CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4202	**Date: January 18, 2019**
	Change Request 10964

SUBJECT: Update to Pub. 100-04 Chapters 8, 20, and 24 to Provide Language-Only Changes for the New Medicare Card Project

I. SUMMARY OF CHANGES: This Change Request (CR) contains language-only changes for updating the New Medicare Card Project-related language in Pub 100-04, Chapters 8, 20, and 24. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE: February 19, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 19, 2019

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	8/50.3/Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS
R	20/100.2.1/Completion of Certificate of Medical Necessity Forms
R	20/100.2.2.2/ Completion of the Elements of PEN CMN
R	24/30.2/New Enrollments and Maintenance of Existing Enrollments

III. FUNDING:
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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4202	Date: January 18, 2019	Change Request: 10964

SUBJECT: Update to Pub. 100-04 Chapters 8, 20, and 24 to Provide Language-Only Changes for the New Medicare Card Project

EFFECTIVE DATE: February 19, 2019
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I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) is implementing changes to remove the Social Security Number (SSN) from the Medicare card. A new number, called the Medicare Beneficiary Identifier (MBI), will be assigned to all Medicare beneficiaries. This CR contains language-only changes for updating the New Medicare Card Project language related to the MBI in Pub 100-04, Chapters 8, 20, and 24.

B. Policy: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires removal of the Social Security Number (SSN)-based Health Insurance Claim Number (HICN) from Medicare cards within four years of enactment. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
10964.1	Medicare Administrative Contractors (MACs) shall be aware of the updated language for the New Medicare Card Project in Pub. 100-04, Chapters 8, 20, and 24.	X	X	X	X					CEDI

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Tracey Mackey, 410-786-5736 or tracey.mackey@cms.hhs.gov , Kimberly Davis, 410-786-4721 or kimberly.davis@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Claims Processing Manual
Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

50.3 - Required Information for In-Facility Claims Paid Under the Composite Rate and the ESRD PPS

(Rev. 4202, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The electronic form required for billing ESRD claims is the ASC X12 837 institutional claim transaction. The paper form, where permissible, is Form CMS-1450.

The coding and related descriptions for the following items are identical for the ASC X12 837 institutional claim format and Form CMS-1450. See the related X12 implementation guide or Chapter 25, respectively, for where the information is reported.

Type of Bill

Acceptable codes for Medicare are:

721 - Admit Through Discharge Claim - This code is used for a bill encompassing an entire course of outpatient treatment for which the provider expects payment from the payer.

722 - Interim - First Claim - This code is used for the first of an expected series of payment bills for the same course of treatment.

723 - Interim - Continuing Claim - This code is used when a payment bill for the same course of treatment is submitted and further bills are expected to be submitted later.

724 - Interim - Last Claim - This code is used for a payment bill which is the last of a series for this course of treatment. The "Through" date of this bill (FL 6) is the discharge date for this course of treatment.

727 - Replacement of Prior Claim - This code is used when the provider wants to correct (other than late charges) a previously submitted bill. The previously submitted bill needs to be resubmitted in its entirety, changing only the items that need correction. This is the code used for the corrected or "new" bill.

728 - Void/Cancel of a Prior Claim - This code indicates this bill is a cancel-only adjustment of an incorrect bill previously submitted. Cancel-only adjustments should be used only in cases of incorrect provider identification numbers, incorrect *Medicare beneficiary identifier*, duplicate payments and some OIG recoveries. For incorrect provider numbers or *Medicare beneficiary identifier*, a corrected bill is also submitted using a code 721.

Statement Covers Period (From-Through) - Hospital-based and independent renal dialysis facilities:

The beginning and ending service dates of the period included on this bill. Note: ESRD services are subject to the monthly billing requirements for repetitive services.

Condition Codes

Hospital-based and independent renal facilities complete these items. Note that one of the codes 71-76 is applicable for every bill. Special Program Indicator codes A0-A9 are not required.

Condition Code Structure (only codes affecting Medicare payment/processing are shown).

02 - Condition is Employment Related - Providers enter this code if the patient alleges that the medical condition causing this episode of care is due to environment/events resulting from employment.

04 - Information Only Bill - Providers enter this code to indicate the patient is a member of a Medicare Advantage plan.

59 – Non-Primary ESRD Facility – Providers enter this code to indicate that ESRD beneficiary received non-scheduled or emergency dialysis services at a facility other than his/her primary ESRD dialysis facility.

71 - Full Care in Unit - Providers enter this code to indicate the billing is for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility.

72 - Self-Care in Unit - Providers enter this code to indicate the billing is for a patient who managed his own dialysis in a hospital or renal dialysis facility.

73 - Self-Care in Training - Providers enter this code to indicate the billing is for special dialysis services where a patient and his/her helper (if necessary) were learning to perform dialysis.

76 - Back-up In-facility Dialysis - Providers enter this code to indicate the billing is for a home dialysis patient who received back-up dialysis in a facility.

