 - $0.152 per unit
CY 2008 - $0.158 per unit
CY 2009 - $0.164 per unit
CY 2010 - $0.170 per unit
CY 2011 - $0.176 per unit
CY 2012 - $0.181 per unit

Annual updates to the clotting factor furnishing fee are subsequently communicated by a Recurring Update Notification.

CMS includes this clotting factor furnishing fee in the nationally published payment limit for clotting factor billing codes. When the clotting factor is not included on the Average Sales Price (ASP) Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, the contractor must make payment for the clotting factor as well as make payment for the furnishing fee.

80.5 - Self-Administered Drugs

(Rev. 1539: Issued: 06-20-08; Effective/Implementation Date: 07-21-08)

See Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.2.

80.6 – Intravenous Immune Globulin

(Rev. 1338: Issued: 09-21-07; Effective: 01-01-08; Implementation: 01-07-08)

Beginning for dates of service on or after January 1, 2004, Medicare pays for intravenous immune globulin administered in the home. (See the Medicare Benefit Policy Manual, Chapter 15 for coverage requirements.) Contractors pay for the drug, but not the items or services related to the administration of the drug when administered in the home, if deemed medically appropriate.

Contractors may pay any entity licensed in the State to furnish intravenous immune globulin. Payment will be furnished to the entity with the authority to furnish the drug. Beneficiaries are ineligible to receive payment for the drug.

Pharmacies and hospitals dispensing intravenous immune globulin for home use would bill the DME MAC. If the beneficiary is receiving treatment in an outpatient hospital, the bill must be sent to the FI or A/B MAC. If the beneficiary is receiving treatment in a physician's office, the bill must be sent to the carrier or A/B MAC. Home Health Agencies dispensing intravenous immune globulin would bill the RHHI. Physicians furnishing intravenous immune globulin for the refilling of an external pump for home infusion would bill the DME MAC.

Effective January 1, 2006, Medicare makes an additional payment once per day per beneficiary for preadministration-related services whenever a beneficiary receives intravenous immune globulin.

80.7 - Pharmacy Supplying Fee and Inhalation Drug Dispensing Fee

(Rev. 754, Issued: 11-10-05, Effective: 01-01-06, Implementation: 01-03-06)

Section 303(e) (2) of the MMA implements a supplying fee for immunosuppressive drugs, oral anti-cancer chemotherapeutic drugs, and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen. Effective January 1, 2005, Medicare paid a separately billable supplying fee of $24.00 to a pharmacy, dialysis facility in the State of Washington or any hospital outpatient department not subject to the OPPS for each supplied prescription of the above-mentioned drugs. In addition, Medicare also paid a separately billable supplying fee of $50.00 for the initial supplied prescription of the immunosuppressive drugs during the first month following the patient's transplant.

Effective January 1, 2006, we are changing the supplying fee when multiple prescriptions are supplied in a 30-day period. Medicare will pay $24 for the first prescription of the above-mentioned drugs supplied by a pharmacy in a 30-day period, and will pay $16 for each subsequent prescription, after the first one, supplied in that 30-day period. A pharmacy will be limited to one $24 fee per 30-day period even if the pharmacy supplies more than one category of the abovementioned drugs (for example, an oral-anticancer drug and an oral anti-emetic drug) to a beneficiary. If two different pharmacies supply the above-mentioned drugs to a beneficiary during a 30-day period, each pharmacy will be eligible for one $24 supplying fee for the first prescription supplied during that 30-day period, and a supplying fee of $16 for each subsequent prescription supplied in that 30-day period. For a refill prescription, Medicare will allow payment of a $24 supplying fee to a particular supplier up to seven days before the end of the 30-day period for which the

last $24 supplying fee was paid to that supplier; however, each supplier will be limited to twelve $24 supplying fees per beneficiary per year. Medicare will pay a supplying fee for each prescription, including prescriptions for different strengths of the same drug supplied on the same day (for example, a prescription for 100 mg tablets and 5 mg Tablets). These changes do not alter the one-time $50 supplying fee for the first immunosuppressive prescription after a transplant.

We are also changing the dispensing fee for inhalation drugs furnished through durable medical equipment. Effective January 1, 2006, Medicare will pay an initial dispensing fee of $57 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This initial 30-day dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary. Except in those circumstances where an initial 30-day dispensing fee is applicable, Medicare will pay a dispensing fee of $33 to a pharmacy/supplier for each 30-day supply of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during the 30 day period. Medicare will pay a dispensing fee of $66 to a pharmacy/supplier for each 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during the 90 days. Only one 30-day dispensing fee will be payable per 30-day period, and only one 90-day dispensing fee will be payable per 90-day period, regardless of the numbers of suppliers used during the respective periods. A 30-day and 90-day supplying fee cannot be paid for drug supplied for the same month. For a refill prescription, Medicare will allow payment of the dispensing fee no sooner than 7 days before the end of usage for the current 30-day or 90-day period for which a dispensing fee was previously paid. Each inhalation drug supplier will be allowed no more than 12 months of dispensing fees per beneficiary per year. Medicare will not pay separately for compounding drugs. This cost is in the dispensing fees.

Supply fees and dispensing fees must be billed on the same claim as the drug.

HCPCS Codes and Fees:

GO369, G0370, G0371, G0374 – not recognized by Medicare as of 1/1/06.

Q0510 – First immunosuppressive prescription after a transplant, $50.00 fee

Q0511 – Pharmacy supplying fee for immunosuppressive, oral-anti-cancer, and oral anti-emetic drugs, first prescription in a one month period. Each pharmacy may receive this fee once in a 30-day period. Fee is $24.00.

Q0512 – Pharmacy supplying fee for immunosuppressive, oral anti-cancer, and oral anti-emetic drugs – each subsequent prescription in a 30-day period. Fee is $16.00.

Q0513 – Pharmacy dispensing fee for inhalation drug(s); per 30-days.

Effective 1/1/06, Medicare will pay a dispensing fee of $33.00 to a pharmacy for a 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that period. Payment will be made on the first claim received.

Q0514 – Pharmacy dispensing fee for inhalation drugs(s); per 90-days.

Effective 1/1/06, Medicare will pay a dispensing fee of $66.00 to a pharmacy for a 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that period. Payment will be made on the first claim received.

G0333- Pharmacy dispensing fee for initial inhalation drug(s); initial 30 day supply to a beneficiary.

Effective January 1, 2006, Medicare will pay an initial dispensing fee of $57.00 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This initial 30-day dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary.

Based on the code descriptions above, a supplying fee and a dispensing fee is not appropriate for one drug. The supplying fee is for immunosuppressives, oral anti-cancer drugs and oral anti-emetic drugs. The dispensing fee is for inhalation drugs only. A supplier cannot be paid for more than one of the following -- an initial dispensing fee (G0333), a 30-day dispensing fee (Q0513), or a 90-day dispensing fee (Q0514) – for a beneficiary for the same period.

80.8 - Reporting of Hematocrit and/or Hemoglobin Levels

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

Effective January 1, 2008, the following claims must report the most recent hematocrit or hemoglobin reading:

1. All claims billing for the administration of an ESA (HCPCS J0881, J0882, J0885, J0886 and Q4081).

2. All claims for the administration of a Part B anti-anemia drug (other than ESAs) used in the treatment of cancer that are not self-administered.

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

For professional paper claims, test results are reported in item 19 of the Form CMS-1500 claim form. For electronic claims (837P), 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.

Effective for dates of service on and after January 1, 2008, contractors will return paper and electronic professional claims when the most recent hemoglobin or hematocrit test results are not reported. Use Reason code 16 and Remark codes MA130 and N395 to return ESA service when the most recent hemoglobin or hematocrit test results are not submitted on the claim.

80.9 - Required Modifiers for ESAs Administered to Non-ESRD Patients

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

Effective January 1, 2008, all non-ESRD claims billing HCPCS J0881 and J0885 must begin reporting one of the following modifiers:

EA: ESA, anemia, chemo-induced
EB: ESA, anemia, radio-induced
EC: ESA, anemia, non-chemo/radio

Institutional claims that do not report one of the above modifiers will be returned to the provider.

Professional claims that are billed without the required modifiers will be returned as unprocessable.

Use Reason code 4 and Remark code MA 130 to return ESA services billed without one of the required modifiers.

ESAs administered for more than one of the indicated therapies are billed as separate line items (i.e., ESAs for chemo-induced anemia (EA modifier) are reported as separate line items (e.g., J0881EA); ESAs for radio-induced anemia (EB modifier) are reported as separate line items (e.g., J0885EB); ESAs for non-chemo/radio induced anemia (EC modifier) are reported as separate line items (e.g., J0881EC). Only one of the three ESA modifiers may be reported at the line item level.

Use Reason code 125 and Remark code N63 to return HCPCS J0881 or J0885 billed with more than one ESA modifier at the line item level.

80.10 - Hospitals Billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

NOTE: For EPO and Aranesp billing instructions for beneficiaries with ESRD, see the Claims Processing Manual, Chapter 8, sections 60.4 and 60.7.

For patients with chronic renal failure who are not yet on a regular course of dialysis, EPO and Aranesp administered in a hospital and billed as an outpatient service on type of bill 13x or inpatient Part B bill type 12x are paid under the Outpatient Prospective Payment System (OPPS). Non-OPPS hospitals are paid on reasonable charges.

Hospitals report charges under revenue code 0636. For EPO, hospitals report charges under revenue code 0636 with HCPCS code J0885 effective January 1, 2006. Aranesp is reported with HCPCS code J0881 effective January 1, 2006.

80.11 - Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)

(Rev. 1212; Issued: 03-30-07; Effective: 01-01-07; Implementation: 06-29-07)

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA), such as epoetin alfa (EPO) and Darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA.

Effective for claims submitted on or after February 1, 2007 with dates of services on or after January 1, 2007, all providers billing for injections of ESA for ESRD beneficiaries are encouraged to include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. All providers billing for injections of ESAs for ESRD beneficiaries will be required to include route of administration when claims processing system changes are completed. Renal dialysis facilities claim including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method.

