CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10479	**Date: November 18, 2020**
	Change Request 11897

Transmittal 10336, dated August 27, 2020, is being rescinded and replaced by Transmittal 10479, dated, November 18, 2020, to revise the effective and implementation date, add information in the background section, revise business requirements 11897.1, 11897.3.1, 11897.4, 11897.5, 11897.7, 11897.8, 11897.8.2, 11897.9, 11897.9.2, 11897.10, 11897.10.3, and to add business requirement 11897.9.1 and move the original requirement 11897.9.1 to 11897.9.2. All other information remains the same.

SUBJECT: Implementation of Nurse Practitioners Certifying Diabetic Shoe Orders Under the Primary Care First (PCF) Model

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) under the Primary Care First (PCF) model is to provide a benefit enhancement to nurse practitioner participants. Specifically, this enhancement is for nurse practitioners in PCF to certify diabetic shoe orders for their attributed beneficiaries.

EFFECTIVE DATE: January 1, 2021 - Applicable to CWF; April 1, 2021 - Applicable to VMS and all other contractors
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2021 - Applicable to the following BRs: 11897.2, 11897.3, 11897.6, 11897.6.1, 11897.6.2, 11897.10.1, 11897.10.2, 11897.10.3, 11897.11, and 11897.13.2; April 5, 2021 - Applicable to the following BRs: 11897.1, 11897.3.1, 11897.4, 11897.5, 11897.7, 11897.7.1, 11897.7.2, 11897.7.3, 11897.8, 11897.8.1, 11897.8.2, 11897.8.3, 11897.8.4, 11897.9, 11897.9.1, 11897.9.2, 11897.10, 11897.12, 11897.13, 11897.13.1, and 11897.14

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
N/A	

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:
Demonstrations

Attachment - Demonstrations

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IMPLEMENTATION DATE: January 4, 2021 - Applicable to the following BRs: 11897.2, 11897.3, 11897.6, 11897.6.1, 11897.6.2, 11897.10.1, 11897.10.2, 11897.10.3, 11897.11, and 11897.13.2; April 5, 2021 - Applicable to the following BRs: 11897.1, 11897.3.1, 11897.4, 11897.5, 11897.7, 11897.7.1, 11897.7.2, 11897.7.3, 11897.8, 11897.8.1, 11897.8.2, 11897.8.3, 11897.8.4, 11897.9, 11897.9.1, 11897.9.2, 11897.10, 11897.12, 11897.13, 11897.13.1, and 11897.14

I. GENERAL INFORMATION

A. Background: Section 1115A of the Social Security Act established a new Center for Medicare and Medicaid Innovation (the Innovation Center) within the Centers for Medicare & Medicaid Services (CMS) to test new payment and service delivery models that have the potential to reduce Medicare, Medicaid, and CHIP expenditures while maintaining or improving the quality of care for beneficiaries.

The Innovation Center has secured approval for a new Primary Care First (PCF) model with two separate but related components: (1) the PCF component and (2) the Seriously Ill Population (SIP) component. Both components will test alternative payments and the provision of technical support to primary care practices. These PCF and/or SIP participants will receive a combination of claims and non-claims-based payments based on their attributed Medicare fee-for-service (FFS) beneficiaries. With fewer reporting requirements, PCF component practices will have the flexibility to implement their own strategies that best target outcomes. SIP component practices will deliver care to a separate patient population that is both higher risk and shows fragmented patterns of care.

Participants in the PCF model are primary care practices that may participate in one or both components, although individual beneficiaries may only be covered under one component at a time. A primary care practice may include one or more physicians, as well as non-physician providers such as nurse practitioners. Every participating practice will be given a unique practice ID by the CMS implementation support contractor. Providers in a practice will be uniquely defined by the combination of each provider's tax ID number (TIN) and national provider identifier (NPI).