H3 – Reoccurrence of GI Bleed comorbid category

H4 – Reoccurrence of Pneumonia comorbid category

H5 – Reoccurrence of Pericarditis comorbid Category

Occurrence Codes and Dates

Codes(s) and associated date(s) defining specific events(s) relating to this billing period are shown. Event codes are two alpha-numeric digits, and dates are shown as six numeric digits (MM-DD-YY). When occurrence codes 01-04 and 24 are entered, make sure the entry includes the appropriate value code, if there is another payer involved.

Occurrence and occurrence span codes are mutually exclusive. Occurrence codes have values from 01 through 69 and A0 through L9. Occurrence span codes have values from 70 through 99 and M0 through Z9.

24 - Date Insurance Denied - Code indicates the date of receipt of a denial of coverage by a higher priority payer.

33 - First Day of Medicare Coordination Period for ESRD Beneficiaries Covered by an EGHP - Code indicates the first day of the Medicare coordination period during which Medicare benefits are payable under an EGHP. This is required only for ESRD beneficiaries.

51 – Date of last Kt/V reading. For in-center hemodialysis patients, this is the date of the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis patients, this date may be before the current billing period but should be within 4 months of the claim date of service.

Occurrence Span Code and Dates

Code(s) and associated beginning and ending dates(s) defining a specific event relating to this billing period are shown. Event codes are two alpha-numeric digits and dates are shown numerically as MM-DD-YY.

74 - Noncovered Level of Care - This code is used for repetitive Part B services to show a period of inpatient hospital care or of outpatient surgery during the billing period. Use of this code will not be necessary for ESRD claims with dates of service on or after April 1, 2007 due to the requirement of ESRD line item billing.

Document Control Number (DCN)

Required for all provider types on adjustment requests. (Bill Type/FL=XX7). All providers requesting an adjustment to a previous processed claim insert the DCN of the claims to be adjusted.

Value Codes and Amounts

Code(s) and related dollar amount(s) identify monetary data that are necessary for the processing of this claim. The codes are two alphanumeric digits and each value allows up to nine numeric digits (0000000.00). Negative amounts are not allowed. Whole numbers or non-dollar amounts are right justified to the left of the dollars and cents delimiter. Some values are reported as cents, so refer to specific codes for instructions. If more than one value code is shown for a billing period, show the codes in ascending alphanumeric sequence.

Value Code Structure (Only codes used to bill Medicare are shown.):

06 - Medicare Blood Deductible - Code indicates the amount the patient paid for un-replaced deductible blood.

13 - ESRD Beneficiary in the 30- Month Coordination Period with an EGHP - Code indicates that the amount shown is that portion of a higher priority EGHP payment on behalf of an ESRD beneficiary that applies to covered Medicare charges on this bill. If the provider enters six zeros (0000.00) in the amount field, it is claiming a conditional payment because the EGHP has denied coverage or there has been a substantial delay in its payment. Where the provider received no payment or a reduced payment because of failure to file a proper claim, this is the amount that would have been payable had it filed a proper claim.

17 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim when an outlier payment is being made. The value is the total claim outlier payment.

19 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim for low volume providers to identify the amount of the low volume adjustment being included in the provider’s reimbursement.

37 - Pints of Blood Furnished - Code indicates the total number of pints of blood or units of packed red cells furnished, whether or not replaced. Blood is reported only in terms of complete pints rounded upwards, e.g., 1 1/4 pints is shown as 2 pints. This entry serves a basis for counting pints towards the blood deductible. Hospital-based and independent renal facilities must complete this item.

38 - Blood Deductible Pints - Code indicates the number of un-replaced deductible pints of blood supplied. If all deductible pints furnished have been replaced, no entry is made. Hospital-based and independent renal facilities must complete this item.

39 - Pints of Blood Replaced - Code indicates the total number of pints of blood donated on the patient’s behalf. Where one pint is donated, one pint is replaced. If arrangements have been made for replacement, pints are shown as replaced. Where the provider charges only for the blood processing and administration,

i.e., it does not charge a “replacement deposit fee” for un-replaced pints, the blood is considered replaced for purposes of this item. In such cases, all blood charges are shown under the 039x revenue code series, Blood Administration. Hospital-based and independent renal facilities must complete this item.

44 - Amount Provider Agreed To Accept From Primary Payer When This Amount is Less Than Charges But Higher than Payment Received - Code indicates the amount shown is the amount the provider was obligated or required to accept from a primary payer as payment in full when that amount is less than the charges but higher than amount actually received. A Medicare secondary payment is due.

47 - Any Liability Insurance - Code indicates amount shown is that portion from a higher priority liability insurance made on behalf of a Medicare beneficiary that the provider is applying to Medicare covered services on this bill. If six zeros (0000.00) are entered in the amount field, the provider is claiming conditional payment because there has been substantial delay in the other payer’s payment.

