2012- 2013
Immunizers' Question & Answer Guide to Medicare Part B, Medicaid and CHIP Coverage of Seasonal Influenza and Pneumococcal Vaccinations

Steps to Promoting Wellness Immunizations

The issues involved in Medicare, Medicaid and CHIP billing and administration can be complex and may vary state to state. For this reason, we recommend that you contact your local fiscal intermediary/AB MAC, carrier/AB MAC (Part B), or the Centers for Medicare & Medicaid Services' Regional Office for more detailed information.

Centers for Medicare & Medicaid Services

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A. Introduction

Purpose

This document addresses immunizers'commonly asked questions about the administration of influenza and pneumococcal vaccines to Medicare, Medicaid and CHIP patients. It also includes questions and answers that are particularly relevant to the 2012-2013 influenza immunizationseason.

The following information will be useful for immunizers; however, the issues involved in Medicare, Medicaid and CHIP billing and administration can be complex and may vary from state to state. For additional, detailed information, contact your local fiscal intermediary, AB MAC, carrier (Part B), or the Centers for Medicare & Medicaid Services (CMS).

The following sections provide a summary of the current recommendations of the Advisory Committee on Immunization Practices (ACIP) as they relate to immunization; Medicare, Medicaid and CHIP coverage and payment policy; requirements for mass immunizers and centralized billing; and a brief discussion of managed care. In addition, a list of definitions is included.

Background of Medicare Pneumococcal and Influenza Vaccination Benefits

Influenza causes an estimated 226,000 hospitalizations and 3000–49,000 deaths annually in the United States. An estimated ninety percent of seasonal influenza-related deaths occur among those aged 65 or older. Invasive pneumococcal infection (e.g., sepsis, meningitis) causes an estimated 40,000 cases and over 4,000 deaths annually in the U.S. Almost half of deaths due to pneumococcal disease occur in persons aged 65 and older.

The U.S. Congress established the Medicare program in 1965. Coverage for individual preventive services has been added since 1980 and use of preventive services has increased over time. These preventive services include vaccinations against: invasive pneumococcal disease, hepatitis B and influenza. The Medicare program has covered pneumococcal polysaccharide vaccine (PPSV) and its administration since July 1, 1981. The Medicare program has covered pneumococcal conjugate vaccine and its administration since January 1, 2008. Coverage for the influenza vaccine and its administration was added May 1, 1993.

Coverage rates for influenza and pneumococcal vaccines among those aged 65 and older increased substantially in the 1990s, but appears to have plateaued in recent years. In 2008, the Centers for Disease Control and Prevention (CDC) reported that 60.1 percent of persons aged 65 years and older had ever received a lifetime pneumococcal vaccine. In 2009, influenza immunization rates for this group were 65.0 percent – almost double the immunization rate in 1989 of 33 percent. The Department of Health and Human Services' Healthy People 2020 target vaccination rates for both vaccines to reach 90 percent for persons aged ≥65 years.

(http://www.cdc.gov/nchs/data/nhis/earlyrelease/200806_04.pdf ,
http://www.cdc.gov/nchs/data/nhis/earlyrelease/200806_05.pdf

ACIP Guidelines

Clinicians should refer to current published guidelines for current recommendations related to immunization. ACIP is an advisory committee to the federal government that makes written recommendations for routine administration of vaccines to pediatric and adult populations. The Infectious Diseases Society of America, the American Thoracic Society, and other professional societies also discuss vaccination of adults in their guidelines. At the time of this writing, the most recent ACIP Recommendations for the Prevention of Pneumococcal Disease that concern persons aged 65 years and older were published in the September 3, 2010 Morbidity and Mortality Weekly (MMWR) and are available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm?s_cid=mm5934a3_w . The ACIP recommendations for use of pneumococcal conjugate vaccine in children aged <5 years was published in 2000 and are available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4909a1.htm . Supplementary guidelines on the new 13-valent pneumococcal conjugate vaccine was published on March 12, 2010 and are available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm . The ACIP influenza immunization guidelines for the 2012-2013 season were published in August 2012 and are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_w. State laws governing who may administer pneumococcal and influenza vaccines and how the vaccines may be transported vary widely. In addition to staying abreast of current guidelines, CMS urges providers and suppliers to stay current with state immunization regulations.

Summary of ACIP Guidelines

Pneumococcal

The ACIP recommends that all persons receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who received pneumococcal vaccine before age 65 years are recommended to receive another dose after they turn age 65 and at least 5 years have elapsed since their previous dose. The pneumococcal vaccine is an once-in-a-lifetime vaccine after age 65 that can be given at any time of the year. All persons whose vaccination status is unknown should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection at a different site).

According to the ACIP, pneumococcal vaccine is recommended for the following groups of persons who are at increased risk for invasive pneumococcal disease or its complications:

- Persons 2 years of age and older with a normal immune system who have a chronic illness such as:
    a) Cardiovascular disease
    b) Pulmonary disease
    c) Diabetes
    d) Alcoholism
    e) Chronic liver disease, including cirrhosis
    f) Cerebrospinal fluid leak
    g) Cochlear implant

- Persons 19 years old or older who are current cigarette smokers
- Persons 19 years old or older who have asthma
- Immuno-compromised persons 2 years of age and older who have:

    h) Splenic dysfunction or absence (either from disease or surgical removal)
    i) Hodgkin disease
    j) Lymphoma
    k) Multiple myeloma
    l) Chronic renal failure
    m) Nephrotic syndrome (type of kidney disease)
    n) Conditions such as organ transplantation associated with immunosuppression
    o) Persons immunosuppressed from chemotherapy or high-dose corticosteroid therapy (14 days for longer)
    p) Asymptomatic or symptomatic HIV infection

- Consider pneumococcal vaccination for the following special groups:

    a) Certain Native American (i.e., Alaska Native, Navajo, and Apache) populations..