CMS will create a provider file that lists all participating providers, their PCF component and/or SIP component practice affiliation, and the effective and termination dates of their participation in the PCF model. A given provider (as defined by the concatenation of TIN and NPI) may only be active in one PCF practice at a time. Providers within a practice may have different effective and termination dates (e.g., as they are hired or leave the practice), but the practice itself will have its own effective and termination date for participation in the model. CMS will also create a beneficiary file detailing all attributed, (which also referred to as aligned) Medicare FFS beneficiaries to participants in PCF and/or SIP components. CMS will detail all information specific to the provider and beneficiary files within the Interface Control Document

(ICD). CMS will upload this file in the following location within eCHIMP:

- CR Form/Files/Interface Control Documents

The first cohort of PCF and SIP component participants will begin operation during the following dates:

• PCF Component: January 1, 2021 – December 31, 2025

• SIP Component: April 1, 2021 – December 31, 2025

The second cohort of PCF and SIP component participants will start one year after the first PCF Component cohort:

• PCF and SIP Components (Cohort #2): January 1, 2022 – December 31, 2026

New practices and providers may be added throughout the duration of the model and CMS will provide updated files of participating providers and attributed beneficiaries on a monthly basis. Please note the beneficiary file for CR 11419 will also be used for this CR. CR 11419 addresses professional (Part B) FFS claims that subject to the following in PCF:

1. Flat Visit Fee (FVF) (PCF and SIP Components)
2. G2020 HCPCS code (SIP Component Only)
3. Prohibited HCPCS codes (Chronic Care Management and Home Health)

For more information regarding those professional FFS payments please refer to CR 11419. In addition to claims-based payments, participating providers will receive quarterly per beneficiary per month payments as well as adjustments for performance-based payments. These payments shall be processed separately from the claims system and are not addressed in this CR and do not require any input from the FFS shared systems and/or Medicare Administrative Contractors (MACs).

In addition to special payment provisions for primary care services, there are special waivers under the model that allow for payment of other Medicare benefits under conditions that would not otherwise be paid for. When claims are paid under these special “waived” conditions, the claims are also to be tagged with the demonstration code.

Under this model, beneficiaries with diabetes are eligible for the standard Medicare diabetic shoe and orthotic supplies benefit if a nurse practitioner refers or certifies the beneficiary. Normally, these items are only paid under traditional Medicare FFS if a physician refers or certifies the beneficiary. The model is not changing the benefit coverage or limits in any other way than that of loosening the requirement for the referring or certifying provider to include nurse practitioners as well as physicians. Volume limits on supplies, any requirements regarding who can bill for the shoes and supplies, and any other edits that may be applicable to current FFS claims processing for these items shall not change under the model.

When a claim for the specified HCPCS codes for diabetic shoes and supplies are submitted, CMS requests the shared systems to perform the following:

Apply demo code ‘96’ to the claim if the claim is not payable under normal Medicare FFS rules and the ONLY reason is that the referring provider is not a physician, then go through the following steps:

a. Look at the beneficiary file provided to determine whether the beneficiary on the claim is participating in the PCF model on the service dates listed on the applicable claim line.

i. If not in the PCF model, process as normal FFS and do not apply demo code ‘96’;

ii. If in the PCF model, then go to step (b) below.

b. If yes (beneficiary in the model on the line date of service), check whether the provider NPI in the referring provider field on the claim is also listed in the model participating provider file on the date of service of the applicable claim line.

i. If not in the PCF model, do not apply demo code ‘96’

ii. If in the PCF model, then go to step (c) below.

c. If the beneficiary and the provider are both participating in the model on the date of service of the applicable claim line, check to make sure that (per the beneficiary participation file) the beneficiary is attributed to the same practice that the referring provider is participating in (per the participating provider file) on that date of service.

i. If the beneficiary is not attributed to the referring provider’s practice, do not apply demo code ‘96’ to the claim;

ii. If the beneficiary is attributed to the referring provider’s practice on the date of service, then go to step (d) below.

d. Tag the claim with the demo code on the header.

i. Any volume or other edits that would apply under traditional Medicare FFS should apply.

ii. Coinsurance/Deductible, sequestration, etc. are all applied as under traditional Medicare FFS.

The business requirements for this CR will be completed across January 2021 and April 2021 releases. CMS has matched each business requirement with its corresponding implementation date. All CWF business requirements still fall under the January 2021 Release with an effective date of January 1, 2021. VMS and other contractors will finalize all of their business requirements set to the April 2021 Release with an effective date of April 1, 2021.

This CR will only apply to DME claims with dates of service from April 1, 2021 to December 31, 2026.