48 - Hemoglobin Reading - Code indicates the most recent hemoglobin reading taken before the start of this billing period. This is usually reported in three positions with a decimal. Use the right of the delimiter for the third digit. The blood sample for the hemoglobin reading must be obtained before the dialysis treatment.

49 - Hematocrit Reading - Code indicates the most recent hematocrit reading taken before the start of this billing period. This is usually reported in two positions (a percentage) to the left of the dollar/cents delimiter. If the reading is provided with a decimal, use the position to the right of the delimiter for the third digit. The blood sample for the hemoglobin reading must be obtained before the dialysis treatment.

67 - Peritoneal Dialysis - The number of hours of peritoneal dialysis provided during the billing period. Count only the hours spent in the home. Exclude travel time. Report amount in whole units right-justified to the left of the dollar/cents delimiter. (Round to the nearest whole hour.)

Reporting value code 67 will not be required for claims with dates of service on or after April 1, 2007.

68 - Erythropoietin Units - Code indicates the number of units of administered EPO relating to the billing period and reported in whole units to the left of the dollar/cents delimiter. **NOTE:** The total amount of EPO injected during the billing period is reported. If there were 12 doses injected, the sum of the units administered for the 12 doses is reported as the value to the left of the dollar/cents delimiter.

Medicare no longer requires value code 68 for claims with dates of service on or after January 1, 2008.

71 - Funding of ESRD Networks - Code indicates the amount of Medicare payment reduction to help fund the ESRD networks. This amount is calculated by the A/B MAC (A) and forwarded to CWF. (See §120 for discussion of ESRD networks).

79 – Not submitted by the provider. The Medicare shared system will display this payer only code on the claim. The value represents the dollar amount for Medicare allowed payments applicable for the calculation in determining an outlier payment.

A8 – Weight of Patient – Code indicates the weight of the patient in kilograms. The weight of the patient should be measured after the last dialysis session of the month.

- A9 – Height of Patient – Code indicates the height of the patient in centimeters. The height of the patient should be measured during the last dialysis session of the month. The measurement is required no less frequently than once per year but must be reported on every claim. This height is as the patient presents.

D5 – Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service.

Revenue Codes

The revenue code for the appropriate treatment modality under the composite rate is billed (e.g., 0821 for hemodialysis). Services included in the composite rate and related charges must not be shown on the bill separately. Hospitals must maintain a log of these charges in their records for cost apportionment purposes. Effective January 1, 2015, ESRD facilities are required to report on the claim the composite rate drugs identified on the consolidated billing list provided at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html
No other composite rate drugs, items or services are to be reported on the claim.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

082X - Hemodialysis - Outpatient or Home Dialysis - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed directly from the blood. Detailed revenue coding is required. Therefore, services may not be summed at the zero level.

0 - General Classification	HEMO/OP OR HOME
1 – Hemodialysis/Composite or other rate	HEMO/COMPOSITE
2 - Home Supplies	HEMO/HOME/SUPPL
3 - Home Equipment	HEMO/HOME/EQUIP
4 - Maintenance 100%	HEMO/HOME/100%
5 - Support Services	HEMO/HOME/SUPSERV
9 - Other Hemodialysis Outpatient	HEMO/HOME/OTHER

083X - Peritoneal Dialysis - Outpatient or Home - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed indirectly by instilling a special solution into the abdomen using the peritoneal membrane as a filter.

0 - General Classification	PERITONEAL/OP OR HOME
1 - Peritoneal/Composite or other rate	PERTNL/COMPOSITE
2 - Home Supplies	PERTNL/HOME/SUPPL
3 - Home Equipment	PERTNL/HOME/EQUIP
4 - Maintenance 100%	PERTNL/HOME/100%
5 - Support Services	PERTNL/HOME/SUPSERV
9 -Other Peritoneal Dialysis	PERTNL/HOME/OTHER

084X - Continuous Ambulatory Peritoneal Dialysis (CAPD) - Outpatient - A continuous dialysis process performed in an outpatient or home setting, which uses the patient's peritoneal membrane as a dialyzer.

0 - General Classification	CAPD/OP OR HOME
1 - CAPD/Composite or other rate	CAPD/COMPOSITE
2 - Home Supplies	CAPD/HOME/SUPPL
3 - Home Equipment	CAPD/HOME/EQUIP
4 - Maintenance 100%	CAPD/HOME/100%
5 - Support Services	CAPD/HOME/SUPSERV
9 -Other CAPD Dialysis	CAPD/HOME/OTHER

085X - Continuous Cycling Peritoneal Dialysis (CCPD) - Outpatient. - A continuous dialysis process performed in an outpatient or home setting, which uses the patient's peritoneal membrane as a dialyzer.