About 78% of adults who have invasive pneumococcal infection have at least one of the previously mentioned underlying medical conditions, including age greater than or equal to 65 years.

Influenza

Primary Changes and Updates in the 2012-2013 Recommendations

The 2012 ACIP recommendations include several principal changes or updates of the 2010 recommendations which are summarized below. The 2010 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s_cid=rr5908a1_w; see also http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5931a4.htm) ACIP Influenza Statement may be consulted for information on issues not updated in 2012-2013.

- ACIP recommends that annual vaccination be administered to all people 6 months old and older.
- There are two types of influenza vaccine: trivalent inactivated vaccine (TIV) and live attenuated influenza vaccine (LAIV).
- All TIV preparations are administered intramuscularly, with the exception of Fluzone Intradermal (Sanofi Pasteur), which is administered intradermally. Each preparation has specific age indications. Fluzone Intradermal is indicated for individuals 18 through 64 years of age and is an alternative (with no preferential ACIP recommendation) to other TIV preparations in the indicated age range. With regard to intramuscular preparations, one (Fluzone Intradermal) is indicated for individuals 65 years old and older, and is an alternative (with no preferential ACIP recommendation) to other TIV preparations in this age group.

Among other intramuscular TIV preparations, minimum age indications vary, but preparations are available for individuals as young as six months of age.

- LAIV is administered intranasally, and is indicated for healthy non-pregnant individuals aged 2 through 49 years. There is no preferential ACIP recommendation for LAIV use; either may be used in the indicated group. LAIV should not be administered to children aged <5 years with possible reactive airways disease, such as those who have had recurrent wheezing or a recent wheezing episode.
- Recommendations for influenza vaccine dosing for children 6 months through 8 years of age are updated for 2012-2013. Children in this age range who are receiving influenza vaccine for the first time require 2 doses, administered at least 4 weeks apart. Some children who have received influenza vaccine previously will also require 2 doses. The number of doses may be determined by one of the following 2 approaches, both of which are acceptable:

    1. The first approach takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. This recommendation is harmonized with that of the American Academy of Pediatrics (*10*). This approach has the advantage of simplicity, particularly in settings in which ascertaining vaccination history before the 2010–11 season is difficult. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they received a total of 2 or more doses of seasonal vaccine since July 1, 2010. Children who did not receive a total of 2 or more doses of seasonal vaccine since July 1, 2010, require 2 doses in 2012–13.
    2. In settings where adequate vaccination history from before the 2010–11 season is available, the second approach may be used. By this approach, if a child aged 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., either 2010–11 or 2011–12 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2012–13. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they have received any of the following:
        - 2 or more doses of seasonal influenza vaccine since July 1, 2010; or
        - 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or
        - 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010.

- Vaccination efforts should begin as soon as vaccine is available and continue through the influenza season.
- Individuals with a history of mild allergy to eggs (specifically, those who only have hives as a symptom) may receive influenza vaccine provided that TIV rather than LAIV is used, the vaccine is administered by a provider familiar with the potential manifestations of egg allergy, the recipient is observed for signs of an allergic reaction for at least 30 minutes following vaccination, and personnel and equipment needed for treatment of a potentially severe reaction are available.

Who Should Be Vaccinated?

- ACIP recommends that annual vaccination be administered to all people 6 months old and older.
- When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons who:

    -- are aged 6 months--4 years (59 months);

    -- are aged ≥50 years;

    -- have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);

    -- are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus);

    -- are or will be pregnant during the influenza season;

    -- are aged 6 months--18 years and receiving long-term aspirin therapy and who therefore might be at risk for experiencing Reye syndrome after influenza virus infection;

    -- are residents of nursing homes and other chronic-care facilities;

    -- are American Indians/Alaska Natives;

    -- are morbidly obese (body-mass index ≥40);

    -- are health-care personnel;

    -- are household contacts and caregivers of children aged <5 years and adults aged ≥50 years, with particular emphasis on vaccinating contacts of children aged <6 months; and

    -- are household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

Health-care Personnel

All health-care personnel (HCP) should be vaccinated against influenza annually. HCP refers to all paid and unpaid persons working in health-care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, administrators, billing, and volunteers) not directly involved in

patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Facilities that employ health-care personnel are strongly encouraged to provide vaccine to personnel by using approaches that maximize vaccination rates. This will protect health-care personnel, their patients, and communities, and will improve prevention of influenza-associated disease. Influenza vaccination rates among health-care personnel should be regularly measured and reported. Although the vaccination rate for health-care personnel in 2008-2009 was 52.9%, with moderate effort, organized campaigns can attain higher rates of vaccination among this population. A number of states and health care facilities have established requirements relating to assessment of vaccination status and/or administration of one or more vaccines, including influenza. The Department of Health and Human Services' Healthy People 2020 target for health-care personnel is 90%.

