

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1412	Date: JANUARY 11, 2008
	Change Request 5699

Subject: 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

I. SUMMARY OF CHANGES: Effective for all claims requesting payment for the administration of ESAs with dates of service on and after January 1, 2008, CMS, in conjunction with section 110 of Division B of the Tax Relief and Health Care Act legislation of 2006, will require that the most recent hematocrit and/or hemoglobin levels be reported, along with one of three designated modifiers. CR 5699 does not pertain to 72X claims since renal dialysis facilities are already reporting. Additionally, for non-ESRD, non-ESA claims requesting payment for the administration of Part B anti-anemia drugs used in the treatment of cancer that are not-self-administered, shall also report either the most recent hematocrit or hemoglobin level.

New / Revised Material

Effective Date: January 1, 2008

Implementation Date: April 7, 2008 (except 5699.8.1 and 5699.10, to be fully implemented at a date not yet determined. See section IV for supporting statements.)

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	8/60/4.3.2/EPO Provided in the Hospital Outpatient Department
R	8/60/7.3.2/Payment for Aranesp in the Hospital Outpatient Department
R	17/Table of Contents
N	17/80.8/Reporting of Hematocrit and/or Hemoglobin Levels
R	17/80.9/Required Modifiers for ESAs Administered to Non-ESRD Patients
R	17/80.10/Hospitals Billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients
R	17/100/The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

R	17/100.2/Claims Processing Instructions for CAP Claims for the Local Carriers
R	26/10.4/Items 14-33 Provider of Service or Supplier Information

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1412	Date: January 11, 2008	Change Request: 5699
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SUBJECT: 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

Effective Date: January 1, 2008

Implementation Date: April 7, 2008 (except 5699.8.1 and 5699.10, to be fully implemented at a date not yet determined. See section IV for supporting statements below.)

I. GENERAL INFORMATION

A. Background: The treatment of anemia in cancer patients includes the use of erythropoiesis stimulating agents (ESAs) such as recombinant erythropoietin and darbepoetin. Though other pharmacologic interventions are possible, ESAs are commonly prescribed. Recently published data regarding the use of ESAs have raised safety concerns. As a result, Congress enacted a reporting requirement.

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

1. Effective January 1, 2008, the Centers for Medicare & Medicaid Services (CMS) is implementing an expanded reporting requirement for all claims billing for administrations of an ESA. Hematocrit or hemoglobin readings are already required for ESRD claims for administrations of an ESA. Therefore, this instruction does not pertain to 72X claims for renal dialysis facilities. Effective January 1, 2008, all other claims for ESA administrations will also require the reporting of either the most recent hematocrit or hemoglobin reading.

2. In addition to non-ESRD claims for administrations of ESAs reporting either the most recent hematocrit or hemoglobin level, they must contain one of the following three modifiers, effective January 1, 2008:

EA: ESA, anemia, chemo-induced

EB: ESA, anemia, radio-induced

EC: ESA, anemia, non-chemo/radio

ESAs administered for more than one of the indicated therapies are to be 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.

3. Lastly, effective January 1, 2008, all claims for the administration of Part B anti-anemia drugs OTHER THAN ESAs used in the treatment of cancer that are not self-administered shall require reporting of either the most recent hematocrit or hemoglobin reading.