0 - General Classification	CCPD/OP OR HOME
1 - CCPD/Composite or other rate	CCPD/COMPOSITE
2 - Home Supplies	CCPD/HOME/SUPPL

3 - Home Equipment	CCPD/HOME/EQUIP
4 - Maintenance 100%	CCPD/HOME/100%
5 - Support Services	CCPD/HOME/SUPSERV
9 -Other CCPD Dialysis	CCPD/HOME/OTHER

088X - Miscellaneous Dialysis - Charges for Dialysis services not identified elsewhere.

0 - General Classification	DAILY/MISC
1 – Ultrafiltration	DAILY/ULTRAFILT
2 – Home dialysis aid visit	HOME DIALYSIS AID VISIT
9 -Other misc. Dialysis	DAILY/MISC/OTHER

HCPCS/Rates

All hemodialysis claims must include HCPCS 90999 on the line reporting revenue code 082x.

Modifiers

Modifiers are required with ESRD Billing for reporting the adequacy of dialysis and the vascular access. For information on modifiers required for these quality measures see 50.9 of this chapter.

For information on reporting modifiers applicable to the Erythropoietin Stimulating Agents refer to section 60.4 of this chapter.

Route of administration modifiers required are JA, JB and JE.

For information on reporting the AY modifier for services not related to the treatment of ESRD, see sections 60.2.1.1 - Separately Billable ESRD Drugs and 60.1 - Lab Services.

Service Date

Report the line item date of service for each dialysis session and each separately payable item or service.

Service Units

Hospital-based and independent renal facilities must complete this item. The entries quantify services by revenue category, e.g., number of dialysis treatments. Units are defined as follows:

0634 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of less than 10,000 units of EPO was administered. For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.

0635 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of 10,000 units or more of EPO was administered. For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.

082X - (Hemodialysis) - Sessions

083X - (Peritoneal) - Sessions

084X - (CAPD) - Days covered by the bill

085X - (CCPD) - Days covered by the bill

Effective April 1, 2007, the implementation of ESRD line item billing requires that each dialysis session be billed on a separate line. As a result, claims with dates of service on or after April 1, 2007 should not report units greater than 1 for each dialysis revenue code line billed on the claim.

Total Charges

Hospital-based and independent renal facilities must complete this item. Hospital-based facilities must show their customary charges that correspond to the appropriate revenue code. They must not enter their composite or the EPO` rate as their charge. Independent facilities may enter their composite and/or EPO rates.

Neither revenue codes nor charges for services included in the composite rate may be billed separately (see §90.3 for a description). Hospitals must maintain a log of these charges in their records for cost apportionment purposes.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

The last revenue code entered in as 000l represents the total of all charges billed.

Principal Diagnosis Code

Hospital-based and independent renal facilities must complete this item and it should include a diagnosis of end stage renal disease.

Other Diagnosis Code(s)

For claims with dates of service on or after January 1, 2011 renal dialysis facilities report the appropriate diagnosis code(s) for co-morbidity conditions eligible for an adjustment.

Medicare Claims Processing Manual
Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

100.2.1 - Completion of Certificate of Medical Necessity Forms
(Rev. 4202, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

1. SECTION A: (This may be completed by supplier.)

   a. Certification Type/Date - If this is an initial certification for this patient, the date (MM/DD/YY) is indicated in the space marked "INITIAL". If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), the initial date is indicated in the space marked "INITIAL", and the revision date is indicated in the space marked "REVISED". If this is a recertification, the initial date is indicated in the space marked "INITIAL", and the recertification date is indicated in the space marked "RECERTIFICATION". Whether a REVISED or RECERTIFIED CMN is submitted, the INITIAL date as well as the REVISED or RECERTIFICATION date is always furnished.

   b. Patient Information - This indicates the patient's name, permanent legal address, telephone number, and his/her *Medicare beneficiary identifier* as it appears on his/her Medicare card and on the claim form.

   c. Supplier Information - This indicates the name of the company (supplier name), address, telephone number, and the Medicare supplier number assigned by the National Supplier Clearinghouse (NSC).

   d. Place of Service - This indicates the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, or end stage renal disease (ESRD) facility is 65. See chapter 23 for place of service codes.

   e. Facility Name - This indicates the name and complete address of the facility, if the place of service is a facility.

   f. HCPCS Codes - This is a list of all HCPCS procedure codes for items ordered that require a CMN. Procedure codes that do not require certification are not listed on the CMN.

   g. Patient Date of Birth (DOB), Height, Weight, and Sex - This indicates patient's DOB (MM/DD/YY), height in inches, weight in pounds, and sex (male or female).

   h. Physician Name and Address - This indicates the treating physician's name and complete mailing address.

   i. UPIN - This indicates the treating physician's unique physician identification number (UPIN).

   j. Physician's Telephone Number - This indicates the telephone number where the treating physician can be contacted (preferably where records would be accessible pertaining to this patient) if additional information is needed.