"The ACIP, with CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) issued recommendations calling for urgent attention to influenza vaccination of HCP (see http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm). (Shefer A, Atkinson W, Friedman C, et al. Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; 60(7):1-46.) These in particular recommend that healthcare institutions:

- Educate HCP regarding the benefits of influenza vaccination and the potential health consequences of influenza illness for themselves and their patients, the epidemiology and modes of transmission, diagnosis, treatment, and non-vaccine infection control strategies, in accordance with their level of responsibility in preventing health-care--associated influenza (category IB).

- Offer influenza vaccine annually to all eligible HCP to protect staff, patients and family members and to decrease HCP absenteeism. Use of either available vaccine (inactivated and live, attenuated influenza vaccine [LAIV]) is recommended for eligible persons. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged when feasible for eligible HCP (category IA).

- Provide influenza vaccination to HCP at the work site and at no cost as one component of employee health programs. Use strategies that have been demonstrated to increase influenza vaccine acceptance, including vaccination clinics, mobile carts, vaccination access during all work shifts and modeling and support by institutional leaders (category IB).

- Obtain a signed declination from HCP who decline influenza vaccination for reasons other than medical contraindications (category II).

- Monitor HCP influenza vaccination coverage and declination at regular intervals during influenza season and provide feedback of ward-, unit- and specialty-specific rates to staff and administration (category IB).

- Use the level of HCP influenza vaccination coverage as one measure of a patient safety quality program (category II).

1. In addition, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has issued a standard requiring critical access hospitals, hospitals and long-term care facilities to offer influenza vaccine to staff and licensed independent practitioners and to report coverage levels among HCP. The standard went into effect January 1, 2007.

Who Should Not Be Vaccinated

People in the following groups should not get an influenza vaccine before talking with their doctor:

- People who have a severe allergy (e.g., anaphylactic allergic reaction or a reaction involving anything other than hives) to eggs (people who have only hives following exposure to egg may receive TIV with additional measures outlined in the 2012-2013 ACIP influenza vaccine statement);
- People who have an allergy to any component of the vaccine, or who have had a prior allergic reaction to a previous dose of vaccine;
- People with a history of Guillain–Barré Syndrome (a severe paralytic illness, also called GBS) that occurred after receiving influenza vaccine and who are not at risk for severe illness from influenza should generally not receive vaccine. These persons should discuss potential risks and benefits of vaccination with their healthcare provider.

  LAIV should not be administered to children aged <5 years with possible reactive airways disease, such as those who have had recurrent wheezing or a recent wheezing episode.

- Children 6 months through 8 years of age should not receive Afluria (TIV manufactured by CSL). Afluria has been associated with febrile seizures in children 6 months through 4 years of age and has been associated with fever in children 6 months through 8 years of age. Providers should use another age-appropriate vaccine for children 6 months through 4 years of age, and children 5 years through 8 years of age who are not high-risk for complications from influenza. For children 5 years through 8 years of age who are high-risk for complications of influenza, Afluria can be used if no other seasonal vaccine is available and parents/guardians have been informed of the potential risk.
- Persons with moderate to severe acute febrile illness usually should not be vaccinated until their symptoms have abated. However, minor illnesses with or without fever do not contraindicate use of influenza vaccine.

Other Vaccination Recommendations for persons 2-49 years old–Use of Live, Attenuated Influenza Vaccine (LAIV)

- Healthy persons who are 2-49 years of age and not pregnant may use the LAIV. This includes health-care personnel (except those who care for severely immunocompromised patients during those periods in which the immunocompromised person requires care in a protective environment), out-of-home caregivers and household contacts of persons in high-risk groups (e.g., persons aged ≥65 years; persons with chronic conditions such as diabetes, heart or lung

disease, or weakened immune systems because of illness or medication; and children aged ≤2 years). The LAIV is administered intranasally.

Other Vaccination Recommendations for persons over 65 years of age – Use of High Dose Vaccine.

- A higher dose formulation of an inactivated seasonal influenza vaccine for use in people age 65 years and older is available and payable by Medicare in the 2012-2013 influenza season. This higher dose formulation in one study of people age 65 years and older produced higher antibody levels, but slightly higher frequency of local reactions. Studies are underway to assess the relative effectiveness of the higher dose formulation compared to standard dose inactivated influenza vaccine, but results from those studies are not yet available. The ACIP has not expressed a preference for this higher dose formulation or any other licensed inactivated influenza vaccine for use in people age 65 and older.

Contacts/Resources for More Information

Influenza Vaccination of Health-Care Personnel

- Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the ACIP http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm .

ACIP Guidelines

- ACIP Recommendations List, http://www.cdc.gov/vaccines/pubs/ACIP-list.htm
- ACIP Recommendations for the Prevention of Pneumococcal Disease, MMWR, April 4, 1997, www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm (html),
- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm

HHS Web Site

- http://insurekidsnow.gov
- http://www.flu.gov

CMS Web Site

- http://www.cms.gov/Immunizations/ (for access to English/Spanish articles, mini-posters and other documents of use with patients).

CDC Web Sites

- http://www.cdc.gov/vaccines/ (National Center for Immunization and Respiratory Diseases)

- http://www.cdc.gov/flu/ (CDC Influenza)

- http://www.cdc.gov/mmwr/?s_cid=mmwr_online_e and http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm?s_cid=mm5934a3_w (Morbidity and Mortality Weekly Reports)

- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm?s_cid=rr5502a1_e (Influenza Vaccination of Health-Care Personnel)

Medicare Learning Network (MLN)

- MLN Preventive Services Educational Products web page located at http://www.cms.hhs.gov/MLNProducts/35_PreventiveServices.asp . At this page, providers will find all MLN educational products related to influenza and all other Medicare Preventive Services.