CMS will use the information to help determine the prevalence and severity of anemia associated with cancer therapy, the clinical and hematologic responses to the institution of anti-anemia therapy, and the outcomes associated with various doses of anti-anemia therapy.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER	
								F I S S	M C S	V M S	C W F		
5699.1	Medicare systems shall return to provider all claims with dates of service on or after January 1, 2008, containing one of the following ESA HCPCS when value code 48 or 49 is not present: J0881, J0882, J0885, J0886 and Q4081.	X		X					X				
5699.2	Medicare systems shall return to provider all non-ESRD ESA claims with dates of service on or after January 1, 2008, containing 1 of the following ESA HCPCS for non-ESRD use (J0881 and J0885) but does not contain one of the following modifiers on the same line with the ESA HCPCS: EA, EB, or EC.	X		X					X				
5699.3	Contractors shall require non-ESRD ESA HCPCS J0881 and J0885 to be billed with 1 of the required modifiers (EA, EB, or EC) as line items on professional claims.	X			X								CAP Designated Carrier
5699.3.1	Contractors shall return non-ESRD ESA claims with HCPCS J0881 and J0885 as unprocessable when they are billed without 1 of the 3 modifiers noted in 5699.3 above.	X			X								CAP Designated Carrier
5699.3.2	Contractors shall use Reason Code 4 and Remark Code MA 130 to return ESA services billed without 1 of the required modifiers noted in 5699.3 above.	X			X								CAP Designated Carrier
5699.4	Contractors shall return as unprocessable HCPCS J0881 or J0885 line items billed with more than 1 of the 3 ESA modifiers noted in 5699.3 above.	X			X				X				CAP Designated Carrier
5699.4.1	Contractors shall use Reason code 125 and Remark code N63 to return line items for HCPCS J0881 or J0885 billed with more than one ESA modifier.	X			X								CAP Designated Carrier
5699.5	Contractors shall require the most recent hematocrit or hemoglobin test results to be reported on claims submitted with HCPCS codes J0881, J0882, J0885, J0886 and Q4081. Hematocrit or hemoglobin test results are reported in the MEA03 segment Loop 2400 of the 837P or item 19 of the Form CMS-1500 claim form.	X			X								CAP Designated Carrier
5699.5.1	Contractors shall return as unprocessable all claims submitted for ESAs with HCPCS codes J0881,	X			X								CAP Designated

Number	Requirement	Responsibility (place an "X" in each applicable column)												
		A / B M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER		
								F I S S	M C S	V M S	C W F			
	administered if the most recent hematocrit or hemoglobin test results are not reported on the claim.													
5699.9.2	Contractors shall return as unprocessable all non-ESRD professional claims for the administration of Part B anti-anemia drugs OTHER THAN ESAs used in the treatment of cancer that are not self-administered when the most current hemoglobin or hematocrit test results are not reported on the claim.	X			X									CAP Designated Carrier
5699.9.2.1	Contractors shall use Reason code 16 and Remark codes MA130 and N395 to return as unprocessable all non-ESRD claims for the administration of Part B anti-anemia drugs OTHER THAN ESAs used in the treatment of cancer that are not self-administered when the most recent hemoglobin or hematocrit test results are not submitted.	X			X									CAP Designated Carrier
5699.10	Contractors shall transmit to CWF the hematocrit or hemoglobin test type and results reported as a line item on the anti-anemia claim. The test type will be denoted by the values R2 and R1, respectively, on the 837P and Form CMS-1500 claim forms. Test results are reported as a numeric value (XX.X).	X	X		X					X	X	X		CAP Designated Carrier
5699.11	Shared systems shall accept and store the hematocrit or hemoglobin test type and test results for anti-anemia claims. The test type is denoted by the value R2 and R1, respectively, on the 837P and Form CMS-1500 claim forms. Test results are reported as a numeric value (XX.X).	X			X					X	X			
5699.12	Contractors shall not retroactively search for claims with dates of service January 1, 2008, through the implementation date of this CR, but may adjust claims if brought to their attention.	X	X	X	X									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)												
		A / B M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER		
								F I S S	M C S	V M S	C W F			
5699.13	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive	X	X	X	X									CAP Designated Carrier

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A C	D M E M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
	notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
5699.1, 5699.2	Claims must have either a value code 48 or a value code 49. It is not required that both be on the claim.
5699.1, 5699.2	Because 72X renal dialysis claims already report hematocrit or hemoglobin levels, these instructions are not applicable to 72X.
5699.8.1, 5699.10	CWF shall report to NCH the hematocrit or hemoglobin test results submitted by DME suppliers and Part B professionals on HUDC/HUBC claim transactions once NCH is modified to accept this data.
5699.8.1, 5699.10	NCH shall be modified as soon as possible to accept and store hematocrit or hemoglobin test results reported to CWF on HUBC and HUDC claim transaction records. NCH will not be able to accept this data as of January 2008.
5699.8.1, 5699.10	Test type and test result data will be housed in CWF history files until such time as NCH is able to accept it.