80.12 - Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy

(Rev. 1413; Issued: 01-14-08; Effective: 07-30-07; Implementation: 04-07-08)

The national coverage determination (NCD) titled, "The Use of ESAs in Cancer and Other Neoplastic Conditions" lists coverage criteria for the use of ESAs in patients who have cancer and experience anemia as a result of chemotherapy or as a result of the cancer itself. The full NCD can be viewed in Publication 100-03 of the NCD Manual, section 110.21.

Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) shall be denied when any one of the following diagnosis codes is present on the claim:

- any anemia in cancer or cancer treatment patients due to folate deficiency (281.2),
- B-12 deficiency (281.1, 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), or
- bleeding (280.0, 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).

Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) 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 chemotherapy-induced anemia,
- prophylactic use to reduce tumor hypoxia,
- patients with erythropoietin-type resistance due to neutralizing antibodies; and
- anemia due to cancer treatment if patients have uncontrolled hypertension.

Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EB (ESA, anemia, radio-induced), shall be denied.

Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 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.

NOTE: ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regime.

Effective for claims with dates of service on and after January 1, 2008, Medicare contractors shall have discretion to establish local coverage policies for those indications not included in NCD 110.21.

Denials of claims for ESAs are based on reasonable and necessary determinations established by NCD 110.21. A provider may have the beneficiary sign an Advanced Beneficiary Notice, making the beneficiary liable for services not deemed reasonable and necessary and thus not covered by Medicare.

Report Medicare Summary Notice message 15.20, "The following policies [NCD 110.21] were used when we made this decision", and remittance reason code 50, "These are non-covered services because this is not deemed a `medical necessity' by the payer" for denied ESA claims.

Medicare contractors have the discretion to conduct medical review of claims and reverse the automated adjudication if the medical review results in a determination of clinical necessity.

90 - Claims Processing Rules for Hospital Outpatient Billing and Payment

(Rev. 1, 10-01-03)

90.1 - Blood/Blood Products and Drugs Classified in Separate APCs for Hospital Outpatients

(Rev. 496, Issued: 03-04-05, Effective: 07-01-05, Implementation: 07-05-05)

Proper Billing for Blood Products and Blood Storage and Processing

Refer to Pub.100-04, Medicare Claims Processing Manual, Chapter 4, §231 regarding billing for blood and blood products under the Hospital Outpatient Prospective Payment System (OPPS).

90.2 - Drugs, Biologicals, and Radiopharmaceuticals

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

A. General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and Radiopharmaceuticals

Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

Payment for drugs, biologicals and radiopharmaceuticals under the OPPS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.

Under the OPPS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug code (J9999 or J3490). In these situations, it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Recurring Update Notifications. The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively, that can be found under the CMS quarterly provider updates on the CMS Web site at:
http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp

Future updates will be issued in a Recurring Update Notification.

B. Correct Reporting of Biologicals When Used As Implantable Devices

When billing for biologicals where the HCPCS code describes a product that is solely surgically implanted or inserted, whether the HCPCS code is identified as having pass-through status or not, hospitals are to report the appropriate HCPCS code for the product. In circumstances where the implanted biological has pass-through status, a separate payment for the biological is made. In circumstances where the implanted biological does not have pass-through status, the OPPS payment for the biological is packaged into the payment for the associated procedure.

When billing for biologicals where the HCPCS code describes a product that may either be surgically implanted or inserted or otherwise applied in the care of a patient, hospitals should not separately report the biological HCPCS codes, with the exception of biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPPS, hospitals are provided a packaged APC payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using biologicals during surgical procedures as implantable devices, hospitals may include the charges for these items in their charge for the procedure, report the charge on an uncoded revenue center line, or report the charge under a device HCPCS code (if one exists) so

these costs would appropriately contribute to the future median setting for the associated surgical procedure.

C. Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Payment for drugs, biologicals, and radiopharmaceuticals may be made under the pass-through provision which provides additional payments for drugs, biologicals, and radiopharmaceuticals that meet certain requirements relating to newness and relative costs. According to section 1833(t) of the Social Security Act, transitional pass-through payments can be made for at least 2 years, but no more than 3 years. For the process and information required to apply for transitional pass-through payment status for drugs, biologicals, and radiopharmaceuticals, go to the main OPPS Web page, currently at http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage to see the latest instructions. (**NOTE:** Due to the continuing development of the new cms.hhs.gov Web site, this link may change.) Payment rates for pass-through drugs, biologicals, and radiopharmaceuticals are updated quarterly. The all-inclusive list of billable drugs, biologicals, and radiopharmaceuticals for pass-through payment is included in the current quarterly Addendum B. The most current Addendum B can be found under the CMS quarterly provider updates on the CMS Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp.

D. Non Pass-Through Drugs and Biologicals

Under the OPPS, drugs and biologicals that are not granted pass-through status receive either packaged payment or separate payment. Payment for drugs and biologicals with estimated per day costs equal to or below the applicable drug packaging threshold is packaged into the payment for the associated procedure, commonly a drug administration procedure. Drugs and biologicals with per day costs above the applicable drug packaging threshold are paid separately through their own APCs.

E. Radiopharmaceuticals

1. General

Beginning in CY 2008, the OPPS divides radiopharmaceuticals into two groups for payment purposes: diagnostic and therapeutic. Diagnostic radiopharmaceuticals function effectively as products that enable the provision of an independent service, specifically, a diagnostic nuclear medicine scan. Therapeutic radiopharmaceuticals are themselves the primary therapeutic modality.

Beginning January 1, 2008, the I/OCE requires claims with separately payable nuclear medicine procedures to include a radiolabeled product (i.e., diagnostic radiopharmaceutical, therapeutic radiopharmaceutical, or brachytherapy source). Hospitals are required to submit the HCPCS code for the radiolabeled product on the same claim as the HCPCS code for the nuclear medicine procedure. Hospitals are also instructed to submit the claim so that the services on the claim each reflect the date the

particular service was provided. Therefore, if the nuclear medicine procedure is provided on a different date of service from the radiolabeled product, the claim will contain more than one date of service. More information regarding these edits is available on the OPPS Web site at http://www.cms.hhs.gov/HospitalOutpatientPPS/.

There are rare situations where a hospital provides a radiolabeled product to an inpatient, and then the patient is discharged and later returns to the outpatient department for a nuclear medicine imaging procedure but does not require additional radiolabeled product. In these situations, hospitals are to include HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) with a token charge (of less than $1.01) on the same claim as the nuclear medicine procedure in order to receive payment for the nuclear medicine procedure. HCPCS code C9898 should only be reported under the circumstances described above, and the date of service for C9898 should be the same as the date of service for the diagnostic nuclear medicine procedure.

2. Diagnostic Radiopharmaceuticals

Beginning in CY 2008, payment for nonpass-through diagnostic radiopharmaceuticals is packaged into the payment for the associated nuclear medicine procedure.

3. Therapeutic Radiopharmaceuticals

The OPPS will continue to pay for therapeutic radiopharmaceuticals at charges adjusted to cost from January 1, 2008 through December 31, 2009.

90.2.1 - HCPCS Codes Replacements

(Rev. 1, 10-01-03)

PM A-02-026 §IX.A

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Program Memorandum. The latest payment rates associated with each APC number may be found in the OPPS PRICER file available on the CMS Web site, as well as in Addendum A and B of OPPS Final Rule. Refer to the current rule found at http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf.

90.3 – Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code

(Rev. 1760, Issued: 06-23-09; Effective Date: 07-01-09; Implementation Date: 07-06-09)

Section 621(a) of the MMA amends Section 1833(t) of the Social Security Act by adding paragraph (15), Payment for New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services for which a product-specific HCPCS code

has not been assigned shall be paid an amount equal to 95 percent of average wholesale price (AWP). This provision applies only to payments under the hospital outpatient prospective payment system (OPPS).

Beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a product-specific HCPCS code has not been assigned. Beginning on or after the date of FDA approval, hospitals may bill for the drug or biological using HCPCS code C9399, Unclassified drug or biological.

Hospitals report in the ANSI ASC X-12 837 I in specific locations, or in the "Remarks" section of the CMS 1450):

1. the National Drug Code (NDC),

2. the quantity of the drug that was administered, expressed in the unit of measure applicable to the drug or biological, and

3. the date the drug was furnished to the beneficiary.

Contractors shall manually price the drug or biological at 95 percent of AWP. They shall pay hospitals 80 percent of the calculated price and shall bill beneficiaries 20 percent of the calculated price, after the deductible is met. Drugs and biologicals that are manually priced at 95 percent of AWP are not eligible for outlier payment.

HCPCS code C9399 is only to be reported for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which there is no HCPCS code that describes the drug.

90.4 – Hospital Billing For Take-Home Drugs

(Rev. 882, Issued: 03-03-06; Effective: 07-01-06; Implementation: 07-03-06)

All hospitals, including critical access hospitals (CAHs), bill the appropriate DMERC for take-home supplies of oral anti-cancer drugs, oral anti-emetic drugs and multi-day supplies of immunosuppressive drugs, as well as the associated supplying fees. All inhalation drugs and the associated dispensing fees are also billed to the DMERC.

Claims for these take-home drugs are billed on the NCPDP, a HIPAA-compliant telecommunication format specifically designed for drug billing. All entities billing on the NCPDP use the NDC for the particular drug being billed, and list units as multiples of the quantity represented by the NDC. Follow this link to reach the DMERC version of the NCPDC implementation guide:
http://www.cms.hhs.gov/transmittals/downloads/R689CP.pdf.

When beneficiaries come to a hospital outpatient department and have an encounter with a physician or mid-level professional (e.g., a physician assistant or nurse practitioner)

during which one or more specimens are collected for laboratory work, treatment is monitored (including anti-cancer drugs, either oral or infused), and a drug is administered, this is considered an outpatient visit. Only when more than a single day's supply of a drug is dispensed to the beneficiary for take home use are the drugs so dispensed to be billed to the appropriate DMERC. When only today's drug(s)is (are) dispensed and other services are rendered in conjunction with the treatment, the entire visit is billed by the hospital to the local FI.