- The Guide to Medicare Preventive Services, Fourth Edition http://www.cms.hhs.gov/MLNProducts/downloads/mps_guide_web-061305.pdf .

CMS Manuals and Transmittals

- Medicare Claims Processing Manual, Chapter 18 – Preventive and Screening Services http://www.cms.hhs.gov/manuals/downloads/clm104c18.pdf .

- See Pub 100-04, Chapter 10 – Home Health Agency (section 90.2) http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf .

Intermediary-Carrier Directory

- http://www.cms.hhs.gov/ContractingGeneralInformation/Downloads/02_ICdirectory.pdf

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Forms

- Form CMS-855-I http://www.cms.hhs.gov/CMSforms/downloads/cms855i.pdf .

- Form CMS-855B http://www.cms.hhs.gov/CMSforms/downloads/cms855b.pdf .

B. Coverage Policy

Coverage Criteria

What vaccinations do Medicaid and CHIP cover?

States must cover all ACIP recommended vaccines for children enrolled in Medicaid and CHIP.

States have the flexibility to choose whether to cover vaccinations for adults, and many states cover some or all of the ACIP recommended vaccines for adults. For further information on what adult immunizations are covered, please refer to your State's Medicaid Manual and/or agency representative.

B.1 What are Medicare's coverage criteria for influenza virus vaccinations?

Effective for services performed on or after May 1, 1993, Medicare will pay for influenza virus vaccines and their administration. Generally, only one influenza virus vaccination is medically necessary per influenza season. Medicare beneficiaries may receive the vaccine once each influenza virus season, paid by Medicare, without a physician's order and without the supervision of a physician. State laws regarding who can administer vaccines still apply. The Medicare Part B deductible and coinsurance do not apply. Additional vaccination may be covered if medically necessary.

B.2 What are Medicare's coverage criteria for pneumococcal vaccinations?

Effective for services performed on or after May 1, 1981, Medicare began paying for the pneumococcal polysaccharide vaccine and its administration. Effective for claims with dates of service on or after July 1, 2000, Medicare no longer requires the pneumococcal vaccine to be ordered by a doctor of medicine or osteopathy. However, state laws regarding who can administer vaccines and under what circumstances, still apply. When allowable under state law, a beneficiary may receive the vaccine upon request without a physician's supervision.

Effective for services performed on or after January 1, 2008, Medicare began paying for the pneumococcal conjugate vaccine and its administration.

In accordance with ACIP recommendations, all persons should receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who receive a dose before age 65 are recommended to receive another dose after they turn age 65, once 5 years have elapsed since their prior dose. The pneumococcal vaccine is generally an once-in-a-lifetime vaccine after age 65 vaccination that can be given at any time during the year. All persons whose vaccine status is unknown should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza virus vaccine (by separate injection in the opposite arm).

Persons 65 years of age or older and immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness are considered at high risk.

Provided that at least five years have passed since receipt of a previous dose of the pneumococcal vaccine, 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. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), human immunodeficiency virus (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. Routine revaccination of people age 65 or older is not appropriate, unless determined medically necessary by a physician, unless initial vaccination was given before age 65, and 5 years has passed. Additional vaccine during an influenza season may be covered if medically necessary.

B.3 Could you provide clarification regarding the "when in doubt rule" concerning re-vaccination of Medicare patients with the pneumococcal vaccine when they don't remember if they have been vaccinated?

Persons aged 65 years or more should be administered a second dose of vaccine if they received the vaccine more than 5 years previously and were less than 65 years at the time of primary vaccination. Persons aged 65 years or older with unknown vaccination status should be administered one dose of vaccine.

B.4 Will Medicare pay for vaccination if an individual cannot produce documentation or is not sure whether they have received a pneumococcal vaccine?

Yes. 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, health professionals may rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about their vaccination history in the past five years, the vaccine should be given. However, if the patient is certain s/he was vaccinated in the last five years, the vaccine should not be given. If the patient is certain that the vaccine was given and that more than five years have passed since receipt of the previous dose, revaccination is not appropriate unless the patient is at highest risk.

B.5 Will Medicare pay for the revaccination if an individual, not at higher risk, is revaccinated with the pneumococcal vaccine?

Yes, if a beneficiary who is not at highest risk is revaccinated because of uncertainty about his or her vaccination status, Medicare will cover the revaccination.

Eligibility

B.6 Is a person with only Part A coverage entitled to receive the influenza virus and pneumococcal vaccinations and have them covered under Part B?

No. The influenza virus and pneumococcal vaccines and their administration are a Part B covered service only. A person's eligibility for Part B coverage is indicated on their Social Security card. The Medicare Card clearly displays Part A and/or Part B.

B.6a. If a person has other insurance, do I need to bill that other insurance company first for influenza virus and pneumococcal vaccinations?

No. Medicare is considered the primary payer for influenza virus and pneumococcal vaccinations and the services will be paid at 100 percent (the co-insurance and deductible do not apply.)

Who Can Bill?

How can providers bill for immunizations administered to Medicaid and CHIP enrollees?

Medicaid
The federally funded Vaccines for Children (VFC) program provides vaccines at no cost to children who are enrolled in Medicaid, uninsured, underinsured, or an American Indian or Alaska Native through age 18.