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Maria Ciccanti, coverage, maria.ciccanti@cms.hhs.gov, 410-786-3107, Pat Brocato-Simons, coverage, patricia.brocatosimons@cms.hhs.gov, 410-786-0261, Tracey Hemphill, DME claims processing, tracey.hemphill@cms.hhs.gov, 410-786-7169, Mel Page-Lasowski, professional claims processing, Melvia.pagelasowski@cms.hhs.gov, 410-786-4727, Sherry Murray, institutional claims processing,

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Post-Implementation Contact(s): Appropriate CMS Regional Office

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC), use only one of the following statements:*

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MAC), use the following statement:*

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

60.4.3.2 - Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments

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

When ESRD patients come to the hospital for a medical emergency their dialysis related anemia may also require treatment. Effective January 1, 2005, EPO will be paid based on the ASP Pricing File.

Hospitals use type of bill 13X (or 85X for Critical Access Hospitals) and report charges under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. Hospitals report the drug units based on the units defined in the HCPCS description. Hospitals do not report value code 68 for units of EPO. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, *and for all claims with dates of service on or after January 1, 2008.*

60.7.3.2 - Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department

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

When ESRD patients come to the hospital for a medical emergency their dialysis related anemia may also require treatment. For patients with ESRD who are on a regular course of dialysis, Aranesp administered in a hospital outpatient department is paid the MMA Drug Pricing File rate. Effective January 1, 2005, Aranesp will be paid based on the ASP Pricing File.

Hospitals use bill type 13X (or 85X for Critical Access Hospitals) and report charges under revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, *and for all claims with dates of service on or after January 1, 2008.*

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents *(Rev.1412, 01-11-08)*

80.8 - Reporting of Hematocrit and/or Hemoglobin Levels

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

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

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.

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 3-year 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.

100.2 - 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.

10.4 - Items 14-33 - Provider of Service or Supplier Information *(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)*

Reminder: For date fields other than date of birth, all fields shall be one or the other format, 6-digit: (MM | DD | YY) or 8-digit: (MM | DD | CCYY). Inter-mixing the two formats on the claim is not allowed.

Item 14 - Enter either an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date of current illness, injury, or pregnancy. For chiropractic services, enter an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date of the initiation of the course of treatment and enter an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date in item 19.

Item 15 - Leave blank. Not required by Medicare.

Item 16 - If the patient is employed and is unable to work in his/her current occupation, enter an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date when patient is unable to work. An entry in this field may indicate employment related insurance coverage.

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

The term "physician" when used within the meaning of [§1861\(r\)](#) of the Act and used in connection with performing any function or action refers to:

1. A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he/she performs such function or action;
2. A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State in which he/she performs such functions and who is acting within the scope of his/her license when performing such functions;
3. A doctor of podiatric medicine for purposes of §§(k), (m), (p)(1), and (s) and [§§1814\(a\)](#), [1832\(a\)\(2\)\(F\)\(ii\)](#), and [1835](#) of the Act, but only with respect to functions which he/she is legally authorized to perform as such by the State in which he/she performs them;
4. A doctor of optometry, but only with respect to the provision of items or services described in [§1861\(s\)](#) of the Act which he/she is legally authorized to perform as a doctor of optometry by the State in which he/she performs them; or,
5. A chiropractor who is licensed as such by a State (or in a State which does not license chiropractors as such), and is legally authorized to perform the services of a chiropractor in the jurisdiction in which he/she performs such services, and who meets uniform minimum standards specified by the Secretary, but only for purposes of §§1861(s)(1) and 1861(s)(2)(A) of the Act, and only with respect to treatment by

means of manual manipulation of the spine (to correct a subluxation). For the purposes of §1862(a)(4) of the Act and subject to the limitations and conditions provided above, chiropractor includes a doctor of one of the arts specified in the statute and legally authorized to practice such art in the country in which the inpatient hospital services (referred to in §1862(a)(4) of the Act) are furnished.