When a beneficiary in a hospital or skilled nursing facility (SNF) non-covered stay, or a hospital/SNF inpatient that has exhausted benefits (TOBs 12x or 22x, respectively) is given a covered oral anti-cancer or anti-emetic drug, or a covered immunosuppressive drug, the hospital or SNF bills its regular FI. Payment to hospitals is dependent on the applicable payment mechanism for the type of hospital (reasonable cost for TEFRA hospitals and CAHs, ambulatory payment classifications (APCs) for hospitals subject to the hospital outpatient PPS (OPPS).

Immunosuppressive drugs and supplying fees provided by a dialysis facility in the State of Washington are billed to and paid by the FI.

Supplying fees and dispensing fees must be billed on the same claim as the drug.

100 - The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

Section 303 (d) of the Medicare Prescription Improvement and Modernization Act (MMA) of 2003 requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after July 1, 2006, physicians will be given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. For purposes of the CAP, the term "a physician" includes individuals defined under §1861(s) of the Social Security Act who are authorized to provide physician services under §1861(s) of the Act and who can, within their State's scope of practice, prescribe and order drugs covered under Medicare Part B.

For 2006, the first CAP year will run from July 1, 2006 through December 31, 2006. In subsequent years, it will run annually on a calendar year basis.

The Secretary may exclude drugs from the CAP if competitive pricing will not result in significant savings, or is likely to have an adverse impact on access to such drugs. The statute gives CMS the authority to select drugs, or categories of drugs, that will be included in the program, to establish geographic competitive acquisition areas, and to phase in these elements as appropriate.

A competition will be held every 3 years to award contracts to approved CAP vendors that will supply drugs and biologicals for the program. A 3-year contract will be awarded to qualified approved CAP vendors in each geographic area who have and maintain: 1) Sufficient means to acquire and deliver competitively biddable drugs within the specified contract area; 2) Arrangements in effect for shipping at least 5 days each week for the competitively biddable drugs under the contract and means to ship drugs in emergency situations; 3) Quality, service, financial performance, and solvency standards; and 4) A grievance and appeals process for dispute resolution. A vendor's contract may be terminated during the contract period if they do not abide by the terms of their contract with CMS. CMS will establish a single payment amount for each of the competitively bid drugs and areas, for this 3year cycle there will be one drug category and one geographic area. After CAP drug prices are determined and vendor contracts are awarded the information will be posted to a directory on the Medicare Web site.

Medicare physicians will be given an opportunity to elect to participate in the CAP on an annual basis. Physicians who elect to participate in CAP will continue to bill their local carrier for drug administration. Except where applicable State pharmacy law prohibits it, the CAP Participating Physicians will supply the following information to the approved CAP vendor at the time that a CAP drug order is placed: date of order, beneficiary name, address, and phone number, physician identifying information: name, practice location/shipping address, group practice information, NPI; drug name, strength, quantity ordered, dose, frequency/ instructions, anticipated date of administration, beneficiary Medicare information/ Health insurance (HIC) number, supplementary insurance information (if applicable), Medicaid information (if applicable), additional patient information: date of birth, allergies, height/weight, and ICD-9-CM if necessary. Claims for erythropoiesis stimulating agents (ESAs) must contain the most recent hematocrit or hemoglobin value. CAP drug claims for any drugs furnished to an individual for the treatment of anemia shall be returned if the most recent laboratory values for hemoglobin or hematocrit are not reported on the claim per Medicare requirements.

The participating CAP physicians will receive all of their drugs from the approved CAP vendor for the drug categories they have selected, with only one exception. The exception will be for "furnish as written" situations where the participating CAP physician requires that, due to medical necessity, the beneficiary must have a specific drug, defined by its National Drug Code (NDC), for one of the HCPCS codes within the approved CAP vendor's drug list if that specific drug NDC is not available on the CAP drug list. The participating CAP physician may buy the drug, administer it to the beneficiary and bill Medicare using the ASP system. The local carrier will monitor drugs obtained using the "furnish as written" provision to ensure that the participating CAP physician is complying with Medicare payment rules.

The CAP will also allow a participating CAP physician to provide a drug to a Medicare beneficiary from his or her own stock and obtain the replacement drug from the approved CAP vendor when certain conditions are met. The local carrier will monitor drugs ordered under the replacement provision to ensure that the participating CAP physician is complying with Medicare payment rules.

Approved CAP vendors must qualify for enrollment in Medicare as a supplier, and will be enrolled as a new provider specialty type. The approved CAP vendor's claims for the drugs will be submitted to one designated Medicare carrier. The approved CAP vendor will bill the Medicare designated carrier for the drug and the beneficiary for any applicable coinsurance and deductible under the MMA, for CAP claims submitted after July 1, 2006 but before April 1, 2007, payment to the approved CAP vendor for the drug was conditioned on verification that the drug was administered to the Medicare beneficiary. Proof that the drug was administered was established by matching the participating CAP physician's claim for drug administration with the approved CAP vendor's claim for the drug in the Medicare claims processing system by means of a prescription number on both claims. When the claims matched in the claims processing system, the approved CAP vendor was paid in full.

Title II, section 108(a) of the Tax Relief and Health Care Act of 2006 (TRHCA), struck language used to develop the existing CAP claims matching process and furthermore required the implementation of a post payment review process effective April 1, 2007. The post payment review process is required to assure that drugs supplied under the CAP have been administered to a beneficiary and the process must establish a mechanism to recoup, offset or collect any overpayments to the approved CAP vendor. The CMS is implementing CAP claims processing changes in order to comply with THRCA by April 1, 2007. Pending CAP claims submitted prior to April 1, 2007, and all new CAP claims submitted on or after April 1 will be subject to the post payment review process. Until drug administration is verified, the approved CAP vendor may not bill the beneficiary and/or his third party insurance for any applicable coinsurance and deductible. For more information on the CAP claims processing see FR70251.

100.1 – Physician Election and Information Transfer Between Carriers and the Designated Carrier for CAP Claims

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Prior to each annual election period, CMS will post on its Web site a list of the vendors that have been selected to participate in the CAP, the categories of drugs they will be providing, and the geographic areas within which each vendor will operate. Physicians will then elect the approved CAP vendors they choose to receive drugs from under the CAP. The election period will end each year approximately 45 days after the list of vendors is posted on the CMS Web site.

100.1.1 – Physician Information for the Designated Carrier

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

10 Calendar days after the end of the annual election period, the 2006 election period, by May 25, 2006 carriers shall create a table and forward it to the designated carrier. The table will indicate which physicians have elected to participate in CAP, for which drugs, and with which vendors. When carriers receive applications, they shall verify that the

chosen vendor is valid per the CMS Web site. If an invalid vendor has been chosen, an educational contact shall be made to resolve the issue.

Carriers shall forward this table each year to the designated carrier by 7calender days after the end of the election period. Should that date fall on a weekend, it shall be extended to the following Monday.

The table shall include the physician's name, the street address, city, state, zip code, and phone number of each practice address/shipping address (the physical location where the drugs will be administered and the CAP drugs shipped to), PIN, UPIN (or NPI when effective), e-mail address (if available). If the mailing/correspondence address (where the participating CAP physician can be contacted directly) is different from the practice/shipping address, the mailing/correspondence shall be included. If the group or individual practice has more than one practice location where drugs are administered, each practice address/shipping location where drugs will be administered shall also be included. For group practices that elect to participate in CAP, the group PIN as well as the individual PINs and UPINs (NPI when effective) shall be included.

The carriers shall manually add any additional practice/shipping addresses and the mailing/correspondence address to the spreadsheet provided to them by the standard system before sending the information to the designated carrier. Carriers shall also remove any members of a group practice who do not qualify to provide services under the CAP. In order to qualify to provide services under the cap the providers must have prescriptive authority in their state to prescribe medications. Examples of provider types that may or may not have prescriptive authority in their states are nurse practitioners and physician's assistants.

Since group practices must commit as a practice to enroll in the CAP program if they bill using the group's PIN, if the carrier receives from the standard system names of providers in a group for whom an election form has not been received, they shall contact the group practice to verbally request the required election form information. Carriers shall only remove names from the CAP provider table when it has been determined that the physician is no longer a member of a group practice. Carriers shall not allow a group practice to participate in the CAP until all election information has been obtained for each eligible practice member within that group who bills using the group's PIN.

The designated carrier shall transmit information to each vendor on the physicians and practitioners who have elected that particular vendor 30 days prior to the start of the CAP year.

100.1.1.1 – Quarterly Updates

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

On a quarterly basis, CMS may provide updates to the HCPCS codes that the participating CAP physician must accept for the CAP. Carriers must add these HCPCS codes to the table created in 100.1.1 by 7 days after receipt of the changes from CMS.

100.1.2 – Format for Data

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

In order to simplify the transfer of physician election information, prior to end of the election period, the carriers and the designated carrier shall determine a common format in which to send the information to the designated carrier. This format shall remain constant for subsequent years unless CMS issues instructions that it is to be changed.

100.1.3 – Physician Information for the Vendors

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

One month before the beginning of the calendar year, the designated carrier shall transmit the following information to each vendor on the physicians who have elected that particular vendor: the name, the street address, city, state, zip code, and phone number of each practice address/shipping address (physical location where the drugs will be administered), UPIN (or NPI when effective), e-mail address (if available) of the physicians who have elected to participate in CAP with that vendor and the drugs they have chosen. If the mailing/correspondence address (where the participating CAP physician can be contacted directly) is different from the practice/shipping address, the mailing/correspondence shall be included. If the group or individual practice has more than one practice location where drugs are administered, each practice address/shipping location where drugs will be administered shall also be included. (**NOTE:** For the 2006 claims processing period, the information must be sent by June 1, 2006).

For group practices that elect to participate in CAP, the individual UPINs (NPI when effective) shall be included.

Each year the date the designated carrier shall transmit information to each vendor on the physicians who have elected that particular vendor shall be 7 calendar days after the final date the carriers forward to the designated carrier the list of all the physicians who have elected to participate in CAP. Should that date fall on a weekend, it shall be extended to the following Monday.