Under this program, the Center for Disease Control (CDC) purchases and distributes vaccines to grantees, such as state health departments and certain local and territorial public health agencies. These grantees distribute the vaccines at no charge to private physicians' offices and public health clinics that are registered as VFC providers.

Because the federal government pays for the vaccine, providers should not bill for the cost of the vaccine product. Instead, they may bill for administering the vaccine. The administration fee varies by state.

CHIP
For CHIP, billing procedures will vary by state depending on whether the state purchases vaccines from private insurers or using the CDC's VFC program contracts. Visit http://www.insurekidsnow.gov/state/index.html to visit your State's web site and find out more.

B.7 Which individuals and what entities may bill Medicare for the influenza virus and pneumococcal vaccines and their administration?

Any individual or entity meeting state licensure requirements may qualify to have payment made for furnishing and administering the influenza virus and pneumococcal vaccines to Medicare beneficiaries enrolled under Part B.

B.8 May a registered nurse/pharmacist employed by a physician/pharmacy use the physician's/pharmacy's provider number if the nurse/pharmacist in a location other than the physician's office/pharmacy provides influenza virus and pneumococcal vaccinations?

No. If the nurse/pharmacist is not working for the physician/pharmacy that has a provider number when the services are provided (e.g., a nurse/pharmacist is "moonlighting," administering influenza virus and pneumococcal vaccinations at a shopping mall (under protocol) and at that time is not functioning as an employee of the physician/pharmacy), then the nurse/pharmacists should obtain a provider number of his/her own and bill the carrier/AB Medicare Administrative Contractor (MAC) directly. However, if the nurse/pharmacist is working and representing the physician/pharmacy when the services are provided, the nurse/pharmacist would use the physician's/pharmacy's provider number.

Who to Bill

B.9 What types of providers and suppliers may bill the intermediary/AB MAC for the influenza virus and pneumococcal vaccinations?

The following participating providers of services may bill intermediaries for this benefit:

- Hospitals (including Critical Access Hospitals (CAHs), Indian Health Service hospitals (IHS); and IHS CAHs)
- Skilled Nursing Facilities (SNFs);
- Certified Home Health Agencies (HHAs);
- Comprehensive Outpatient Rehabilitation Facilities (CORFs);
- Independent and Hospital-Based Renal Dialysis Facilities (RDFs).

B. 10 Many Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) bill the intermediary for the influenza virus and pneumococcal vaccinations.

RHCs and FQHCs do not bill the intermediary/AB MAC for the influenza virus and pneumococcal vaccinations. Payment is made based on information provided on the cost report.

B.11 What type of providers and suppliers may bill the carrier/AB MAC for influenza virus and pneumococcal vaccinations?

- Physicians
- Suppliers
- Hospices
- Public Health Clinics
- Pharmacists/Pharmacies
- Self Employed Nurses
- Senior Centers*
- Shopping Malls*
- Non Skilled Nursing Homes
- Assisted Living Facilities
- Mass Immunization Providers
- Non-certified Home Health Agencies*

* These are possible locations where a mass immunization provider may provide vaccination services.

B.12 May a non-participating provider submit a bill for the patient or get paid for vaccine cost from the fiscal intermediary/AB MAC?

No. A non-participating provider would not bill an institutional (Part A) claim for influenza virus and pneumococcal immunizations. The provider would bill the carrier/AB MAC for professional Part B services.

B.13 May certified institutional providers submit claims to a carrier/AB MAC?

No. With the exception of hospice providers, certified institutional providers must bill their intermediary for this Part B benefit. Hospice providers bill the carrier/AB MAC.

B.14 How should nonparticipating provider facilities (e.g., nursing homes) bill Medicare?

Non-Medicare-participating provider facilities bill their local carrier/AB MAC.

B.15 May Home Health Agencies (HHA) that have a Medicare-certified component and a non-Medicare certified component elect to furnish influenza virus and PPV benefit through the non-certified component and bill the Part B carrier/AB MAC?

Yes for certain circumstances. See Pub 100-04, Chapter 10 – Home Health Agency (section 90.2) http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf . When an HHA provides the influenza vaccine in a mass immunization setting, it does not have the option to choose which contractor to roster bill for this service. If the service is being provided by employees from the certified portion, and as a result, reports the costs on the cost report, the HHA must bill its Regional Home Health Intermediary (RHHI) or MAC with home health and hospice workload (HH&H MAC) on an institutional claim (837I or Form CMS-1450).

If employees from the non-certified portions (employees of another entity that is not certified as part of the HHA) are providing the service and as a result, payment will not be made on the cost report for these costs, the HHA must obtain a provider number and bill its carrier/AB MAC on the Form CMS-1500.

If employees from both certified and non-certified portions of your facility are used to furnishing the vaccine at a single mass immunization site, the HHA must prepare two separate rosters, i.e., one for employees of the certified portion of the facility to be submitted to your RHHI/HH&H MAC, and one for employees of the non-certified portion of the facility to be submitted to the carrier/AB MAC.

B.16 How do carrier/AB MACs handle influenza virus and pneumococcal vaccination claims for Railroad Retirement Board (RRB) beneficiaries? Who should be billed for these services?

Carrier/AB MACs will return as unprocessable assigned claims and deny unassigned claims. The physician, non-physician practitioner or supplier must submit the claim to Palmetto GBA (the RRB carrier/AB MAC) at P.O. Box 10066, Augusta, GA 30999.