B. Policy: Under numerous states' laws, a nurse practitioner can provide primary care services, which include certifying home health services and diabetic shoe orders; however, under Medicare rules a physician (M.D or D.O) is required to certify diabetic shoe orders for beneficiaries. Many beneficiaries lack access to primary care physicians and are under the care of a nurse practitioner who serve their primary care provider. Prohibiting nurse practitioners from certifying diabetic shoe orders results in higher total cost of care and unnecessary utilization. Allowing nurse practitioners to certify diabetic shoe orders is consistent with numerous states’ Medicaid rules, other PCF payer partners, CMS’ direction of allowing greater use of non-physician practitioners, and the goal of supporting existing patient/provider relationships under the PCF Model.

Currently, Medicare pays for diabetic shoes only if a physician certifies the beneficiary’s eligibility for this benefit – not a nurse practitioner. This CR would waive Section 1861(s)(12) of the Act and the implementing regulations at 42 CFR 410.12 to allow nurse practitioners to certify that an order for diabetic shoes is required according to Section 1861(s)(12). This CR applies to all DME MAC Jurisdictions.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11897.1	The CMS specialty/operations contractor shall send the VDC the initial production provider participant files detailing PCF participating providers that are designated nurse practitioners using the attached file layout by 04/02/2021 for VMS. The CMS operations contractor contacts are: Salauddin Shaik (Salauddin.Shaik@softrams.com); Vivek Trehan (Vivek.Trehan@softrams.com); Yani Mellacheruvu (Yani.Mellacheruvu@cms.hhs.gov); Aparna Vyas (Aparna.Vyas@cms.hhs.gov)							X		ACO OS
11897.2	The CMS specialty/operations contractor shall include data elements on the aligned beneficiary file as identified in the attached ICD (to be provided prior to final issuance of this CR).									ACO OS
11897.3	The VDC shall accept the initial production beneficiary file layout for the PCF model for VMS as defined in the attached layout from CWF by 12/30/2020.								X	VDC
11897.3.1	VMS shall accept the ACO-OS provider file layout for the PCF model processing changes. **NOTE: The ICD shall be added as an attachment and loaded to eCHIMP.**							X		VDC
11897.4	VMS shall accept the new beneficiary participation model file from CWF using the attached CWF file layout.							X		
11897.5	The contractors shall retain the last maintenance date in the provider and beneficiary VMS internal files which shall reflect the date the updated files were loaded into the shared system. **NOTE:** The date field shall be viewable to the MACs.							X		
11897.6	The CMS specialty/operations contractor shall deliver the provider participant and beneficiary alignment files to the Virtual Data Centers (VDCs) when they become available.									ACO OS, CMS, VDC
11897.6.1	The CMS specialty/operations contractor shall transmit the provider participant and beneficiary									ACO OS

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	alignment files through electronic file transfer (EFT). **NOTE:** The ICD shall identify the file names.									
11897.6.2	The CMS specialty/operations contractor shall notify the contractors of the provider participant and beneficiary alignment file names when they become available									ACO OS, CMS, VDC
11897.7	Shared systems shall create response files acknowledging receipt of the provider participant files.							X		ACO OS, CMS, VDC
11897.7.1	The contractors shall perform limited editing to ensure the file is well-formed. The validation checks shall include: • the Header Record must be present and fields populated with valid information; • the Trailer Record must be present and fields populated with valid information; and • the actual count of detail records must match the count in the Trailer Record. **NOTE:** The Interface Control Document (ICD) shall define the response file layout and detailed error conditions.							X		
11897.7.2	VMS shall produce a response file that indicates the file was processed and contained no errors if no validation errors were encountered.							X		
11897.7.3	If validation errors are encountered, VMS shall produce a response file that indicates specific records and fields that did not pass the validation checks using defined error codes as defined in the ICD.							X		
11897.8	The CMS specialty/operations contractor shall provide the initial provider participant and beneficiary alignment testing files to the Virtual Data Centers (VDCs) no later than March 1, 2021 via EFT and shall make the files available to the DME MACs. The CMS operations contractor contacts are: Salauddin Shaik (Salauddin.Shaik@softrams.com); Vivek Trehan (Vivek.Trehan@softrams.com); Yani				X					ACO OS