The designated carrier shall not send a vendor any information pertaining to other vendors.

100.2 - Claims Processing Instructions for CAP Claims for the Local Carriers

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

The carrier shall not process CAP claims submitted for United Mine Worker or Medicare Advantage or Railroad Board beneficiaries. Carriers shall follow normal procedures for the disposition of these claims.

Carriers shall pay for the administration of the drugs for which physicians have elected to receive under CAP. CAP claims are required to comply with Medicare rules and requirements for modifiers and other supporting information unless specific exceptions are made. The local carriers shall process CAP claims from physicians per the following instructions.

100.2.1 - CAP Required Modifiers

(Rev. 1409, Issued: 01-11-08, Effective/Implementation: 02-11-08)

The carrier shall identify physicians who have elected CAP and will no longer pay the physician for drugs under the ASP system that were obtained through CAP. Carriers shall continue to pay physicians for the administration of CAP drugs. Unless claims for the CAP drugs include the no-pay (J1), furnish as written (J3) modifier, or MSP (M2) modifier the claim will be denied.

Carriers shall return the following Medicare Summary Notice (MSN) messages and Remittance Advice (RA) messages when physicians submit a claim for a drug they have provided under the CAP without the J1, J3, or MSP modifiers:

MSN 7.7 – Your physician has elected to participate in the Competitive Acquisition Program for these drugs. Claims for these drugs must be billed by the appropriate drug vendor rather than your physician.

Spanish Version 7.7 - Su médico eligió participar en el Programa de Adquisición Competitiva para estas medicinas. Las reclamaciones para estas medicinas deben ser facturadas por el distribuidor de medicinas adecuado y no por su médico.

Claim Adjustment Reason Code 96 – Non-covered charges.

RA Remark Code N348 - You chose that this service/supply/drug would be rendered/supplied and billed by a different practitioner/supplier.

Carriers shall treat as unprocessable CAP claims with the following invalid modifier combinations on CAP claims:

J1 + J3 – invalid
J2 without a J1 – invalid
J2 + J3 – invalid

Carriers shall treat as unprocessable claims received with invalid modifier combinations. Carriers shall return any appropriate Remittance Advice Reason Codes and the following Remark Code messages when claims are received with invalid modifier combinations:

Remark Code MA130 – Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information.

and

Remark Code MA78 – Missing/incomplete/invalid HCPCS modifier

100.2.2 – Submitting the Charges for the Administration of a CAP Drug and the No Pay Service Lines

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

No pay service lines are identified by the modifier code: J1 – Competitive Acquisition Program, no-pay submission for a prescription number.

On both paper and electronic claims, the physician must submit their charges for the administration of the CAP drug and an additional no-pay service line for each prescription number. Each no-pay service line shall include the no-pay modifier J1, a HCPCS drug code, and a prescription number. The J1 modifier should always be entered in the first modifier position.

The no-pay service lines shall be submitted with the regular billed charges for the administration of these drugs. No payment shall be made for services received with the CAP no-pay modifier and they shall bypass the MSP Pay module.

100.2.3 – Submitting the Prescription Order Numbers and No Pay Modifiers

(Rev. 1453: Issued: 02-22-08; Effective/Implementation Dates: 07-07-08)

On paper claims the prescription numbers must be entered in Item 19. On electronic claims the prescription number must be entered at the line level in the ANSI X12 837P LOOP 2410 REF02 (REF01=XZ) of the 4010A1 version. As the Implementation Guide requires the entry of the National Drug Code (NDC) number in the LIN segment in order to enter the prescription number, the NDC will be required as well. The NDC must be submitted in LOOP 2410 LIN03 (LIN02=N4).

The prescription number will consist of the vendor identification (ID) number, the HCPCS code, and the vendor controlled prescription number. Each vendor controlled prescription number shall be a unique number and shall not consist of all zero's.

The standard system shall add the prescription number received on either paper or electronic claims to the claims screen and retain the information in history. Carriers shall forward the prescription number on both paper and electronic claims to CWF.

For paper claims, the carriers shall return as unprocessable paper claims submitted with the J1 modifier, but no prescription number. The contractors shall return the following Remittance Advice Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Codes (RARCs):

CARC 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using remittance advice remarks codes whenever appropriate. This change to be effective 4/1/2007: At least one Remark Code must be provided (may be comprised of either the Remittance Advice Remark Code or NCPDP Reject Reason Code.)

RARC 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 the complete/correct information.

RARC N388 – Missing/incomplete/invalid prescription number.

The standard system shall create a pre-pass edit to reject claims from physicians or practitioners submitted with a no-pay modifier on a line, but without a prescription number on that same line. The carriers shall return the following messages:

RARC MA130 – Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

RARC N388 – Missing/incomplete/invalid prescription number.

100.2.3.1 - Further Editing on the Prescription Order Number

(Rev. 1453: Issued: 02-22-08; Effective/Implementation Dates: 07-07-08)

Prescription order numbers submitted with inappropriate spaces inserted disrupt the matching process between the physician/provider claims and the vendor claims. Effective for claims processed on or after July 7, 2008, contractors shall implement edits to treat these claims as unprocessable.

Prescription order numbers submitted with less than 10 characters on CAP claims will also be treated as unprocessable. The Contractors shall return the following Remittance Advice Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Codes (RARCs) for either of the two prior situations:

CARC 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using remittance advice remarks codes whenever appropriate. This change to be effective 4/1/2007: At least one Remark Code must be provided (may be comprised of either the Remittance Advice Remark Code or NCPDP Reject Reason Code.)

RARC 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 the complete/correct information.

RARC N388 – Missing/incomplete/invalid prescription number.

In addition, CAP physicians/providers and CAP vendors may not submit new claims (processed as entry code 1) with prescription order numbers that they have already submitted on previously adjudicated claims, even if the prior claims have been denied. The CAP physicians/providers and CAP vendors must request an adjustment to the original claim (processed as entry code 5). Claims that have been returned as unprocessable may be accepted with the original prescription order number when resubmitted after being corrected.

CWF will create a new utilization error code that will be returned when it receives a claim that has a prescription order number on it that matches a prescription order number already on file from a different claim. This claim could be from the same physician/provider/supplier or a different physician/provider/supplier. CWF coding will differentiate between claims from the physicians/providers and claims from the CAP vendors. It will be acceptable to allow a claim with a duplicate prescription order number as long as one claim is from a physician/provider and the other claim is from the vendor. This will allow the prescription order number matching process to continue.

Contractors shall treat as unprocessable the entire claim when a claim receives the new CWF utilization error code. Contractors shall not allow appeals rights on claims treated as unprocessable in response to the new error code.

The Contractors shall return the following Remittance Advice Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Codes (RARCs):

CARC 18 – Duplicate claim/service.

RARC MA130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

RARC N389 – Duplicate prescription number submitted.

RARC M16 – Please see our Web site, mailings, or bulletins for more details covering this policy/procedure/decision.

RARC N185 – **Alert:** Do not resubmit this claim/service.

100.2.4 – CAP Claims Submitted With Only the No Pay Line

(Rev. 1055, Issued: 09-11-06; Effective: 10-01-06; Implementation: 10-02-06)

Physicians must submit their charges for the administration of CAP drugs and the no-pay lines on the same claim. Carriers shall treat as unprocessable claims received that only have services submitted with the no-pay modifier. Carriers shall return the following RA messages:

Claim Adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.

MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

Remark Code M67 – Missing/incomplete/invalid other procedure code(s).

100.2.5 – Use of the "Restocking" Modifier

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The restocking modifier is: J2 – Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration.

Under certain circumstances, physicians will be permitted to administer a drug they have on hand and go through the CAP program to restock it. Once the participating CAP physician orders and receives the restocking drug from the approved CAP vendor, the physician will bill for the administration fee. The physician will also include no-pay lines on the claim for each of the drugs as usual. These lines will include the restocking modifier in addition to the no-pay modifier (in the first modifier position), the procedure code for the drug, the prescription number and all other elements normally required. Carriers shall consider "restocking" drug claims for payment when the following requirements are met:

a) The physician has elected to receive the drug under CAP;

b) The physician has submitted the claim with the "restocking" modifier;

c) The physician received the drug from the CAP vendor to replace a drug he or she used from pre-existing stock.

d) The claim was submitted with the "restocking" modifier:

J2 – Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration.

By including the "restocking" modifier on the claim, the physician is asserting that:

a) The drug was required immediately;

b) The need couldn't be anticipated;

d) The drug was administered in an emergency situation; and

e) Documentation is being maintained in the file to validate the information in a – d and will be made available to the carrier at their request.

100.2.6 – Use of the "Furnish as Written" Modifier

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The "furnish as written" modifier is: J3 – Competitive Acquisition Program, (CAP) drug not available through CAP as written, reimbursed under average sales price methodology.

When the J3 modifier is used, the physician will be allowed to bill Medicare for a CAP drug in addition to the claim for the administration of that drug.

Carriers shall consider "furnish as written" drug administration claims for payment outside of the CAP program when the new "furnish as written" modifier is used.

By using only the J3 modifier on the claim, the physician is asserting that:

a) A specific drug product was medically necessary;

b) The selected drug vendor could not provide that specific brand and/or NDC for the CAP HCPCS code;

and

c) Documentation is being maintained on file to validate the information in a) and b) and will be made available to the carrier at their request.

100.2.7 – Monitoring of Claims Submitted With the J2 and/or J3 Modifiers

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

As part of their normal data analysis, carriers shall monitor these claims submitted with the J2, "restocking" modifier, or J3, the "furnish as written" modifier, for patterns of abuse and follow the Progressive Corrective Action (PCA) process described in the Program Integrity Manual, Chapter 3, Section 11.

100.2.8 – Claims Submitted for Only Drugs Listed on the Approved CAP Vendor's Drug List

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The carrier shall edit to verify that the no-pay lines (lines with the CAP drug HCPCS code and the J1modifier) that the participating CAP physician has billed is for a drug included in the CAP and is from the particular CAP vendor they have chosen to receive drugs from.