2. SECTION B: (This may not be completed by the supplier. While this section may be completed by a non-physician clinician, or a physician employee, it must be reviewed by the treating physician. A/B MACs (B) and (HHH) and DME MACs publish this requirement about section B in their bulletins at least annually.)

a. Estimated Length of Need - This indicates the estimated length of need (the length of time (in months) the physician expects the patient to require use of the ordered item). If the treating physician expects that the patient will require the item for the duration of his/her life, 99 is entered. For recertification and revision CMNs, the cumulative length of need (the total length of time in months from the initial date of need) is entered.

k. Diagnosis Codes - Listed in the first space is the diagnosis code that represents the primary reason for ordering this item. Additional diagnosis codes that would further describe the medical need for the item (up to 3 codes) are also listed. A given CMN may have more than one item billed, and for each item, the primary reason for ordering may be different. For example, a CMN is submitted for a manual wheelchair (K0001) and elevating leg rests (K0195). The primary reason for K0001 is stroke, and the primary reason for K0195 is edema.

l. Question Section - This section is used to gather clinical information regarding the patient's condition, the need for the DME, and supplies.

m. Name of Person Answering Section B Questions - If a clinical professional other than the treating physician (e.g., home health nurse, physical therapist, dietician, or a physician employee) answers the questions in section B, he/she must print his/her name, give his/her professional title, and the name of his/her employer, where indicated. If the treating physician answered the questions, this space may be left blank.

3. SECTION C: (This is completed by the supplier.)

a. Narrative Description of Equipment and Cost - The supplier indicates (1) a narrative description of the item(s) ordered, as well as all options, accessories, supplies, and drugs; (2) the supplier's charge for each item, option, accessory, supply, and drug; and (3) the Medicare fee schedule allowance for each item, option, accessory, supply, or drug, if applicable.

4. SECTION D: (This is completed by the treating physician.)

a. Physician Attestation - The treating physician's signature certifies the CMN that he/she is reviewing includes sections A, B, C, and D, the answers in section B are correct, and the self-identifying information in section A is correct.

b. Physician Signature and Date - After completion and/or review by the treating physician of sections A, B, and C, the treating physician must sign and date the CMN in section D, verifying the attestation appearing in this section. The treating physician's signature also certifies the items ordered are medically necessary for this patient. Signature and date stamps are not acceptable.

Certifications and recertifications may not be altered by "whiting out" or "pasting over" and entering new data. Such claims are denied and suppliers that show a pattern of altering CMNs are identified for educational contact and/or audit.

Also suppliers who have questionable utilization or billing practices or who are under sanction are considered for audit.

100.2.2.2 - Completion of the Elements of PEN CMN

(Rev. 4202, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The patient's name, address, and *Medicare beneficiary identifier* and the nature of the certification (i.e., initial, renewed, or revised) must be entered on all certifications by the supplier, physician, or physician's designated employees. The supplier identifying information is required on all PEN certifications.

All medical and prescription information must be completed from the patient's records by the attending/ordering physician, or an employee of the physician authorized to act on the physician's behalf, and reviewed and signed by the physician.

1. Place of Service - The CMN must identify the site where the patient is receiving PEN services. A patient may receive services at home, in a nursing home setting (e.g., skilled nursing facility), or another site that must be indicated by the supplier/physician.

2. Patient's General Condition - The attending physician must complete information about the patient's age, height, and weight. The general condition of the patient also includes an estimated duration of therapy (i.e., in months, years, or for life), the ambulatory status, and whether the patient is conscious. The physician should also indicate food allergies/sensitivities, other medical treatments, therapies, and/or medical conditions that may affect the patient's nutritional needs.

3. Patient's Clinical Assessment - The attending physician must indicate all the diagnoses related to the PEN therapy and describe the patient's functional impairment of the digestive tract that precludes the enteral patient from swallowing and the parenteral patient from absorbing nutrients. The physician must certify that PEN therapy meets the requirement that a patient is not able to maintain weight and strength due to pathology or nonfunction of the ingestion system and that the enteral therapy serves as the source of nutrition for the patient who has a functioning digestive tract, but whose disability prevents ingestion of sufficient nutrients to the alimentary tract for metabolism. Nutritional supplements for patients capable of ingesting normally, even if required to maintain weight and strength, cannot be covered under the prosthetic device benefit. The physician must have a basis for certifying or recertifying the need for PEN services. The physician is expected to see the patient within 30 days prior to certifying or recertifying PEN services. However, if the physician did not see the patient, he/she must explain why and describe what other monitoring methods were used to evaluate the patient's PEN needs.

4. Patient's Nutritional Prescription - Subsequent to an examination of the patient and/or a review of the patient's medical information, the attending physician must complete the patient's nutritional requirements (prescription) to certify the PEN therapy provided.

For the parenteral patient, the CMN must contain the following information:

- The infusion frequency per week,
- The route of administration,
- A reason for the use of pre-mixed parenteral formulas,
- An explanation for the use of special formulas such as hepatic, renal, or stress
- formulas, and
- The amino acid/dextrose formula components of the parenteral solution mix.