Referring physician - is a physician who requests an item or service for the beneficiary for which payment may be made under the Medicare program.

Ordering physician - is a physician or, when appropriate, a non-physician practitioner who orders non-physician services for the patient. See Pub 100-02, Medicare Benefit Policy Manual, chapter 15 for non-physician practitioner rules. Examples of services that might be ordered include diagnostic laboratory tests, clinical laboratory tests, pharmaceutical services, durable medical equipment, and services incident to that physician's or non-physician practitioner's service.

The ordering/referring requirement became effective January 1, 1992, and is required by §1833(q) of the Act. **All claims** for Medicare covered services and items that are the result of a physician's order or referral shall include the ordering/referring physician's name. See Items 17a and 17b below for further guidance on reporting the referring/ordering provider's UPIN and/or NPI. The following services/situations require the submission of the referring/ordering provider information:

- Medicare covered services and items that are the result of a physician's order or referral;
- Parenteral and enteral nutrition;
- Immunosuppressive drug claims;
- Hepatitis B claims;
- Diagnostic laboratory services;
- Diagnostic radiology services;
- Portable x-ray services;
- Consultative services;
- Durable medical equipment;
- When the ordering physician is also the performing physician (as often is the case with in-office clinical laboratory tests);

- When a service is incident to the service of a physician or non-physician practitioner, the name of the physician or non-physician practitioner who performs the initial service and orders the non-physician service must appear in item 17;
- When a physician extender or other limited licensed practitioner refers a patient for consultative service, submit the name of the physician who is supervising the limited licensed practitioner.

Item 17a – Enter the ID qualifier 1G, followed by the CMS assigned UPIN of the referring/ordering physician listed in item 17. The UPIN may be reported on the Form CMS-1500 until May 22, 2007, and MUST be reported if an NPI is not available.

NOTE: Field 17a and/or 17b is required when a service was ordered or referred by a physician. Effective May 23, 2007, and later, 17a is not to be reported but 17b MUST be reported when a service was ordered or referred by a physician.

When a claim involves multiple referring and/or ordering physicians, a separate Form CMS-1500 shall be used for each ordering/referring physician. All physicians who order or refer Medicare beneficiaries or services must report either an NPI or UPIN or both prior to May 23, 2007. After that date, an NPI (but not a UPIN) must be reported even though they may never bill Medicare directly. A physician who has not been assigned a UPIN shall contact the Medicare carrier. Refer to Pub. 100-08, chapter 14, section 14.6 for additional information regarding UPINs.

Item 17b Form CMS-1500 (08-05) – Enter the NPI of the referring/ordering physician listed in item 17 as soon as it is available. The NPI may be reported on the Form CMS-1500 (08-05) as early as January 1, 2007.

NOTE: Field 17a and/or 17b is required when a service was ordered or referred by a physician. Effective May 23, 2007, and later, 17a is not to be reported but 17b MUST be reported when a service was ordered or referred by a physician.

Item 18 - Enter either an 8-digit (MM | DD | CCYY) or a 6-digit (MM | DD | YY) date when a medical service is furnished as a result of, or subsequent to, a related hospitalization.

Item 19 – Enter either a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) date patient was last seen and the UPIN (NPI when it becomes effective) of his/her attending physician when a physician providing routine foot care submits claims.

For physical therapy, occupational therapy or speech-language pathology services, effective for claims with dates of service on or after June 6, 2005, the date last seen and the UPIN/NPI of an ordering/referring/attending/certifying physician or non-physician practitioner are not required. If this information is submitted voluntarily, it must be correct or it will cause rejection or denial of the claim. However, when the therapy service is provided incident to the services of a physician or non-physician practitioner,

then incident to policies continue to apply. For example, for identification of the ordering physician who provided the initial service, see Item 17 and 17a, and for the identification of the supervisor, see item 24K of this section.