If the carrier determines that the physician has billed no-pay lines along with the codes for the payment of the administration for drug HCPCS code(s) that are not provided by the approved CAP vendor that the physician had selected, it shall return as unprocessable

those no-pay lines along with the lines for the codes for the payment of the administration for these drugs. The carrier shall return the following messages:

Remittance Advice Messages:

Claim Adjustment Reason Code 96 – Non-covered charges.

Remark Code N348 – You chose that this service/supply /drug would be rendered/supplied and billed by a different practitioner/supplier.

MSN Message 7.8 - Your physician has elected to participate in the Competitive Acquisition Program (CAP) for Medicare Part B drugs. Medicare cannot pay for the administration of the drug(s) being billed because these drug(s) are not available from the CAP vendor.

Spanish version 7.8: Su médico ha elegido participar en el Programa de Adquisición Competitiva (CAP, por sus siglas en inglés) para las medicinas cubiertas por la Parte B de Medicare. Medicare no puede pagar por el suministro de las medicinas cobradas porque estas medicinas no están disponibles del vendedor CAP.

100.2.9 - Submission of Claims With the Modifier JW, "Drug Amount Discarded/Not Administered to Any Patient"

(Rev. 1313; Issued: 07-23-07; Effective/Implementation Dates: 08-23-07)

The JW modifier must not be used on Medicare Part B Drug CAP claims; providers shall not code for wastage for drugs furnished under the CAP. Claims for drugs provided under CAP submitted with the JW modifier will be treated as unprocessable.

100.2.10 - MSP Situations Under CAP

(Rev. 1088, Issued: 10-27-06, Effective: 01-01-07, Implementation: 01-02-07)

Drugs Obtained Through the CAP for Beneficiaries With Insurance Primary to Medicare

Providers who elect into the CAP voluntarily agree to obtain CAP drugs for Medicare beneficiaries exclusively through an approved CAP vendor. In situations where participating CAP providers obtain a drug from the CAP vendor for a beneficiary who is incorrectly determined to have Medicare as their primary insurer, but the provider and the CAP vendor must first bill the appropriate primary insurer for the drug and the administration service.

Upon receipt of the primary insurer's payment, MSP claims should then be submitted by the physician to their local carrier for the administration service and by the approved CAP vendor to the CAP designated carrier for the drug. Providers are required to submit MSP claims even if they believe there is no outstanding balance due. Such claims must adhere to CAP guidelines and include the drug HCPCS code, the prescription number

provided by the approved CAP vendor and an appropriate CAP no-pay modifier. Approved CAP vendor claims must also adhere to CAP requirements and include the assigned prescription number.

All participating CAP providers to submit MSP claims for drug administration services where the drug was obtained from the approved CAP vendor. Failure to submit an MSP claim for the drug administration prevents the processing of the vendor's MSP claim by the CAP designated carrier.

Drugs Obtained Outside of the CAP for Beneficiaries With Medicare

In certain rare situations, participating CAP providers may mistakenly obtain drugs for Medicare beneficiaries outside of the CAP vendor because they had determined that the beneficiary had another insurer that was primary to Medicare. In order to make an appropriate payment for drugs administered under these unusual circumstances, we are allowing temporary use of the J3 modifier to bypass CAP edits and pay the participating CAP provider at the current ASP rate.

We have requested a modifier for use in this rare situation. Local carriers will be notified through the usual quarterly update process when a new modifier is available. At that time, the J3 modifier will no longer be accepted for this purpose.

As we expect the situations that require this modifier to be infrequent, local carriers have the ability to review claims with this modifier to monitor for proper use and educational opportunities.

MSP Claims For Drugs Present on the Provider's CAP Drug List

In order to prevent processing errors for MSP claims where the drug billed on the provider's claim is present on the selected CAP drug list, local carriers are to implement a SCF rule allowing an override of the CAP claims processing edits. This SCF rule will allow claims to be identified as MSP and not require the CAP modifiers or prescription number.

100.3 - Application of Local Medical Review Policies

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Carriers and/or Program Safeguard Contractors shall apply all Local Coverage Determination (LCD) policies and National Coverage Determination (NCD) policies to the administration and no-pay drug code lines on the CAP claims.

Should it be determined that a drug administration or drug code service line does not meet the requirements of the LCD, the carrier shall follow current processes to determine how to adjudicate the related services.

If appropriate, the carriers shall include messages on the MSN and RA to indicate which LCD was applied.

The carriers shall also apply all regular edits to the administration and no-pay drug lines and send appropriate denial messages.

100.4 - Claims Processing Instructions for the Designated Carrier
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall follow normal procedures to enroll the Drug Vendors as provider specialty type, 95, Competitive Acquisition Program (CAP) for Part B Drug Vendors.

A separate 4 position, alpha-numeric vendor identification number (VIN) shall be assigned to be used in the prescription number and a master list of which numbers are assigned to which vendors shall be kept.

The designated carriers shall forward the VIN to the carriers and to CMS 14 days after new CAP vendor contractors have been announced by CMS. CMS will post the VIN on the CMS Web site. Carriers shall download these identification codes from the CMS Web site and added them to the Carriers table.

For subsequent CAP years, this date will be the first Monday in November.

These codes shall be added to the Carriers table by 14 days after receipt.

The designated carrier shall track the name, the address, zip code, and phone number of each practice location/shipping address (location where the drugs will be administered), PIN, UPIN, (or NPI when effective), and e-mail (if available) of the physicians and physician groups and which vendors and which drugs they have chosen. In addition, the mailing/correspondence address (where the participating CAP physician can be contacted directly) for each physician shall also be tracked. This information shall be made available to CMS upon request.

On a quarterly basis, the designated carrier shall manually add additional HCPCS codes to the information above when received from the carriers. They shall add this information by 14 days after its receipt from the carriers.

The designated carrier shall only process CAP claims from approved drug vendors submitted in a HIPAA-compliant standard electronic format 4010A1 version (or later). All vendor claims shall be processed by the designated carrier. These will not include claims for United Mine Worker, Railroad or Medicare Advantage beneficiaries.

100.4.1 – Creation of Internal Vendor Provider Files
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall create an internal provider file for each vendor which includes the names, addresses, and UPINs, (NPI when effective), of those physicians who have elected that vendor.

The designated carrier shall edit incoming vendor claims to verify that the UPIN number on the claim for the ordering physician is one of the UPINs on the provider file for that vendor. The designated carrier shall treat the claim as unprocessable when it receives claims from vendors with ordering physician UPINs that do not match a physician UPIN on the provider file and return the following messages:

Remittance Advice Messages:

Reason Code 96 - Non-covered charge(s).

Remark Code: N265 – Missing/incomplete/invalid ordering provider primary identifier.

Medicare Summary Notice Messages:

17.11 This item or service can not be paid as billed.

and

9.7 – We have asked your provider/supplier to resubmit the claim with the missing or correct information.

Spanish:

17.11 -Este servicio no se puede pagar según facturado.

and

9.7 - Le hemos pedido a su proveedor que envíe la reclamación con la información omitida o incorrecta.

100.4.2 – Submission of Paper Claims by Vendors

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall treat as unprocessable paper claims submitted by vendors and return the following RA messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

Remark Code M117 – Not covered unless submitted via electronic format.

100.4.3 – Submission of Claims from Vendors With the J1 No Pay Modifier

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall treat as unprocessable claims submitted by vendors with a no-pay modifier and return the following RA messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

RA Remark Code MA130 – Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

100.4.4 - Submission of Claims from Vendors Without a Provider Primary Identifier for the Ordering Physician

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carriers shall edit to determine if a UPIN, (or NPI when effective), of the ordering physician has been entered on the claim. If the UPIN, (or NPI when effective), has not been entered on the claim, the designated carrier shall treat the claim as unprocessable.

Along with any other appropriate reason and remark codes, the following remark code shall be returned:

Remark Code N265 – Missing/incomplete/invalid ordering provider primary identifier.

100.4.5 – New MSN Message to Be Included on All Vendor Claims

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

On all vendor claims, whether paid or denied, the designated carriers shall include the following new Medicare Summary Notice Message:

Your physician participates in the Competitive Acquisition Program for Medicare Part B drugs (CAP). The drug(s) you received in your physician's office were provided by an approved CAP vendor. You will receive two separate Medicare Summary Notices (MSNs). This MSN is from the Medicare carrier that processes claims for your drug that came from the approved CAP vendor. You will receive another MSN from the Medicare carrier that processes claims for your physician, for the administration of the drug(s). If you appeal the determination for this drug vendor claim, you must send your appeal to the Medicare carrier address listed on the physician administration MSN, and not this vendor claim MSN.

Spanish:

Su médico participa en el Programa de Adquisición Competitiva para las medicinas cubiertas por la Parte B de Medicare (CAP, por sus siglas en inglés). Las medicinas que usted recibió en la oficina de su médico fueron provistas por un suplidor autorizado del

CAP. Usted recibirá dos Resúmenes de Medicare por separado. Este Resumen es de la empresa de seguros Medicare que procesa las reclamaciones de sus medicinas provistas por el suplidor autorizado del CAP. Usted recibirá otro Resumen de la empresa de seguros Medicare que procesa las reclamaciones de su médico, por el suministro de sus medicinas. Si usted apela la decisión de esta reclamación del suplidor de medicinas, debe enviar la apelación a la empresa de seguros Medicare que se menciona en el Resumen de la reclamación de su médico y no a la dirección que aparece en este Resumen.

100.4.6 – Additional Medical Information

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated carrier shall reserve the right to solicit, at any time, medical information to support adjudication of the drug vendor's claim.

100.4.7 – CAP Fee Schedule

(Rev. 1055, Issued: 09-11-06; Effective: 10-01-06; Implementation: 10-02-06)

CMS will provide a fee schedule for the payment of CAP drugs to the designated carrier and MCS. The fees will be provided in a file on the CMS mainframe at a later date. The file layout is attached.