Amino acids serve as a source of protein. Adult parenteral nutrition patients generally need 1 to 1.5 grams of protein per day for each kilogram (2.2 pounds) of body weight. Dextrose concentrations less than 10

percent must be explained by the physician. The physician must document the reason for using more than 12 units (@ 500ml per unit) of lipids per month.

Parenteral nutrition may be either "self-mixed" (i.e., the patient is taught to prepare the nutrient solution aseptically) or "pre-mixed" (i.e., the nutrient solution is prepared by trained professionals employed or contracted by the PEN supplier). The attending physician must provide information to justify the reason for "pre-mixed" parenteral nutrient solutions.

Renal dialysis patients sometimes undergo parenteral therapy to replace fluids and nutrients lost during dialysis. Patients are usually infused less than daily and parenteral feeding is often supplemental and, therefore, not covered as a PEN benefit. The renal dialysis patient must meet all the requirements for PEN coverage. The attending physician must document that the patient, despite the need for renal dialysis, suffers from a permanently impaired functional impairment that precludes swallowing or absorption of nutrients.

For the enteral patient, the attending physician must include the following information on the CMN:

- The name of the nutrient product or nutrient category,
- The number of calories per day (100 calories = 1 unit),
- The frequency per day,
- The method of administration (i.e., syringe, gravity, or pump),
- The route of administration (i.e., nasogastric tube, gastrostomy tube, jejunostomy tube, percutaneous enteral gastrostomy tube, or naso-intestinal tube), and
- The reason for the use of a pump.

Categories of enteral nutrition are based on the composition and source of ingredients in each enteral nutrient product. Category IB of enteral nutrients contains products that are natural intact protein/protein isolates commonly known as blenderized nutrients. Additional documentation is required to justify the necessity of Category IB nutrients. The attending physician must provide sufficient information to indicate that the patient:

- Has an intolerance to nutritionally equivalent (semi-synthetic) products;

- Had a severe allergic reaction to a nutritionally equivalent (semi-synthetic) product; or

- Was changed to a blenderized nutrient to alleviate adverse symptoms expected to be of permanent duration with continued use of semi-synthetic products.

Enteral nutrient categories III through VI require additional medical justification for coverage. These categories represent formulas for special needs or use.

- Category III (code B4153): hydrolyzed protein/amino acids. These products contain a high nitrogen availability as a result of chemical treatment to reduce high molecular protein compounds into smaller molecules and amino acids that are easier to digest.

- Category IV (code B4154): defined formulas for special metabolic needs and conditions such as abnormal glucose tolerance, renal disease, liver disease, HIV, respiratory insufficiency, and malnutrition.

- Category V (code B4155): modular components (proteins, carbohydrates, fats).

- Category VI (code B4156): standardized nutrients. These products contain low residue ingredients.

If the patient exhibits a problem with any particular formula in Nutrient Category I (HCPCS B4150) or II (HCPCS B4152), the physician must document the unfavorable events that resulted in prescribing a higher category formula.

Generally, daily enteral intake of 750 to 2,000 calories is considered sufficient to maintain body weight. Patients with medical complications may require an intake outside the range. The attending physician must document the reason for prescribing less than 750 calories per day or more than 2000 calories per day.

Enteral nutrition may be administered by syringe, gravity, or pump. The attending physician must specify the reason that necessitates the use of an enteral feeding pump. Some enteral patients may experience complications associated with syringe or gravity method of administration. DME MACs provide coverage for enteral pumps if the medical necessity is documented by the attending physician on the CMN. Examples of circumstances that indicate the need for a pump include, but are not limited to:

- Aspiration or Dumping Syndrome;
- Severe diarrhea remedied by regulated feeding;
- Insulin-dependent diabetics who require a flow rate of less than 100cc's per hour for proper regulation of nutrients;
- Patients with congestive heart failure who require a pump to prevent circulatory overload; or
- Patients with a jejunostomy tube for feeding.

The DME MAC reviews the claims to ensure that the equipment for which payment is claimed is consistent with that prescribed (e.g., expect a claim for an I.V. pole, if a pump is used).

5. Attending Physician's Signature and Identification - A handwritten, original signature and date must be on each certification. The form must be dated to show reasonable association to the dates of active PEN therapy. The full name, address, telephone number (including area code), and Unique Physician Identification Number (UPIN) allows the DME MAC to determine if the prescriber is authorized to order Medicare services and facilitate claims development.

6. PEN Supplier's Identification - The PEN supplier's name, address, telephone number, and PEN identification number must be on each certification. This information allows the DME MAC to determine if the supplier is authorized to provide PEN supplies and facilitate claims development.

