CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 145	**Date: July 8, 2011**
	Change Request 7453

SUBJECT: Influenza Virus Vaccine

I. SUMMARY OF CHANGES: The instructions in this transmittal are revising the Center for Medicare and Medicaid Services' (CMS) current language regarding the timing of seasonal influenza vaccine administration to better conform to the Center for Disease Control and Prevention's (CDC) recommendations for the prevention and control of influenza.

EFFECTIVE DATE: August 8, 2011
IMPLEMENTATION DATE: August 8, 2011

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/50.4.4.2/Immunizations

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-02	Transmittal: 145	Date: July 8, 2011	Change Request: 7453

SUBJECT: Influenza Virus Vaccine

Effective Date: August 8, 2011
Implementation Date: August 8, 2011

I. GENERAL INFORMATION

A. Background: The instructions in this transmittal are revising the Center for Medicare & Medicaid Services (CMS) current language regarding the timing of seasonal influenza vaccine administration to better conform to the Center for Disease Control and Prevention's (CDC) recommendations for the prevention and control of influenza. Recent CDC recommendations state that vaccination efforts should begin as soon as the seasonal influenza vaccine is available and continue through the influenza season (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s_cid=rr5908a1_w). CMS also recognizes that the beginning and duration of influenza season cannot be precisely determined. Consistent with previous instructions, CMS' policy continues to recognize that typically one seasonal influenza vaccination is allowable per influenza season and it is not anticipated that significant changes to contractors' procedures will be required to comply with these instructions.

B. Policy: Effective for services furnished on or after May 1, 1993, the influenza virus vaccine and its administration are covered when furnished in compliance with any applicable State law. Typically, this vaccine is administered once a flu season. Medicare Part B provides 100% coverage for the influenza vaccine and its administration as a preventive service. The Part B deductible and coinsurance do not apply for the influenza vaccine and its administration.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7453-02.1	Contractors shall note the instructions included in this transmittal supersede all prior instructions regarding the definition of a "flu season".	X		X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	None.										

IV. SUPPORTING INFORMATION

Section A:For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

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

V. CONTACTS

Pre-Implementation Contact(s): Bridgitté Davis at (410)786-4573 or Bridgitte.Davis@cms.hhs.gov; Joscelyn Lissone at (410) 786-5116 or Joscelyn.Lissone@cms.hhs.gov; or Prabath Mallua-Wadu (410) 786-4620 or Prabath.Mallua-Wadu@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

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

Section B: *For Medicare Administrative Contractors (MACs)*, include the following statement:

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.

50.4.4.2 - Immunizations

(Rev.145, Issued: 07-08-11, Effective: 08-08-11, Implementation: 08-08-11)

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

Effective for services furnished on or after May 1, 1981, the Medicare Part B program covers 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. This includes revaccination of patients at highest risk of pneumococcal infection. Typically, these vaccines are administered once in a lifetime except for persons at highest risk. Effective July 1, 2000, Medicare does not require for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

An initial vaccine may be administered only to persons at high risk (see below) of pneumococcal disease. Revaccination may be 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 have [passed since the previous dose of pneumococcal vaccine.

Persons at high risk for whom an initial vaccine may be administered include all people age 65 and older; immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks); and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Persons at highest risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. It is not appropriate for routine revaccination of people age 65 or older that are not at highest risk.

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. If the patient is uncertain about his or her vaccination history in the past 5 years, the vaccine should be given. However, if the patient is certain he/she was were vaccinated in the last 5 years, the vaccine should not be given. If the patient is certain that the vaccine was given more than 5 years ago, revaccination is covered only if the patient is at high risk.

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. This coverage is effective for services furnished on or after September 1, 1984. 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; and
- Illicit injectable drug abusers.

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 osteopathy, by a doctor of medicine or osteopathy, 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 osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.