Enter either a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) x-ray date for chiropractor services (if an x-ray, rather than a physical examination was the method used to demonstrate the subluxation). By entering an x-ray date and the initiation date for course of chiropractic treatment in item 14, the chiropractor is certifying that all the relevant information requirements (including level of subluxation) of Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, *is* on file, along with the appropriate x-ray and all are available for carrier review.

Enter the drug's name and dosage when submitting a claim for Not Otherwise Classified (NOC) drugs.

Enter a concise description of an "unlisted procedure code" or an NOC code if one can be given within the confines of this box. Otherwise an attachment shall be submitted with the claim.

Enter all applicable modifiers when modifier -99 (multiple modifiers) is entered in item 24d. If modifier -99 is entered on multiple line items of a single claim form, all applicable modifiers for each line item containing a -99 modifier should be listed as follows: 1=(mod), where the number 1 represents the line item and "mod" represents all modifiers applicable to the referenced line item.

Enter the statement "Homebound" when an independent laboratory renders an EKG tracing or obtains a specimen from a homebound or institutionalized patient. (See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," and Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, "Laboratory Services From Independent Labs, Physicians and Providers," and Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, "Definitions," respectively for the definition of "homebound" and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

Enter the statement, "Patient refuses to assign benefits" when the beneficiary absolutely refuses to assign benefits to a non-participating physician/supplier who accepts assignment on a claim. In this case, payment can only be made directly to the beneficiary.

Enter the statement, "Testing for hearing aid" when billing services involving the testing of a hearing aid(s) is used to obtain intentional denials when other payers are involved.

When dental examinations are billed, enter the specific surgery for which the exam is being performed.

Enter the specific name and dosage amount when low osmolar contrast material is billed, but only if HCPCS codes do not cover them.

Enter a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) assumed and/or relinquished date for a global surgery claim when providers share post-operative care.

Enter demonstration ID number "30" for all national emphysema treatment trial claims.

Enter the PIN (or NPI when effective) of the physician who is performing a purchased interpretation of a diagnostic test. (See Pub. 100-04, chapter 1, section 30.2.9.1 for additional information.)

Method II suppliers shall enter the most current HCT value for the injection of Aranesp for ESRD beneficiaries on dialysis. (See Pub. 100-04, chapter 8, section 60.7.2.)

Individuals and entities who bill carriers or A/B MACs for administrations of ESAs or Part B anti-anemia drugs not self-administered (other than ESAs) in the treatment of cancer must enter the most current hemoglobin or hematocrit test results. The test results shall be entered as follows: TR= test results (backslash), R1=hemoglobin, or R2=hematocrit (backslash), and the most current numeric test result figure up to 3 numerics and a decimal point[xx.x]). Example for hemoglobin tests: TR/R1/9.0, Example for Hematocrit tests: TR/R2/27.0.

Item 20 - Complete this item when billing for diagnostic tests subject to purchase price limitations. Enter the purchase price under charges if the "yes" block is checked. A "yes" check indicates that an entity other than the entity billing for the service performed the diagnostic test. A "no" check indicates "no purchased tests are included on the claim." When "yes" is annotated, item 32 shall be completed. When billing for multiple purchased diagnostic tests, each test shall be submitted on a separate claim Form CMS-1500. Multiple purchased tests may be submitted on the ASC X12 837 electronic format as long as appropriate line level information is submitted when services are rendered at different service facility locations. See chapter 1.

NOTE: This is a required field when billing for diagnostic tests subject to purchase price limitations.

Item 21 - Enter the patient's diagnosis/condition. With the exception of claims submitted by ambulance suppliers (specialty type 59), all physician and non-physician specialties (i.e., PA, NP, CNS, CRNA) use an ICD-9-CM code number and code to the highest level of specificity for the date of service. Enter up to four diagnoses in priority order. All narrative diagnoses for non-physician specialties shall be submitted on an attachment.