CAP PROGRAM FEE SCHEDULE FILE RECORD DESCRIPTION

Field Name	Position	Length	Format	Description
HCPCS	1-5	5	Character	Healthcare Common Procedure Coding System
Filler	6-7	2		Space Filled
State	8-9	2	Character	Alpha Abbreviation
Filler	10-11	2		Space Filled
Current Year	12-15	4	Character	YYYY
Filler	16-17	2		Space Filled
Current Quarter	18	1	Character	Calendar Quarter – value 1-4
Filler	19-20	2		Space Filled
Fee	21-29	9	Numeric	Fee to Pay For Drug $$$$$$¢¢(Pic9(6)v999)

Field Name	Position	Length	Format	Description
Filler	30-80	51	Character	Space Filled

CMS will upload the CAP Part B Drug file to the Direct Connect each calendar quarter. Approximately six weeks prior to the beginning of each calendar quarter (i.e., approximately 6 weeks prior to January 1, April 1, July 1, and October 1) an email will be sent out providing notification of the availability of the updated file. The updated file will be available in the early November for the January 1 release, early February for the March 1 release, early May for the July 1 release, and early August for the September 1 release.

100.5 - Matching the Physician Claim to the Vendor Claim
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF shall match physician submitted claim lines with prescription numbers and no-pay modifiers to vendor submitted claim lines with prescription numbers.

The local carrier shall send to CWF a pay/process indicator for each line of the claim, (including the lines with HCPCS codes for the administration of the CAP drug and the lines for the CAP drug HCPCS code), to indicate whether it is approved, not-payable due to medical necessity, or not payable due to a reason other than medical necessity.

When CWF finds a prescription number that matches a prescription number on the claim, it shall notify the designated carrier. The designated carrier shall make payment for the drug lines that have a pay/process indicator of approved. It shall deny any lines not approved.

100.5.1 – Denials Due to Medical Necessity
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the lines are not approved due to medical necessity, the designated carrier shall return the following messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

MSN -16.48 – Medicare does not pay for this item or service for this condition.

100.5.2 – Denials For Reasons Other Than Medical Necessity
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the designated carrier denies the lines due to other reason, it shall use the following messages:

Claim Adjustment Reason Code 96 – Non-covered charge(s).

MSN 16.10 – Medicare does not pay for this item or service.

100.5.3 – Changes to Pay/Process Indicators
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Should local carriers make adjustments to the physician claims, they shall forward any changes in the pay/process indicators to CWF and CWF shall make any changes to the pay/process indicator as necessary to keep it current. CWF shall notify the designated carrier of any changes to the pay/process indicators so that they may respond accordingly.

100.5.4 – Post-Payment Overpayment Recovery Actions
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If it is determined on a post-pay basis that based on a change to the pay-process indicator the designated carrier has now made an overpayment, the designated carrier shall initiate an overpayment recovery action. If it is determined that they have made an underpayment, they shall also take appropriate action. Carriers and the designated carrier shall follow the instructions in the Program Integrity Manual, Chapter 3 and the Medicare Financial Management Manual, Chapter 3, for overpayment recovery.

100.5.5 – Pending and Recycling the Claim When All Lines Do Not Have a Match
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the designated carrier receives a claim from the vendor and CWF determines some or all of the lines on the claim do not have a match, the designated carrier shall pend the claim for 90 days. However, prior to the end of the 90 day period, if at the vendor's request the designated carrier can determine that a matching paper physician claim is on file, the designated carrier shall allow payment of the approved services on the claim.

The designated carrier may also recycle the claim back to CWF at their discretion to determine if a matching electronic claim has been received prior to the end of the 90 day period. No interest shall be paid on the pending claim.

100.5.6 – Creation of a Weekly Report for Claims That Have Pended More Than 90 Days and Subsequent Action
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The standard system shall create a weekly report for the designated carrier providing information on claims that have pended for more than 90 days. The designated carrier shall review the weekly report to identify and deny claim lines for which the 90 day time period has expired. Before denying the claim lines, the designated carrier shall determine if the physician claim had been submitted as a paper claim. If there is an approved physician paper claim for the beneficiary with the same HCPCS code and a date of

service within 7 days of the date of service of the vendor drug claim posted at CWF and the details are not denied, the designated carrier shall pay the claim lines. If there is no claim on file that matches these criteria, or some details are denied, the designated carrier shall deny the corresponding claim lines.

The designated carrier shall return the following messages:

RA Claim Adjustment Reason Code - 107 – Claim/service denied because the related or qualifying service was not previously paid or identified on this claim.

MSN – 21.21 – This service was denied because Medicare only covers this service under certain circumstances.

Spanish: 21.21 - Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias.

100.6 – Coordination of Benefits

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF and the designated carrier shall submit claims for full payment of drug claims to the Coordination of Benefits Contractor (COBC) for crossover to trading partners, in accordance with the requirements specified in Transmittal 138 (Change Request 3218).

100.7 – National Claims History

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF shall pass the prescription number to National Claims History (NCH) where it will be stored.

100.8 – Adding New Drugs to CAP

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The carriers and the Designated Carrier shall develop the capacity to manually add new vendor specific HCPCS codes and identify to which vendor lists these have been added for the table developed in 4064.1.1.2.1 on a quarterly basis upon notification by CMS. Carriers shall add these codes to their table by 7 days after receipt of notification from CMS.

100.8.1 - Updating Fee Schedule for New Drugs in CAP

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The Designated Carrier shall develop the capacity to add the prices for the new vendor specified HCPCS codes to the pricing table. Prices will be available on the CMS website for the quarterly update of prices to the of new drug prices.

100.8.2 – Changes to the List of Drugs Supplied by Approved CAP Vendors

(Rev. 1506; Issued: 05-16-08; Effective Date: 10-01-08; Implementation Date: 10-06-08)

The CAP will be implemented with a single category of drugs and one geographic area, however as the program evolves, additional geographic areas and additional drug categories may be created. Approved CAP vendors will also be able to request approval for changes to the lists of drugs that they supply under the CAP.

As CMS continues to develop the CAP, additional geographical areas and additional drug categories may be created. If additional drug categories are created, certain drugs may appear in more than one drug category.

Approved CAP vendors will be permitted to request certain changes to the list of drugs that they supply under the CAP. Beginning in July 2006 with changes to be effective October 1, 2006, approved CAP vendors may request that CMS (or its designee) approve the following types of changes:

Substitution: Approved CAP vendor may request approval to replace one or more drug products as identified by national drug codes (NDCs) in a Healthcare Common Procedure Coding System (HCPCS) code supplied by the approved CAP vendor with one or more NDCs.

Add newly issued HCPCS Codes: Approved CAP vendor may request that CMS allow it to supply additional drug products with new HCPCS codes under the CAP.

Additional NDCs: Approved CAP vendor may request that CMS allow it to supply additional NDCs under a HCPCS code that the approved CAP vendor already supplies under the CAP.

Orphan Drugs: Approved CAP vendor may request that CMS allowed it to supply single indication orphan drugs under the CAP.

Regulation text describing the above may be found at 42 CFR 414 Subpart K.

Changes to the drug list. Written requests for changes to the approved CAP vendor's drug list must be submitted to CMS and the CAP designated carrier. The requests must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for cost savings. If approved, routine changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS Web site (www.cms.hhs.gov/CompetitiveAcquisforBios/) and notify the carriers and participating CAP physicians of any changes on a quarterly basis via a recurring Change Request (CR). Physicians who participate in the CAP are required to obtain all CAP drugs on the updates from the approved CAP vendor unless medical necessity requires the use of a formulation not supplied by the vendor. Please note that approved

changes will apply only to the list of drugs supplied by the approved CAP vendor who submitted the request; therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved.

Timeline for changes. There will be one timeline for the submission of changes to the approved CAP vendor's drug list. For new HCPCS and/or NDC codes, and substitutions or changes to NDC codes supplied under an existing HCPCS code, the approved CAP vendor will be required to submit requests for drug list changes no later than four months before the beginning of the quarter in which the changes will take effect. Updated tables listing the HCPCS codes under a specific vendor's drug categories will be available 30 days prior to the start of the following quarter. NDC number changes will not require associated table modifications and will not affect established payment amounts. Physicians will be notified of these changes 30 days before the start of a quarter. Price files incorporating these changes will be available 7-14 days prior to the effective date for the corresponding changes. An example of the timeline for the July 1, 2008 HCPCS and NDC code changes appears below.

Example of Timeline for HCPCS and NDC Additions

Date	Action
3/1/2008	Vendor deadline to submit request for new HCPCS and/or NDCs
3/12/2008	CMS begins approval process to evaluate vendor request
5/24/2008	HCPCS and/or NDC changes approved to become effective July 1, 2008
5/30/2008	Per the approval of all clearance processes, CMS issues a CR regarding approved drug list changes and tables that will become effective July 1, 2008
6/2/2008	Designated carrier downloads HCPCS changes to the drug table. List posted onto the CMS Web site. Physicians receive updated list of drugs from the CAP vendor.
6/5/2008	Local Carriers shall acquire HCPCS changes from the Designated Carrier
6/17-6/24/2008	Price file with new codes posted
7/1/2008	Effective date for additional HCPCS codes; beginning of next quarter

Payment amount. The payment amount for new HCPCS codes added to an approved CAP drug vendor's drug list will be ASP + 6%. Addition or substitution of NDC numbers under an existing HCPCS code supplied by an approved CAP vendor will not

change the CAP single payment amount for that HCPCS code. CMS will update the single payment amount based on the approved CAP vendor's reported net acquisition costs for the category of drugs on an annual basis.

100.8.3 - CAP Not Otherwise Classified (NOC) Drugs

(Rev. 1034, Issued: 08-18-06; Effective: 01-01-07; Implementation: 01-02-07)

As described in Section 100.8.2, approved CAP vendors are able to request approval for changes to the list of drugs that they supply under the CAP. In an effort to improve beneficiary access to newly marketed drugs, approved CAP vendors will be able to request the addition of certain NOC drugs as defined by CMS to their drug lists for claims with dates of service on or after January 1, 2007.