Medicare Claims Processing Manual
Chapter 24 – General EDI and EDI Support Requirements, Electronic Claims, and Mandatory Electronic Filing of Medicare Claims

30.2 - New Enrollments and Maintenance of Existing Enrollments
(Rev. 4202, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The Medicare EDI Enrollment process provides for collection of the information needed to successfully exchange EDI transactions between Medicare and EDI trading partners and also establishes the expectations for both parties in the exchange. This agreement must be executed by each provider that submits/receives EDI either directly to or from Medicare or through a third party. Each provider that will use EDI either directly or through a billing agent or clearinghouse to exchange EDI transactions with Medicare must sign the EDI Enrollment Form and submit it to the A/B MAC or CEDI with which EDI transactions will be exchanged before the A/B MAC, or CEDI will accept claims or other incoming EDI transactions from that provider, or a third party for that provider, or send outbound EDI transactions. A/B MACs and CEDI may accept a signed EDI Enrollment Form from providers via fax, email, internet portal, or hard copy and may accept electronic signature formats, "wet", or a combination of the two. The EDI Enrollment Form is effective as specified in the terms of the agreement.

Providers who will be accessing the A/B MACs Direct Data Entry (DDE) system will have access to enter and correct claims directly at the A/B MAC and must submit an EDI Enrollment Form to A/B MAC with their request for this access.

NOTES:

1. Although a type of electronic transaction, electronic funds transfers (EFTs) between an A/B MAC or DME MAC and a bank are not considered EDI for EDI Enrollment Form purposes. A provider that uses EFT but no EDI transactions should not complete an EDI Enrollment Form.

2. Medicaid state agencies are not required to complete an EDI Enrollment Form as a condition for receipt of COB claims.

In accord with a particular MAC's business processes, providers who have a signed EDI Enrollment Form on file with a particular A/B MAC or CEDI may or may not be required to submit a new signed EDI Enrollment Form to the same A/B MAC or CEDI each time they change their method of electronic billing or begin to use another type of EDI transaction, e.g., changing from direct submission to submission through a clearinghouse or changing from one billing agent to another. Additionally, providers may or may not be required to notify their A/B MAC (HHH), A/B MAC or CEDI if their existing clearinghouse begins to use alternate software; the clearinghouse is responsible for notification in that instance.

A/B MACs and CEDI must inform providers that providers are obligated to notify their A/B MAC or CEDI in writing in advance of a change that involves a change in the billing agent(s) or clearinghouse(s) used by the provider, the effective date on which the provider will discontinue using a specific billing agent and/or clearinghouse, if the provider wants to begin to use additional types of EDI transactions, or of other changes that might impact their use of EDI.

When an A/B MAC or CEDI receives a signed request from a provider or supplier to accept EDI transactions from or send EDI transactions to a third party, the A/B MAC or CEDI must verify that an EDI Enrollment Form is already on file for that provider or supplier, and that the third party has already been issued an EDI number and password to permit submission/receipt of EDI transactions. The request cannot be processed until both are submitted/issued.

The binding information in an EDI Enrollment Form does not expire if the person who signed that form for a provider is no longer employed by the provider, or that A/B MAC or CEDI is no longer associated with the Medicare program. Medicare responsibility for EDI oversight and administration is simply transferred in that case to that entity that CMS chooses to replace that A/B MAC or CEDI, and the provider as an entity retains responsibility for those requirements mentioned in the form regardless of any change in personnel on staff.

An organization comprised of multiple components that have been assigned more than one Medicare provider number, supplier number, or National Provider Identifier (NPI) may elect to execute a single EDI Enrollment Form on behalf of the organizational components to which such numbers have been assigned. The organization is responsible for the performance of its components.

The note at the end of the enrollment agreement language indicates that either party can terminate that agreement by providing 30 days advance notice. There is an exception to that requirement. In the event A/B MAC, DME MAC or CEDI detects abuse of use of an EDI system ID or password, or discovers potential fraud or abuse involving claims submitted electronically, electronic requests for beneficiary eligibility data, or other EDI transactions, that A/B MAC, DME MAC or CEDI is to immediately terminate system access for submission or receipt of EDI transactions by that individual or entity. A decision by A/B MAC, DME MAC or CEDI to terminate or suspend EDI access in such a situation is not subject to appeal by the individual or entity that loses EDI access.

Electronic Data Interchange (EDI) Enrollment Information Required for Inclusion at a Minimum in Each A/B MAC, and CEDI EDI Enrollment Form.

A. The provider agrees to the following provisions for submitting Medicare claims electronically to CMS or to CMS' A/B MACs or CEDI:

1. That it will be responsible for all Medicare claims submitted to CMS or a designated CMS contractor by itself, its employees, or its agents;

2. That it will not disclose any information concerning a Medicare beneficiary to any other person or organization, except CMS and/or its A/B MACs, DME MACs or CEDI without the express written permission of the Medicare beneficiary or his/her parent or legal guardian, or where required for the care and treatment of a beneficiary who is unable to provide written consent, or to bill insurance primary or supplementary to Medicare, or as required by State or Federal law;

3. That it will submit claims only on behalf of those Medicare beneficiaries who have given their written authorization to do so, and to certify that required beneficiary signatures, or legally authorized signatures on behalf of beneficiaries, are on file;

4. That it will ensure that every electronic entry can be readily associated and identified with an original source document. Each source document must reflect the following information:

    - Beneficiary's name;
    - Beneficiary's *Medicare beneficiary identifier*;
    - Date(s) of service;
    - Diagnosis/nature of illness; and
    - Procedure/service performed.