Item 22 - Leave blank. Not required by Medicare.

Item 23 - Enter the Quality Improvement Organization (QIO) prior authorization number for those procedures requiring QIO prior approval.

Enter the Investigational Device Exemption (IDE) number when an investigational device is used in an FDA-approved clinical trial. Post Market Approval number should also be placed here when applicable.

For physicians performing care plan oversight services, enter the 6-digit Medicare provider number (or NPI when effective) of the home health agency (HHA) or hospice when CPT code G0181 (HH) or G0182 (Hospice) is billed.

Enter the 10-digit Clinical Laboratory Improvement Act (CLIA) certification number for laboratory services billed by an entity performing CLIA covered procedures.

NOTE: Item 23 can contain only one condition. Any additional conditions should be reported on a separate Form CMS-1500.

Item 24 (Form CMS-1500 (08-05)) – The six service lines in section 24 have been divided horizontally to accommodate submission of both the NPI and legacy identifier during the NPI transition and to accommodate the submission of supplemental information to support the billed service. The top portion in each of the six service lines is shaded and is the location for reporting supplemental information. It is not intended to allow the billing of 12 service lines.

When required to submit NDC drug and quantity information for Medicaid rebates, submit the NDC code in the red shaded portion of the detail line item in positions 01 through position 13. The NDC is to be preceded with the qualifier N4 and followed immediately by the 11 digit NDC code (e.g., N499999999999). Report the NDC quantity in positions 17 through 24 of the same red shaded portion. The quantity is to be preceded by the appropriate qualifier: UN (units), F2 (international units), GR (gram) or ML (milliliter). There are six bytes available for quantity. If the quantity is less than six bytes, left justify and space fill the remaining positions (e.g. UN2 or F2999999).

Item 24A - Enter a 6-digit or 8-digit (MMDDCCYY) date for each procedure, service, or supply. When "from" and "to" dates are shown for a series of identical services, enter the number of days or units in column G. This is a required field. Return as unprocessable if a date of service extends more than 1 day and a valid "to" date is not present.

Item 24B - Enter the appropriate place of service code(s) from the list provided in Section 10.5. Identify the location, using a place of service code, for each item used or service performed. This is a required field.

NOTE: When a service is rendered to a hospital inpatient, use the “inpatient hospital” code.

Item 24C - Medicare providers are not required to complete this item.

Item 24D - Enter the procedures, services, or supplies using the CMS Healthcare Common Procedure Coding System (HCPCS) code. When applicable, show HCPCS code modifiers with the HCPCS code. The Form CMS-1500 (08-05) has the ability to capture up to four modifiers.

Enter the specific procedure code without a narrative description. However, when reporting an "unlisted procedure code" or a "not otherwise classified" (NOC) code, include a narrative description in item 19 if a coherent description can be given within the confines of that box. Otherwise, an attachment shall be submitted with the claim. This is a required field.

Return as unprocessable if an "unlisted procedure code" or an (NOC) code is indicated in item 24d, but an accompanying narrative is not present in item 19 or on an attachment.

Item 24E - Enter the diagnosis code reference number as shown in item 21 to relate the date of service and the procedures performed to the primary diagnosis. Enter only one reference number per line item. When multiple services are performed, enter the primary reference number for each service, either a 1, or a 2, or a 3, or a 4. This is a required field.

If a situation arises where two or more diagnoses are required for a procedure code (e.g., pap smears), the provider shall reference only one of the diagnoses in item 21.

Item 24F- Enter the charge for each listed service.

Item 24G - Enter the number of days or units. This field is most commonly used for multiple visits, units of supplies, anesthesia minutes, or oxygen volume. If only one service is performed, the numeral 1 must be entered.

Some services require that the actual number or quantity billed be clearly indicated on the claim form (e.g., multiple ostomy or urinary supplies, medication dosages, or allergy testing procedures). When multiple services are provided, enter the actual number provided.