The process for adding NOC drugs to an approved CAP vendor's drug list will generally follow the process for adding new drugs to the CAP. An approved CAP vendor is required to submit a written request to add specific NOC drugs to the CAP designated carrier. The request must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for cost savings. The CAP designated carrier will review the application and forward the information to CMS along with a recommendation for approval or denial. CMS will make a final decision upon review of the application and the designated carrier's recommendation. If approved, changes will become effective at the beginning of the following quarter. CMS will post the approved NOC additions along with other changes to the CAP Drug List on the CMS Web site (www.cms.hhs.gov/CompetitiveAcquisforBios).

Additions of NOC drugs apply only to the approved CAP vendor and the CAP category identified on the request. Therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved. The timeline for this process follows the timeline for HCPCS code changes described in manual section 100.8.2. CMS will also continue to notify local carriers of any changes to the CAP drug list on a quarterly basis. Participating CAP physicians will also be notified of changes at least 30 days before the approved changes will become effective.

The process to approve CAP NOC drugs differs from the process for other CAP drug approvals in two significant ways. First, CMS will define a list of CAP NOC drugs that the approved CAP vendor must use when requesting the addition of NOC drugs to the CAP. The CAP NOC drug list is based on the current ASP NOC list and is limited to drugs that are likely to fit the existing CAP drug category (or categories) and drugs that have a single national ASP-based payment amount. The list of CAP NOC drugs will be posted on the CMS CAP Web site (www.cms.hhs.gov/CompetitiveAcquisforBios/) and updated quarterly. The CAP NOC drug payment amount is set at the rate published on the ASP NOC file consistent with the next quarterly update; the CAP NOC payment amount will be updated annually.

Second, physician administration claims and vendor drug claims for services related to CAP NOC drugs are required to use the CAP-specific Q-code for all CAP NOC drug

claims along with the appropriate CAP modifiers. This code is necessary to distinguish CAP NOC drug claims from ASP NOC claims and to provide payment for CAP NOC drugs within the CAP. In addition to the use of the CAP NOC Q-code, CAP NOC claims must identify the specific NOC drug that had been administered. All remaining requirements concerning the proper submission of a claim continue to be effective, and claims processing for CAP NOC drug claims will follow procedures described in previous CAP CRs and applicable Manual sections. All current editing for other NOC codes shall also be applied to the CAP NOC code.

Participating CAP physicians will continue to use ASP NOC codes when billing for NOC drugs that are not included in the CAP category they have chosen. Participating CAP physicians are required to obtain all CAP drugs from the approved CAP vendor including any drugs added to the CAP drug list under this process, unless medical necessity requires the use of a formulation not supplied by the vendor.

100.8.3.1 – Editing for CAP NOC Drugs

(Rev. 1034, Issued: 08-18-06; Effective: 01-01-07; Implementation: 01-02-07)

Should the carrier receive a CAP NOC code, but the description does not match a CAP NOC drug on the approved list, carriers shall treat the claim as unprocessable and return the following RA messages:

Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.

Remark Codes

MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

N350 – Missing/incomplete/invalid description of a service for a Not Otherwise Classified (NOC) code or an Unlisted procedure.

Should a non-CAP physician submit the CAP NOC code, the carrier shall treat the claims as unprocessable and return the following RA messages:

Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.
Remark Codes

MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

N56 – Procedure code billed is not correct/valid for the services billed or the date of service billed.

Should a CAP physician submit a J NOC code with a description of a CAP approved NOC drug, the carriers shall treat the claim as unprocessable and return the following RA messages:

Reason Code 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using the remittance codes whenever appropriate.

MA 130 – Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

N56 – Procedure code billed is not correct/valid for the services billed or the date of service billed.

100.9 - Non-Participating Physicians Who Elect the CAP

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Participating CAP physicians must appeal drug administration denials. For a non-participating physician that elects to participate in the CAP, he or she must agree to accept assignment for all CAP drug administration charges to allow for the Medicare beneficiary's and approved CAP vendor's appeal rights.

Carriers shall pay all HCPCS codes that provide payment for the administration of CAP drugs on an assigned basis.

101 - The Competitive Acquisition Program (CAP) for Drugs and Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

All appeals of denied CAP claims will be processed by the local carrier. This includes an appeal for the denial of an approved CAP vendor's drug product claim. This break from the traditional administrative appeals process is necessitated by the arrangement whereby the CAP designated carrier pays the approved CAP vendor claim only after a match is found in the central claims processing system indicating the corresponding participating CAP physician's drug administration claim was paid by the local carrier. As a result, the only appealable issues attach to the decision of the local carrier.

The CAP claims processing arrangement departs from the standard Part B claims processing routine. The local carrier will make an initial determination on whether the participating CAP physician's claim for drug administration is payable by applying local coverage determinations (LCDs) to the administration and to the drugs billed as no-pay on the claim. If the local carrier finds the no-pay or administration lines are contrary to

the LCDs, it will deny the administration and pass on a non-approved indicator on the no-pay lines. The local carrier sends a pay process indicator to CWF for each of the no-pay lines. When the designated carrier enters the vendor claim into the system, CWF looks for a match. When CWF goes to find the match, it will not match against non-approved lines. If it finds a match among the approved lines, then it lets the designated carrier know and the claim is paid. If it doesn't find a match, the claim recycles for 90 days. Periodically during the 90 days, the designated carrier looks for a match again. If it finds one, the claim pays. If after 90 days it doesn't find a match, then the claim denies. The local carrier will notify CWF whether the approved CAP vendor's claim for the drug is payable. If the vendor's claim is not payable because of a determination of the local carrier, then the designated carrier will be notified. In turn, the designated carrier will deny the approved CAP vendor's claim. The claims processing requirements for this process have been described in previous CAP Change Requests.

Because the local carrier's initial determination on the drug administration claim decides the outcome of the of the approved CAP vendor's drug product claim, CMS interprets the initial determination to be an initial determination of the approved CAP vendor's drug product claim for the purposes of the Part B appeals regulations found at 42 CFR 405.801. Accordingly, the approved CAP vendor shall not file its appeal with the CAP designated carrier. Rather, the approved CAP vendor shall file its appeal with the local carrier, with one exception.

That exception is the case where the approved CAP vendor's drug product claim was denied because there was no matching claim filed by the participating CAP physician after 90 days of recycling. In this instance, the designated carrier will deny the approved CAP vendor's drug product claim and suppress appeal rights. The remittance notice will instruct the approved CAP vendor that it may request a reopening. Upon receipt of a reopening request, the designated carrier will contact the participating CAP physician and request that he or she fulfill his or her CAP participation agreement by filing the drug administration claim. If the participating CAP physician does not follow through as required, then the designated carrier will initiate the dispute resolution track discussed below.

In the role of the furnishing Medicare supplier, the approved CAP vendor is a party to any appeal of a denied drug administration claim filed by a participating CAP physician with the local carrier. The balance of the rules pertaining to the local carrier's adjudication of Part B appeals applies (See Pub. 100-04, Chapter 29), with the following exceptions:

a) The local carrier will check for duplicate appeals. If the participating CAP physician and the approved CAP vendor filed independent appeals connected with the same service, then the local carrier will merge the two files.

b) The local carrier will ensure the approved CAP vendor is copied on all correspondence connected with the participating CAP physician's appeal of the denied drug administration claim.

101.1 - Dispute Resolution Services for Vendors
(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

The CAP designated carrier has responsibility to deliver dispute resolution services to the approved CAP vendor when the approved CAP vendor's drug product claims are not paid because the participating CAP physician has either failed to file a payable drug administration claim or has failed to file a successful appeal of the denied drug administration claim.

The approved CAP vendor may file its drug product claim on the day it delivers the drug to the participating CAP physician. The participating CAP physician is contractually obligated to file his or her CAP drug administration claim within 14 days of administering the drug.

The approved CAP vendor may determine its own threshold for financial exposure. If the approved CAP vendor does not receive payment within 14 days, then the approved CAP vendor may request assistance from the CAP designated carrier in encouraging the participating CAP physician to fulfill his or her contractual obligations. If the CAP designated carrier's dispute resolution services do not yield adequate results for the approved CAP vendor, then the approved CAP vendor may request that the CAP designated carrier investigate the participating CAP physician's performance and recommend that the participating CAP physician's CAP election agreement be terminated. If the CAP designated carrier does recommend termination, then a suspension, hearing, and final termination process set forth in 42 CFR 414.916 will be employed by CMS.

101.2 - Dispute Resolution Services for Physicians
(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

If a participating CAP physician has an issue concerning the quality or safety of the services and/or drug delivered by the approved CAP vendor, then the participating CAP physician should address that issue through the approved CAP vendor's grievance process. If the participating CAP physician is not satisfied with the results of the approved CAP vendor's grievance process, then the participating physician may ask the CAP designated carrier to review the situation and encourage the approved CAP vendor to comply with its contractual obligations. If the approved CAP vendor refuses to comply with its contractual CAP obligations, then the CAP designated carrier may recommend to CMS that the approved CAP vendor's participation in CAP be terminated. If the CAP designated carrier does recommend termination, then a suspension, hearing, and final termination process set forth in 42 CFR 414.917 will be employed by CMS.