Physician Presence/Order

B.17 Does a physician have to be present when the influenza virus and pneumococcal vaccines are administered?

No. Medicare does not require a physician to be present. However, laws in individual states may require a physician's presence.

B.18 Is a physician order (written or verbal), plan of care, or any other type of physician involvement required for Medicare coverage of the influenza virus and pneumococcal vaccinations?

No. For Medicare coverage purposes, it is no longer required that either of the vaccines be ordered by a doctor of medicine or osteopathy though individual state law may require a physician order or other physician involvement. Therefore, when allowable under state law, the beneficiary may receive the vaccines upon request without a physician's order.

Frequency

B.19 There has been some confusion about how often a beneficiary can receive an influenza virus vaccination and have it covered by Medicare. If a beneficiary receives an influenza virus vaccination more than once in a 12-month period, will Medicare still pay for it?

Yes. Generally, Medicare pays for one influenza virus vaccination **per influenza season**. Medicare beneficiaries may receive the vaccine once each influenza season, paid by Medicare, without a physician's order and without the supervision of a physician.

B.20 What if a beneficiary needs more than one influenza virus vaccine in an influenza season?

Medicare will pay for more than one influenza virus vaccination per influenza season if a physician determines and documents that the vaccination is reasonable and medically necessary. The administering provider should maintain documentation.

B.21 Will Medicare cover more than one pneumococcal vaccine in a patient's lifetime?

Yes, in accordance with ACIP all persons should receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who receive a dose before age 65 are recommended to receive another dose after they turn age 65, once 5 years have elapsed since their prior dose. The pneumococcal vaccine is generally a once-in-a-lifetime after age 65 vaccination that can be given at any time during the year. All persons who have unknown vaccination status should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza virus vaccine (by separate injection in the opposite arm).

Home Health Agencies (HHA)

B.22 Will Medicare pay an HHA for a nurse's visit when he or she goes into a patient's home to furnish the influenza virus or pneumococcal vaccine?

It depends on the circumstances. If the sole purpose for a HHA visit is to administer a vaccine (influenza, pneumococcal), Medicare will not pay for a skilled nursing visit by an HHA nurse under the HHA benefit. However, the seasonal vaccine and its administration are covered under the vaccine benefit. The administration should include charges only for the supplies being used and the cost of the injection. HHA are not permitted to charge for travel time or other expenses (e.g., gasoline).

B.23 May HHAs that have a Medicare-certified component and a non-Medicare certified component elect to furnish the influenza and pneumococcal vaccine benefit through the non-certified component and bill the Part B carrier/AB MAC?

Yes, for certain circumstances. See Pub 100-04, Chapter 10 – Home Health Agency (section 90.2) http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf. When you provide the influenza virus vaccine in a mass immunization setting, you do not have the option to pick and choose who to roster bill for this service. If you are using employees from your certified portion, and as a result will be reflecting these costs on your cost report, you must bill your Regional Home Health Intermediary (RHHI) on the Form CMS-1450 (the electronic version is called the X12 837 Institutional.
If you are using employees from your non-certified portions (employees of another entity that is not certified as part of your HHA), and as a result, payment will not be made on the cost report for these costs, you must obtain a provider number and bill your carrier/AB MAC on the Form CMS-1500.

If employees from both certified and non-certified portions of your facility are used to furnish the vaccine at a single mass immunization site, you must prepare two separate rosters, i.e., one for employees of the certified portion of your facility to be submitted to your RHHI HH&H MAC, and one for employees of the non-certified portion of your facility to be submitted to your carrier/AB MAC.

B.24 Does a physician have to be present when the influenza virus and pneumococcal vaccines are administered?

No. Medicare does not require a physician to be present. However, laws in individual states may require a physician's presence.

B.25 If the sole purpose for an HHA visit is to administer a vaccine (influenza virus, pneumococcal, or hepatitis B), will Medicare pay for a skilled nursing visit by an HHA nurse under the HHA benefit?

No, however, the vaccine and its administration are covered under the vaccine benefit. The administration should include charges only for the supplies being used and the cost of the injection. The HHA bills using the Health Care Procedure Coding System (HCPCS) code for the vaccine and revenue code 0771 along with the appropriate HCPCS code for the administration.

B.26 If a vaccine (influenza, pneumococcal, or Hepatitis B) is administered during the course of an otherwise covered home health visit (e.g., to perform wound care), is the visit covered by Medicare?

Yes, the visit would be covered as normal, but the HHA must not include the vaccine or its administration in their visit charge. In this case, the HHA is entitled to payment for the vaccine and its administration under the vaccine benefit. In this situation, the HHA bills under bill type 34x and reports revenue code 0636 along with the appropriate HCPCS code for the vaccine and revenue code 0771 along with the appropriate HCPCS code for the administration.

B.27 If during a HHA visit a patient's spouse is a Medicare beneficiary and requests an influenza virus or pneumococcal vaccination, can Medicare be billed?

The vaccine cost and administration is billable along with the supplies, but the visit is not billable for the spouse. The injection may be given at the time of a scheduled visit for the patient.

HHA Mass Billers

Please refer to Section D: Mass Immunizers and Roster Billing.

C. Payment Policy

Medicare Vaccine/Administration Payment

The total payment received for administration of influenza virus and pneumococcal vaccines is based upon:

Cost of Vaccine Reimbursement + Compensation for Vaccine Administration

C.1 Why is there such a variation between states and even within states in Medicare reimbursement rates for influenza virus and pneumococcal vaccine and its administration?