For anesthesia, show the elapsed time (minutes) in item 24g. Convert hours into minutes and enter the total minutes required for this procedure.

For instructions on submitting units for oxygen claims, see chapter 20, section 130.6 of this manual.

NOTE: This field should contain at least 1 day or unit. The carrier should program their system to automatically default "1" unit when the information in this field is missing to avoid returning as unprocessable.

Item 24H - Leave blank. Not required by Medicare.

Item 24I Form CMS-1500 (12-90) - Leave blank. Not required by Medicare.

Item 24I Form CMS-1500 (08-05) – Enter the ID qualifier 1C in the shaded portion.

Item 24J Form CMS-1500 (12-90) - Leave blank. Not required by Medicare.

Item 24J Form CMS-1500 (08-05) – Prior to May 23, 2007, enter the rendering provider's PIN in the shaded portion. In the case of a service provided incident to the service of a physician or non-physician practitioner, when the person who ordered the service is not supervising, enter the PIN of the supervisor in the shaded portion.

Effective May 23, 2007, and later, do not use the shaded portion. Beginning no earlier than January 1, 2007, enter the rendering provider's NPI number in the lower portion. In the case of a service provided incident to the service of a physician or non-physician practitioner, when the person who ordered the service is not supervising, enter the NPI of the supervisor in the lower portion.

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

Item 24K Form CMS-1500 (08-05) – There is no Item 24K on this version.

Item 25 - Enter the provider of service or supplier Federal Tax ID (Employer Identification Number or Social Security Number) and check the appropriate check box. Medicare providers are not required to complete this item for crossover purposes since the Medicare contractor will retrieve the tax identification information from their internal provider file for inclusion on the COB outbound claim. However, tax identification information is used in the determination of accurate National Provider Identifier reimbursement. Reimbursement of claims submitted without tax identification information will/may be delayed.

Item 26 - Enter the patient's account number assigned by the provider's of service or supplier's accounting system. This field is optional to assist the provider in patient identification. As a service, any account numbers entered here will be returned to the provider.

Item 27 - Check the appropriate block to indicate whether the provider of service or supplier accepts assignment of Medicare benefits. If Medigap is indicated in item 9 and Medigap payment authorization is given in item 13, the provider of service or supplier shall also be a Medicare participating provider of service or supplier and accept assignment of Medicare benefits for all covered charges for all patients.

The following providers of service/suppliers and claims can only be paid on an assignment basis:

- Clinical diagnostic laboratory services;
- Physician services to individuals dually entitled to Medicare and Medicaid;
- Participating physician/supplier services;
- Services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, and clinical social workers;
- Ambulatory surgical center services for covered ASC procedures;
- Home dialysis supplies and equipment paid under Method II;
- Ambulance services;
- Drugs and biologicals; and,
- Simplified Billing Roster for influenza virus vaccine and pneumococcal vaccine.

Item 28 - Enter total charges for the services (i.e., total of all charges in item 24f).

Item 29 - Enter the total amount the patient paid on the covered services only.

Item 30 - Leave blank. Not required by Medicare.

Item 31 - Enter the signature of provider of service or supplier, or his/her representative, and either the 6-digit date (MM | DD | YY), 8-digit date (MM | DD | CCYY), or alpha-numeric date (e.g., January 1, 1998) the form was signed.

In the case of a service that is provided incident to the service of a physician or non-physician practitioner, when the ordering physician or non-physician practitioner is directly supervising the service as in 42 CFR 410.32, the signature of the ordering physician or non-physician practitioner shall be entered in item 31. When the ordering physician or non-physician practitioner is not supervising the service, then enter the signature of the physician or non-physician practitioner providing the direct supervision in item 31.

NOTE: This is a required field; however, the claim can be processed if the following is true. If a physician, supplier, or authorized person's signature is missing, but the signature is on file; or if any authorization is attached to the claim or if the signature field has "Signature on File" and/or a computer generated signature.