101.3 - Dispute Resolution Services for Beneficiaries
(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

The approved CAP vendor is not permitted to bill the beneficiary for any coinsurance or

deductible until the approved CAP vendor's drug product claim has been paid by the designated carrier. If the approved CAP vendor does bill the beneficiary before payment on the drug claim has been received, or if the approved CAP vendor bills the beneficiary too much after the drug product claim has been paid, then the beneficiary may use the approved CAP vendor's grievance process to challenge the inappropriate billing. If the approved CAP vendor's grievance process does not yield satisfactory results for the beneficiary, then the beneficiary may ask the CAP designated carrier to counsel the approved CAP vendor on its contractual CAP obligations.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R2424CP	03/16/2012	Influenza Virus Vaccine Annual Payment Limit Effective Date	08/01/2012	7741
R2279CP	08/19/2011	Annual Clotting Factor Furnishing Fee Update 2012	01/03/2012	7543
R2271CP	08/05/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – Rescinded and replaced by Transmittal 2312	10/01/2011	7397
R2251CP	07/01/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – rescinded and replaced by Transmittal 2271	08/15/2011	7397
R2214CP	05/13/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – Rescinded and replaced by Transmittal 2251	06/29/2011	7397
R2115CP	12/10/2010	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service – Rescinded and replaced by Transmittal 21214 (CR 7397)	03/14/2011	7109
R2068CP	10/15/2010	Annual Clotting Factor Furnishing Fee Update 2011	01/03/2011	7168
R1962CP	04/30/2010	Discarded Drugs and Biologicals Updates	07/30/2010	6711
R1908CP	02/05/2010	Clotting Factor Furnishing Fee-Conforming Manual Change to "Unit"	03/05/2010	6811
R1829CP	10/16/2009	Annual Clotting Factor Furnishing Fee Update	01/04/2010	6673
R1760CP	06/23/2009	July 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/06/2009	6492
R1745CP	05/22/2009	July 2009 Update of the Hospital Outpatient	07/06/2009	6492

Rev #	Issue Date	Subject	Impl Date	CR#
		Prospective Payment System (OPPS) - Rescinded and replaced by Transmittal 1760		
R1657CP	12/31/2008	January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/05/2009	6320
R1653CP	12/19/2008	Annual Clotting Factor Furnishing Fee Update	01/05/2009	6277
R1599CP	09/19/2008	October Update of the Hospital Outpatient Prospective Payment System (OPPS)	10/06/2008	6196
R1581CP	08/29/2008	Discarded Erythropoietin Stimulating Agents for Home Dialysis	12/01/2008	6133
R1564CP	07/25/2008	New Hemophilia Clotting Factor and HCPCS Code	01/05/2009	6006
R1551CP	07/18/2008	New Hemophilia Clotting Factor and HCPCS Code - Rescinded and replaced by Transmittal 1564	01/05/2009	6006
R1539CP	06/20/200/	Self-Administered Drug Exclusion Lists	07/21/2008	5988
R1513CP	05/23/2008	Average Sales Price Updates	06/23/2008	5798
R1506CP	05/16/2008	Competitive Acquisition Program (CAP): Updating Submission Deadlines for Quarterly Drug List Updates	10/06/2008	6010
R1478CP	03/14/2008	Additional Clarification to Chapter 17, Section 40, Regarding Processing of Drug Claims with the JW Modifier	04/14/2008	5923
R1472CP	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
R1453CP	02/22/2008	Systems Changes for Prescription Order Numbers for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals	07/07/2008	5855
R1448CP	02/15/2008	Adjudicating Claims for Immunosuppressive Drugs When Medicare	07/07/2008	5916

Rev #	Issue Date	Subject	Impl Date	CR#
		Did Not Pay for the Original Transplant		
R1445CP	02/08/2008	January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS)-Manualization	03/10/2008	5946
R1421CP	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
R1413CP	01/14/2008	Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions	04/07/2008	5818
R1412CP	01/11/2008	Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD Indications, and Reporting of Hematocrit/Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs	04/07/2008	5699
R1409CP	01/11/2008	Correction to Pub. 100-04, Chapter 17, Section 100.2.1	02/11/2008	5857
R1357CP	10/26/2007	Payment: Allowances for the Influenza Virus Vaccine and the Pneumococcal Vaccine When Payment is Based on 95 Percent of the Average Wholesale Price (AWP)	11/26/2007	5744
R1338CP	09/21/2007	Medicare Payment for Preadministration Related Services Associated With IVIG Administration – Payment Extended Through CY 2008	01/07/2008	5713
R1313CP	07/23/2007	Response to Competitive Acquisition for Part B Drugs and Biologicals (CAP) Claims When the Common Working File (CWF) 69XD Error Code is Received	08/23/2007	5658
R1281CP	07/06/2007	Clarification on Billing for Oral Three Drug Combination Anti-Emetic (Aprepitant)	01/07/2008	5655

Rev #	Issue Date	Subject	Impl Date	CR#
R1248CP	05/25/2007	Revisions, in the Medicare Claims Processing Manual, to Section 40, titled, "Discarded Drugs and Biologicals," and Section 100.2.9, titled, "Submission of Claims With the Modifier JW, 'Drug Amount Discarded/Not Administered to Any Patient."	07/02/2007	5520
R1212CP	03/30/2007	Requirements for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)	06/29/2007	5480
R1207CP	03/19/2007	Competitive Acquisition Program (CAP) for Part B Drugs	04/19/2007	5546
R1076CP	10/13/2006	Competitive Acquisition Program (CAP) – Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services	11/13/2006	5207
R1055CP	09/11/2006	Competitive Acquisition Program (CAP) - Creation of Automated Tables for Provider Information, Expansion of CAP Fee Schedule File Layout, and Additional Instructions for Claims Received from Railroad Retirement Board (RRB) Beneficiaries	10/02/2006	5079
R1034CP	08/18/2006	Competitive Acquisition Program (CAP) - Claim Processing for Not Otherwise Classified ("NOC") Drugs	01/02/2007	5259
R953CP	05/19/2006	CAP-Creation of Automated tables for Providers Information, Expansion of CAP Fee Schedule	10/02/2006	5079
R882CP	03/03/2006	Hospital Billing for Take-Home Drugs	07/03/2006	4301
R867CP	02/17/2006	Elimination of the Durable Medical Equipment Regional Carriers (DMERC) Information Form (DIF)	04/03/2006	4241
R866CP	02/17/2006	Additional Requirements for the Competitive Acquisition Program (CAP)	07/03/2006	4309

Rev #	Issue Date	Subject	Impl Date	CR#
		for Part B Drugs		
R840CP	02/06/2006	Hospital Billing for Take-Home Drugs	07/03/2006	4301
R839CP	02/06/2006	Additional Requirements for the Competitive Acquisition Program (CAP) for Part B Drugs	07/03/2006	4309
R754CP	11/10/2005	Fees for Supplying Inhalation Drugs Fee Dispensing Fee Revisions and Clarifications	01/03/2006	3990
R745CP	11/4/2005	Elimination of the Durable Medical Equipment Regional Carriers (DMERC) Information Form (DIF)	04/03/2006	4040
R736CP	10/31/2005	Clarification and Update to Hospital Billing Instructions and Payment for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Beneficiaries with End Stage Renal Disease (ESRD)	04/03/2006	4103
R719CP	10/21/2005	Clarification and Update to Hospital Billing Instructions and Payment for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Beneficiaries with End Stage Renal Disease (ESRD)	04/03/2006	4103
R684CP	09/23/2005	Correction to Chapter 17, Section 80.2.3, MSN/ANSIX12 Denial Messages for Anti-Emetic Drugs	12/23/2005	4001
R590CP	06/24/2005	Aprepitant for Chemotherapy-Induced Emesis	07/05/2005	3831
R576CP	06/03/2005	Correction to Chapter 17, Section 80.2.3, MSN/ANSIX12N Denial Messages for Anti-Emetic Drugs	Not Applicable	3918
R551CP	04/29/2005	Dispensing/Supply Fee Code, Payment, and Common Working File (CWF) Editing for Immunosuppressive Drugs	10/03/2005	3830
R521CP	04/08/2005	Hemophilia Blood Clotting Factors	05/09/2005	3755
R509CP	03/18/2005	Number of Drug Pricing Files That Must Be	07/05/2005	3584

Rev #	Issue Date	Subject	Impl Date	CR#
		Maintained Online by DMERCs		
R496CP	03/04/2005	Billing for Blood and Blood Products Under the Hospital Outpatient Prospective Payment System (OPPS)	07/05/2005	3681
R455CP	01/28/2005	Number of Drug Pricing Files That Must Be Maintained Online by DMERCs	07/05/2005	3584
R397CP	12/16/2004	Drug Pricing Limits as of January 1, 2005	01/03/2005	3232
R396CP	12/16/2004	New Dispensing/Supply Fee Codes for Oral Anti-Cancer, Oral Ant-Emetic, Immunosuppressive, and Inhalation Drugs	01/17/2005	3620
R394CP	12/10/2004	New Dispensing/Supply Fee Codes for Oral Anti-Cancer, Oral Ant-Emetic, Immunosuppressive, and Inhalation Drugs	01/17/2005	3620
R374CP	11/22/2004	Carrier Processing of Claims for Blood Clotting Factors	11/22/2004	3370
R352CP	11/03/2004	Use of Three Places after the Decimal Point for ASP Drug File	04/04/2005	3436
R346CP	10/29/2004	Use of Three Places after the Decimal Point for ASP Drug File	04/05/2005	3436
R327CP	10/22/2004	Carrier Processing of Claims for Blood Clotting Factors	11/22/2004	3370
R269CP	08/03/2004	Required Number Of Online Pricing Files to Be Maintained By Carriers	01/03/2005	3231
R248CP	07/23/2004	Replaced by Revision 397CP	01/01/2005	3232
R244CP	07/23/2004	Replaced by Revision 269CP	01/03/2005	3231
R188CP	05/28/2004	Hospital Outpatient Billing and Payment under OPPS for New, Unclassified Drugs or Biologicals Approved by the FDA After January 1, 2004, But Before Assignment of a Product-Specific Drug/Biological HCPCS Code	07/06/2004	3287

Rev #	Issue Date	Subject	Impl Date	CR#
R136CP	04/09/2004	New "WW" codes to identify Xeloda.	07/06/2004	3169
R131CP	03/26/2004	Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis	03/26/2004	3153
R104CP	02/20/2004	Instructions for Processing NDC Codes for DMERCs and VMS	04/05/2004	3141
R074CP	01/23/2004	Payment for intravenous immune globulin in the home for the treatment of primary immune deficiency diseases	04/05/2004	3060
R055CP	12/24/2003	Implementation of drug payment under the "Medicare Prescription Drug, Improvement, and Modernization Act" (MPDIMA) of 2003	01/05/2004	3025
R054CP	12/24/2003	Implementation of drug payment under the "Medicare Prescription Drug, Improvement, and Modernization Act" (MPDIMA) of 2003	01/05/2004	3022
R035CP	11/28/2003	Number of Required Carrier Pricing Files for the Single Drug Pricer	01/01/2004	2755
R001CP	10/01/2003	Initial Publication of Manual	NA	NA

Back to top of chapter