When billing Medicare Part B for the cost of the vaccine, there is a nationally established payment allowance in Medicare reimbursement, however, there can be a variation in the reimbursement for the vaccine administration fee.

Medicare's payment allowance limits for the cost of the influenza and pneumococcal vaccines are established nationally as 95% of the average wholesale price (AWP) as reflected in such published drug pricing compendia as the Red Book or Medispan. The payment allowances for the influenza vaccines are updated based on the published AWP data that appear in the pricing compendia preceding each flu season, and the updated payment allowances typically appear on the fiscal agent payment files by October 1st. The payment allowances for the PPV vaccines are updated quarterly based on published AWP data.

Since administration fee schedules are adjusted for each Medicare payment locality, there can be a variation in the administration payment amount nationwide. Medicare payment by carrier/AB MACs for the administration of the vaccines is linked to payment for services under the physician fee schedule, but is not actually paid under the physician fee schedule. The compensation for the administration is the lesser of the actual charge or the fee schedule amount for a comparable injection (i.e., vaccine administration CPT 90471). This fee schedule is determined each year with an effective date of January 1.

C.2 When will this year's vaccine reimbursement rate be set?

Since the Medicare vaccine payment rate is based on the Average Wholesale Price (AWP) for the current year's vaccines, (not the AWP for the previous season), Carrier/AB MACs cannot use this year's payment rate until CMS confirms that the AWPs are published in sources, such as the Red Book or Medispan. This occurs when the vaccines are licensed in the summer. Medicare cannot adjust reimbursement rates until the AWPs are published, but can retroactively adjust claims to August 1.

C.3 How are the payment rates for the administration of the influenza virus and pneumococcal vaccines determined?

The allowed amount for the administration of the influenza virus and pneumococcal vaccines is based on the same rate as the HCPCS code 90471 (Immunization Administration, Hepatitis B Virus (HBV) Vaccine) as priced on the physician fee schedule database. When billing Medicare, providers will

submit the code G0008 (influenza) or G0009 (pneumococcal) for the administration of vaccine. Therefore, the allowable fee for the administration of the seasonal influenza virus and/or pneumococcal vaccines will vary based on the locality of the provider.

2012 Physician Fee Schedule = Fee Schedule Amount

The Fee Schedule Amount for any given service, including vaccine administration, is determined based upon the resources required to furnish the service expressed as relative value units (RVUs) for the three primary components of physician services: work, practice expense and malpractice. The RVUs for each of these is adjusted for specific payment localities by multiplying the RVUs for each payment component of a physician service by the Geographic Practice Cost Index (GPCI) for that in the appropriate payment locality. The resulting RVUs for each component are then added together to determine the payment amount for a service in a specific locality. The formula is:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x CF.

Current Administration and Vaccine Reimbursement Rates

Administration Rates: For the influenza and pneumococcal vaccine administration services, the payment rates are updated annually, effective January 1; so, from now until December 31, you may use the current physician fee schedule search engine available on the CMS website: http://www.cms.gov/PFSlookup - follow the prompts to find the specific administration pricing per locality. Remember, the actual service codes are G0008 or G0009, but these payments are based upon a link to CPT code 90471; so, the HCPC code to "look up" is 90471."

Vaccine Reimbursement Rates may be obtained at
Beginning with the 2012-2013 influenza season, vaccine reimbursement rates will be effective August 1, 2012. Corresponding claims processing instructions have recently been posted at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2424CP.pdf.

C.1 Describe the process for updates and changes to the Revisions to Payment Policies. What is legislatively set? What parts can CMS propose changes to?

The formula for determining the update to vaccine administration is statutorily defined. CMS sets the relative value of physician services following long-established processes that are described in Medicare regulations. In general, CMS proposes relative values in new payment rates around early July for the following year. The proposed rule has a 60-day comment period. Comments are encouraged and considered before the final rule is issued. The reimbursement for vaccine cost is determined in accordance with statutory guidelines and changes each year based upon published AWPs for each year's licensed vaccines around November 1st. The reimbursement for vaccine cost is determined in accordance with statutory guidelines and changes each year based upon published AWPs that appear in the pricing compendia preceding each flu season,

C.2 Do Medicare's changes in payment for vaccine administration affect Medicaid payment?

No. Medicaid sets its own payment rate for immunization based on factors other than Medicare payment.

Vaccine /Administration Payment When Billing Contractors/AB MACs

C.3 In the outpatient setting, is the administration payment a set fee no matter what it costs to administer the vaccine (Seasonal influenza virus and pneumococcal)? Where is the regional variability as far as cost for vaccine; is it the administration or the vaccine cost or both?

Payment for vaccines at hospital outpatient departments (including CAHs), outpatient SNFs, hospital-based RDFs, and HHAs is made under reasonable cost. Payment for vaccines at IHS outpatient departments (including IHS CAHs), CORFs, and independent-based RDFs is made based on the lower actual charge or 95% of the AWP.

