

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13295	Date: July 25, 2025
	Change Request 14031

Transmittal 13248 issued May 29, 2025, is being rescinded and replaced by Transmittal 13295, dated July 25, 2025, to add GA modifier language to be applicable for institutional claims, to shift liability. This correction also revises the IOM chapter 60, Pub. 100-04, the NCD 210.3 spreadsheet and updates business requirements 14031 - 04.3.1, 14031 - 04.4.1, 14031 - 04.5, 14031 - 04.6.1, 14031 - 04.7.1 and 14031 - 04.8.1. This correction does not make any revisions to Pub. 100-02. All other information remains the same.

SUBJECT: Omnibus Change Request (CR) Covering Updates for the Medicare Physician Fee Schedule (MPFS) Rule 2025: (1) Updates to Colorectal Cancer Screening and Hepatitis B Vaccine Policies

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make contractors aware of policy updates for Colorectal Cancer Screening and Hepatitis B resulting from changes specified in the Calendar Year (CY) 2025 Physician Fee Schedule (PFS) Final Rule (89 FR 97710), published in the Federal Register (FR) on December 9, 2024.

EFFECTIVE DATE: January 1, 2025

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

IMPLEMENTATION DATE: October 6, 2025

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	15/50.4.4/50.4.4.2/Immunizations

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. 100-02	Transmittal: 13295	Date: July 25, 2025	Change Request: 14031
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II. GENERAL INFORMATION

A. Background: On November 1, 2024, CMS issued a rule finalizing changes for Medicare payments for calendar year 2025 under the Physician Fee Schedule (PFS) and other Medicare Part B policies. The final rule was published in the Federal Register on December 9, 2024, (89 FR 97710), and was effective January 1, 2025. The final rule is available at: <https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other>

This Change Request (CR) includes a policy change finalized in this rule, related to coverage and payment of Hepatitis B Vaccine.

Hepatitis B Vaccine:

Hepatitis B is a vaccine-preventable, communicable disease of the liver. Hepatitis B vaccines are covered as a Medicare Part B benefit under section 1861(s)(10)(B) of the Act. Medicare beneficiaries who are at high or intermediate risk of contracting hepatitis B can receive hepatitis B vaccines, with no cost to Medicare beneficiaries. The statute authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B by issuing regulations. The Secretary, through past rulemaking, defined high and intermediate risk groups for hepatitis B vaccine at 42 Code of Federal Regulations (CFR) 410.63.

B. Policy: Updates to Hepatitis B Vaccine: Effective January 1, 2025, CMS is expanding coverage of hepatitis B vaccinations to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. A physician's order is no longer required for the administration of a hepatitis B vaccine under Part B, which will facilitate roster billing by mass immunizers for hepatitis B vaccine administration. Additionally, CMS finalized policy to set payment for hepatitis B vaccines and their administration at 100% of reasonable cost in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), separate from payment under the FQHC Prospective Payment System (PPS) or the RHC All-Inclusive Rate (AIR) methodology, to streamline payment for all Part B

vaccines in those settings. To read the discussions of changes, see Section III.M Expand Hepatitis B Vaccine Coverage (preamble pages 98326 – 98329 and changes to 42 C.F.R. 405.2466 on page 98554, and 42 C.F.R. 410.63 on page 98556), and related payment changes at Section III. H Medicare Part B Payment for Preventive Services (§§ 410.10,410.57, 410.64, 410.152), (on preamble pages 98213- 98228).

III. 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	
14031 - 02.1	Effective for services furnished on or after January 1, 2025, contractors shall provide coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. Please refer to Pub. 100-02 Benefit Policy Manual, Chapter 15, section 50.4.4.2, for further information.	X	X							

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part B, A/B MAC Part A

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

VI. CONTACTS

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

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 0

Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services

50.4.4.2 - Immunizations

(Rev. 13295; Issued: 07-25-25; Effective: 01-01-25; Implementation: 10-06-25)

B. Hepatitis B Vaccine

Effective for services furnished on or after January 1, 2025, (originally September 1, 1984, P.L. 98-369) provides coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B.

High-risk groups currently identified include (see exception below):

- ESRD patients;
- Hemophiliacs who receive Factor VIII or IX concentrates;
- Clients of institutions for *individuals with intellectual disabilities*;
- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men;
- Illicit injectable drug abusers;
- *Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii); and,*
- Persons diagnosed with diabetes mellitus.

Intermediate risk groups currently identified include:

- Staff in institutions for *individuals with intellectual disabilities and classroom employees who work with individuals with intellectual disabilities*;
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work *(including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions)*;
- *Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years); and,*
- *Individuals who have not previously received a completed hepatitis B vaccination series or whose previous vaccination history is unknown.*

EXCEPTION: Persons in both of the above-listed groups in paragraph B, would not be considered at high or intermediate risk of contracting hepatitis B, however, if there were laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.