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Mellacheruvu (Yani.Mellacheruvu@cms.hhs.gov); Aparna Vyas (Aparna.Vyas@cms.hhs.gov)									
11897.8.1	The CMS specialty/operations contractor shall provide a template of this CSV file.									ACO OS
11897.8.2	To assist with the testing files creation, the DME MACs shall provide the CMS specialty/operations contractor the beneficiary and participant (provider) data to create test files by February 12, 2021. These samples of providers and beneficiaries shall include a list of 5 to 15 test HICNs, and NPIs in a single Comma Separated Value (CSV) file using a HICN, and NPI layout. **NOTE:** Effective dates for testing files need to be 03/01/2021 - 03/31/2021 The CMS operations contractor contacts are: Salauddin Shaik (Salauddin.Shaik@softrams.com); Vivek Trehan (Vivek.Trehan@softrams.com); Yani Mellacheruvu (Yani.Mellacheruvu@cms.hhs.gov); Aparna Vyas (Aparna.Vyas@cms.hhs.gov)				X					ACO OS
11897.8.3	The VDCs shall make available to the contractors testing environments for the provider participant and beneficiary alignment files.									VDC
11897.8.4	The Virtual Data Centers (VDCs) shall run the jobs to load the test files.									VDC
11897.9	The CMS specialty/operations contractor shall deliver the initial provider participant and beneficiary alignment production files via electronic file transfer (EFT) to the BDC no later than 04/02/2021.									ACO OS
11897.9.1	CWF Host shall deliver a beneficiary alignment production file to the VDC no later than 04/02/2021.									CWF Host, VDC
11897.9.2	The VDCs shall run the jobs to load the production files after the April 2021 release is fully implemented.									VDC
11897.10	The Single Testing Contractor (STC) shall perform testing on the provider participant and beneficiary alignment file, working with the VDCs as necessary to obtain the file.									ACO OS, STC, VDC

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	NOTE: The STC shall begin sending test data on February 15, 2021 to ACO-OS. STC shall begin testing on February 4, 2021.									
11897.10.1	ACO-OS shall deliver a participant provider test file to VMS no later than October 1, 2020. CMS Specialty/Operations Contractor Contacts:Salauddin Shaik (Salauddin.Shaik@softrams.com); Vivek Trehan (Vivek.Trehan@softrams.com); Yani Mellacheruvu (Yani.Mellacheruvu@cms.hhs.gov); Aparna Vyas (Aparna.Vyas@cms.hhs.gov) **NOTE: All participant provider files shall only contain nurse practitioners.**									ACO OS, VDC
11897.10.2	CWF Host shall deliver a beneficiary alignment test file to VMS no later than October 1, 2020.							X		CWF Host
11897.10.3	ACO-OS shall deliver a beneficiary alignment test file to CWF no later than October 1, 2020. CMS Specialty/Operations Contractor Contacts:Salauddin Shaik (Salauddin.Shaik@softrams.com); Vivek Trehan (Vivek.Trehan@softrams.com); Yani Mellacheruvu (Yani.Mellacheruvu@cms.hhs.gov); Aparna Vyas (Aparna.Vyas@cms.hhs.gov)								X	ACO OS
11897.11	After the initial production provider participant and beneficiary alignment file transmission, the CMS operations/specialty contractor shall provide full replacement participant and beneficiary files the last Friday of each month.									ACO OS
11897.12	The contractor shall use the PCF Model Identifier in the matching of the beneficiary to the nurse practitioner's PCF Model Identifier for the HCPCS noted in BR 11897.13.							X		
11897.13	When one of the following HCPCS are present on the claim, VMS shall verify model participation with the PCF beneficiary alignment and participant provider files:							X		

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5508, A5510, A5512, A5513, A5514									
11897.13.1	VMS shall append the demo code ‘96’ when the beneficiary is participating in the PCF model for the date of service and the order/referring NP is aligned with the beneficiary in the PCF provider file.							X		
11897.13.2	CWF shall modify consistency edit ‘0014’ to allow DEMO Code '96' on (DME) HUDC claim and forward the value to NCH when present.								X	NCH
11897.14	For line items billing a HCPCS identified in requirement 13 above, DME MACs when performing medical review shall not deny the line based on the ordering/referring being a nurse practitioner when demo code ‘96’ is present on the claim.				X					

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): Wendy Jones, Wendy.Jones@cms.hhs.gov , Tammy Luo, Tammy.Luo@cms.hhs.gov , Donna Schmidt, Donna.Schmidt@cms.hhs.gov , Bobbett Plummer, Bobbett.Plummer@CMS.hhs.gov , ACO-OS OIT, ACO-OIT@cms.hhs.gov , Chris Coutin, christopher.coutin@cms.hhs.gov , Cynthia Thomas, cynthia.thomas2@cms.hhs.gov , Jason Kerr, jason.kerr@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