

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-02 Medicare Benefit Policy</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 202</b>	<b>Date: December 31,2014</b>
	<b>Change Request 9051</b>

**SUBJECT: Modifications to Medicare Part B Coverage of Pneumococcal Vaccinations**

**I. SUMMARY OF CHANGES:** The purpose of this CR is to inform contractors that CMS is updating the Medicare coverage requirements to align with the updated Advisory Committee on Immunization Practices (ACIP) recommendations for Coverage of Pneumococcal Vaccinations.

**EFFECTIVE DATE: September 19, 2014**

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

**IMPLEMENTATION DATE: February 2, 2015**

*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

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	15/50.4.4.2/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

<b>Pub. 100-02</b>	<b>Transmittal: 202</b>	<b>Date: December 31, 2014</b>	<b>Change Request: 9051</b>
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**EFFECTIVE DATE: September 19, 2014**

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## I. GENERAL INFORMATION

**A. Background:** Medicare Part B covers certain vaccinations including pneumococcal vaccines. Generally, pneumococcal vaccine was covered once in a beneficiary's lifetime, with revaccinations covered for those at highest risk if 5 years have passed since the last vaccination, or if the beneficiary's vaccination history was unknown.

The ACIP recently updated its guidelines regarding pneumococcal vaccines. The ACIP recommends administration of two different pneumococcal vaccinations.

**B. Policy:** CMS is updating the Medicare coverage requirements to align with the updated ACIP recommendations. An initial pneumococcal vaccine may be administered to all Medicare beneficiaries who have never received a pneumococcal vaccine under Medicare Part B. A different, second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered).

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
9051 - 02.1	Contractors shall be aware that effective for dates of service on and after September 19, 2014 contractors shall pay claims for pneumococcal vaccinations under Part B as described in Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.4.4.2, and Pub. 100-04, Medicare Claims Processing Manual, chapter 18, section 10.1.1.	X	X	X							
9051 - 02.2	Contractors shall not search for and adjust any claims for pneumococcal vaccines and their administration, with dates of service on and after September 19, 2014. However, contractors may adjust claims brought to their attention.	X	X	X							

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
9051 - 02.3	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive 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 sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's 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.	X	X	X		

### 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):** Wanda Belle, 410-786-7491 or [wanda.belle@cms.hhs.gov](mailto:wanda.belle@cms.hhs.gov) (Coverage) , William Ruiz, 410-786-9283 or [William.Ruiz@cms.hhs.gov](mailto:William.Ruiz@cms.hhs.gov) (Institutional Claims Processing) , Jamie Hermansen, 410-786-2064 or [Jamie.Hermansen@cms.hhs.gov](mailto:Jamie.Hermansen@cms.hhs.gov) (Coverage) , Bridgitte Davis-Hawkins, 410-786-4573 or [Bridget.DavisHawkins@cms.hhs.gov](mailto:Bridget.DavisHawkins@cms.hhs.gov) (Practitioner Claims Processing) , Patricia Brocato-Simons, 410-786-0261 or [Patricia.BrocatoSimons@cms.hhs.gov](mailto:Patricia.BrocatoSimons@cms.hhs.gov) (Coverage)

**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**

## 50.4.4.2 - Immunizations

*(Rev. 202, Issued: 12-31-14, Effective: 09-19-14, Implementation: 02-02-15)*

Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as anti-rabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. (See items A, B, and C below.) In cases where a vaccination or inoculation is excluded from coverage, related charges are also not covered.

### A. Pneumococcal Pneumonia Vaccinations

#### 1. Background and History of Coverage:

*Section 1861(s)(10)(A) of the Social Security Act and regulations at 42 CFR 410.57 authorize Medicare coverage under Part B for pneumococcal vaccine and its administration.*

*For services furnished on or after May 1, 1981 through September 18, 2014, the Medicare Part B program covered pneumococcal pneumonia vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. Coverage included an initial vaccine administered only to persons at high risk of serious pneumococcal disease (including all people 65 and older; immunocompetent adults at increased risk of pneumococcal disease or its complications because of chronic illness; and individuals with compromised immune systems), with revaccination administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years had passed since the previous dose of pneumococcal vaccine.*

Those administering the vaccine *did* not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor *were* they compelled to review the patient's complete medical record if it *was* not available, *relying* on the patient's verbal history to determine prior vaccination status.

Effective July 1, 2000, Medicare *no longer required* for coverage purposes that a doctor of medicine or osteopathic medicine order the vaccine. Therefore, a beneficiary *could* receive the vaccine upon request without a physician's order and without physician supervision.

#### 2. Coverage Requirements:

*Effective for claims with dates of service on and after September 19, 2014, an initial pneumococcal vaccine may be administered to all Medicare beneficiaries who have never received a pneumococcal vaccination under Medicare Part B. A different, second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered).*

*Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient's verbal history to determine prior vaccination status.*

*Medicare does not require for coverage purposes that a doctor of medicine or osteopathic medicine order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.*

## **B. Hepatitis B Vaccine**

Effective for services furnished on or after 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 the mentally retarded;
- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men;
- Illicit injectable drug abusers; and
- Persons diagnosed with diabetes mellitus.

Intermediate risk groups currently identified include:

- Staff in institutions for the mentally retarded; and
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

**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.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathic medicine, by a doctor of medicine or osteopathic medicine, or by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, and persons recognized under the incident to physicians' services provision of law.

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

## **C. Influenza Virus Vaccine**

Effective for services furnished on or after May 1, 1993, the Medicare Part B program covers influenza virus vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. Typically, these vaccines are administered once a flu season. Medicare does not require, for coverage purposes, that a doctor of medicine or osteopathic medicine order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.