5. That the Secretary of Health and Human Services or his/her designee and/or the A/B MAC, DME MAC, CEDI, or other contractor if designated by CMS has the right to audit and confirm information submitted by the provider and shall have access to all original source documents and medical records related to the provider's submissions, including the beneficiary's authorization and signature. All incorrect payments that are discovered as a result of such an audit shall be adjusted according to the applicable provisions of the Social Security Act, Federal regulations, and CMS guidelines;

6. That it will ensure that all claims for Medicare primary payment have been developed for other insurance involvement and that Medicare is the primary payer;

7. That it will submit claims that are accurate, complete, and truthful;

8. That it will retain all original source documentation and medical records pertaining to any such particular Medicare claim for a period of at least 6 years, 3 months after the bill is paid;

9. That it will affix the CMS-assigned unique identifier number (submitter ID) of the provider on each claim electronically transmitted to the A/B MAC, CEDI, or other contractor if designated by CMS;

10. That the CMS-assigned unique identifier number (submitter identifier) or NPI constitutes the provider's legal electronic signature and constitutes an assurance by the provider that services were performed as billed;

11. That it will use sufficient security procedures (including compliance with all provisions of the HIPAA security regulations) to ensure that all transmissions of documents are authorized and protect all beneficiary-specific data from improper access;

12. That it will acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law;

13. That it will establish and maintain procedures and controls so that information concerning Medicare beneficiaries, or any information obtained from CMS or its A/B MAC, DME MAC, CEDI, or other contractor if designated by CMS shall not be used by agents, officers, or employees of the billing service except as provided by the A/B MAC, DME MAC or CEDI (in accordance with §1106(a) of Social Security Act (the Act) (See section 40.1.2.2 below for a complete reference to Medicare's security requirements);

14. That it will research and correct claim discrepancies;

15. That it will notify the A/B MAC, CEDI, or other contractor if designated by CMS within 2 business days if any transmitted data are received in an unintelligible or garbled form (See section 40.1.2.2 below for a complete reference to Medicare's security requirements).

B. The Centers for Medicare & Medicaid Services (CMS) agrees to:

1. Transmit to the provider an acknowledgment of claim receipt;

2. Affix the A/B MAC, DME MAC, CEDI or other contractor if designated by CMS number, as its electronic signature, on each remittance advice sent to the provider;

3. Ensure that payments to providers are timely in accordance with CMS' policies;

4. Ensure that no A/B MAC, CEDI, or other contractor if designated by CMS may require the provider to purchase any or all electronic services from the A/B MAC, CEDI or from any subsidiary of the A/B MAC, CEDI, other contractor if designated by CMS, or from any company for which the A/B MAC, CEDI has an interest. The A/B MAC, CEDI, or other contractor if designated by CMS will make alternative means available to any electronic biller to obtain such services;

5. Ensure that all Medicare electronic billers have equal access to any services that CMS requires Medicare A/B MACs, CEDI, or other contractors if designated by CMS to make available to providers or their billing services, regardless of the electronic billing technique or service they choose. Equal access will be granted to any services sold directly, indirectly, or by arrangement by the A/B MAC, CEDI, or other contractor if designated by CMS;

6. Notify the provider within 2 business days if any transmitted data are received in an unintelligible or garbled form.

NOTE: Federal law shall govern both the interpretation of this document and the appropriate jurisdiction and venue for appealing any final decision made by CMS under this document.

This document shall become effective when signed by the provider. The responsibilities and obligations contained in this document will remain in effect as long as Medicare claims are submitted to the A/B MAC, DME MAC, CEDI, or other contractor if designated by CMS. Either party may terminate this arrangement by giving the other party thirty (30) days written notice of its intent to terminate. In the event that the notice is mailed, the written notice of termination shall be deemed to have been given upon the date of mailing, as established by the postmark or other appropriate evidence of transmittal.

C. Signature

I certify that I have been appointed an authorized individual to whom the provider has granted the legal authority to enroll it in the Medicare Program, to make changes and/or updates to the provider's status in the Medicare Program (e.g., new practice locations, change of address, etc.) and to commit the provider to abide by the laws, regulations and the program instructions of Medicare. I authorize the above listed entities to communicate electronically with (MAC name) on my behalf.

Provider’s Name

Title

Address

City/State/Zip

By _____ _____
(signature) (printed name)

Date