Item 32 Form CMS-1500 (12-90) - Enter the name and address, and ZIP Code of the facility if the services were furnished in a hospital, clinic, laboratory, or facility other than the patient's home or physician's office. Effective for claims received on or after April 1, 2004, enter the name, address, and ZIP Code of the service location for all services other than those furnished in place of service home – 12.

Effective for claims received on or after April 1, 2004, on the Form CMS-1500, only one name, address and ZIP Code may be entered in the block. If additional entries are needed, separate claim forms shall be submitted.

Providers of service (namely physicians) shall identify the supplier's name, address, ZIP Code and PIN when billing for purchased diagnostic tests. When more than one supplier is used, a separate Form CMS-1500 shall be used to bill for each supplier.

For foreign claims, only the enrollee can file for Part B benefits rendered outside of the United States. These claims will not include a valid ZIP Code. When a claim is received for these services on a beneficiary submitted Form CMS-1490S, before the claim is entered in the system, it should be determined if it is a foreign claim. If it is a foreign claim, follow instructions in chapter 1 for disposition of the claim. The carrier processing the foreign claim will have to make necessary accommodations to verify that the claim is not returned as unprocessable due to the lack of a ZIP Code.

For durable medical, orthotic, and prosthetic claims, the name, address, or PIN of the location where the order was accepted must be entered (DMERC only).

This field is required. When more than one supplier is used, a separate Form CMS-1500 shall be used to bill for each supplier.

This item is completed whether the supplier's personnel performs the work at the physician's office or at another location.

If a modifier is billed, indicating the service was rendered in a Health Professional Shortage Area (HPSA) or Physician Scarcity Area (PSA), the physical location where the service was rendered shall be entered if other than home.

If the supplier is a certified mammography screening center, enter the 6-digit FDA approved certification number.

Complete this item for all laboratory work performed outside a physician's office. If an independent laboratory is billing, enter the place where the test was performed, and the PIN.

Item 32 Form CMS-1500 (08-05) - Enter the name and address, and ZIP Code of the facility if the services were furnished in a hospital, clinic, laboratory, or facility other than the patient's home or physician's office. Effective for claims received on or after April 1, 2004, enter the name, address, and ZIP Code of the service location for all

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For durable medical, orthotic, and prosthetic claims, the name and address of the location where the order was accepted must be entered (DMERC only). This field is required. When more than one supplier is used, a separate Form CMS-1500 shall be used to bill for each supplier. This item is completed whether the supplier's personnel performs the work at the physician's office or at another location.

If a modifier is billed, indicating the service was rendered in a Health Professional Shortage Area (HPSA) or Physician Scarcity Area (PSA), the physical location where the service was rendered shall be entered if other than home.

If the supplier is a certified mammography screening center, enter the 6-digit FDA approved certification number.

Complete this item for all laboratory work performed outside a physician's office. If an independent laboratory is billing, enter the place where the test was performed.

Item 32a Form CMS-1500 (08-05) – If required by Medicare claims processing policy, enter the NPI of the service facility.

Item 32b Form CMS-1500 (08-05) - If required by Medicare claims processing policy, enter the PIN of the service facility. Be sure to precede the PIN with the ID qualifier of 1C. There should be one blank space between the qualifier and the PIN.

Item 33 - Enter the provider of service/supplier's billing name, address, ZIP Code, and telephone number. This is a required field.

Item 33a Form CMS-1500 (08-05) - Effective May 23, 2007, and later, you MUST enter the NPI of the billing provider or group. The NPI may be reported on the Form CMS-1500 (08-05) as early as January 1, 2007. This is a required field.

Item 33b Form CMS-1500 (08-05) - Enter the ID qualifier 1C followed by one blank space and then the PIN of the billing provider or group. Effective May 23, 2007, and later, 33b is not to be reported. Suppliers billing the DME MAC will use the National Supplier Clearinghouse (NSC) number in this item.