For hospital outpatient departments and HHAs, the payment for administering the vaccine is paid under the hospital outpatient prospective payment system (OPPS). For hospital not subject to OPPS, payment is based on reasonable cost. Payment for the administration at outpatient SNFs, independent-based RDFs, and CORFs is made based on the Medicare Physician,s Fee Schedule (MPFS). For CAHs and hospital-based RDFs, payment is based on reasonable cost. For IHS outpatient departments (including CAH), payment is made based on MPFS. Payment rates for the administration of the vaccine itself (i.e., the injection) and the vaccine vary based on differences in costs across regions. CMS uses the same factor to adjust other services provided under the hospital OPPS. We also note that the payment rate for the administration of the vaccine when provided in a physician's office is also adjusted for geographic differences in costs.

Collecting Payment

Under Section 114 of the Benefits Improvement and Protection Act of 2000 (BIPA), payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis (note: Influenza virus and PPV Vaccines are covered under Medicare Part B, not Part D). Therefore, all physicians, non-physician practitioners and suppliers who administer influenza virus or pneumococcal vaccines after February 1, 2001, must take assignment on the claim for the vaccine.

C.4 Does the limiting charge provision apply to the influenza virus or PPV benefit?

Yes. All physicians and suppliers, regardless of participation status, must accept assignment of the Medicare vaccine payment rate.

However, non-participating physicians and suppliers who do not accept assignment for the administration of influenza virus or pneumococcal vaccines benefit may collect their usual charges (i.e., the amount charged a patient who is not a Medicare beneficiary) for influenza virus and pneumococcal

vaccines administration. The beneficiary is responsible for paying the difference between what the physician or supplier charges and the amount Medicare allows for administration.

C.5 Does the 5 percent payment reduction for physicians who do not accept assignment for the administration of the vaccine apply to the influenza virus and pneumococcal vaccination benefit?

No. Only items and services covered under limiting charge are subject to the 5 percent payment reduction.

If a beneficiary receives an influenza virus vaccination from a non-participating physician, provider or supplier who does not accept assignment, the physician may collect his or her usual charge for the administration of the vaccine, but may not collect any fee upfront for the vaccine. The non-participating physician, provider or supplier must accept the Medicare approved amount. The influenza virus and PPV vaccines are subject to mandatory assignment regardless of whether the physician normally does not accept assignment.

C.6 May providers, physicians, and suppliers charge and collect payment from Medicare beneficiaries for the influenza virus or pneumococcal vaccinations?

Non-participating physicians, providers and suppliers that do not accept assignment on the administration of the vaccines may collect payment from the beneficiary, but they must submit an unassigned claim on the beneficiary's behalf. All physicians, non-physician practitioners and suppliers must accept assignment for the Medicare vaccine payment rate and may not collect payment from the beneficiary for the vaccine.

Participating physicians, non-physician practitioners and suppliers that accept assignment must bill Medicare if they charge a fee to cover any or all costs related to the provision and/or administration of the influenza virus or pneumococcal vaccine. They may not collect payment from beneficiaries.

C.7 May a physician, provider, or supplier charge a Medicare beneficiary more for an immunization than he or she charges a non-Medicare patient?

No. According to Section 1128(b) (6) (A) of the Social Security Act, a physician/supplier may not charge a Medicare beneficiary more for an immunization than they would charge a non-Medicare patient. (For exceptions to this rule, see C15)

C.8 There has been some concern about the confusion caused by providers advertising influenza and pneumococcal vaccination as "free." When patients later receive Medicare Summary Notices (MSNs), they contact the carrier/AB MAC to report fraudulent billing. Should providers advertise this as a "free" service?

Participating physicians, providers, and suppliers that accept assignment may advertise that there will be no charge to the beneficiary, but they should make it clear that a claim will be submitted to Medicare on their behalf.

Non-participating physicians, providers, and suppliers that do not accept assignment for the service of administering the vaccine should never advertise the service as free since there could be an out-of-pocket expense for the beneficiary after Medicare has paid at 100 percent of the Medicare-allowed amount.

C.9 Is a coinsurance amount or deductible required for the influenza virus and PPV vaccine benefits?

No. Medicare pays 100 percent of the Medicare approved charge or the submitted charge, whichever is lower. Neither the annual Part B deductible nor the 20 percent coinsurance applies.

C.10 May a physician, provider or supplier collect payment for an immunization from a beneficiary and instruct the beneficiary to submit the claim to Medicare for payment?

No. Section 1848 (g) (4) (A) of the Social Security Act requires that physicians, providers and suppliers submit a claim for services to Medicare on the beneficiary's behalf.

C.11 How should carrier/AB MACs handle influenza virus or pneumococcal vaccine claims that are submitted by beneficiaries?

Carriers should refer to instructions provided in CR 5683 (Publication 100-04, Transmittal 1588) and CR 66434 (Publication 100-04, Transmittal 1747).

C.12 May providers, physicians and suppliers submit claims for the influenza and pneumococcal benefit to Medicare if they provide the benefits free of charge or on a sliding fee scale to other patients?

Non-governmental entities (providers, physicians or suppliers) that provide immunizations free of charge to all patients, regardless of their ability to pay, must provide the benefit free of charge to Medicare beneficiaries and may not bill Medicare.

However, a non-governmental entity that does not charge patients who are unable to pay or reduces its charge for patients of limited means (sliding fee scale), but does expect to be paid if a patient can afford or has health insurance which covers the items or services provided, may bill Medicare and receive Medicare program payment.

State and local government entities, such as public health clinics, may bill Medicare for immunizations given to beneficiaries even if they provide immunizations free to all patients, regardless of their ability to pay.

C.13 Historically, some entities that have provided mass immunization programs have not charged patients the full cost of the vaccine and/or its administration because they have subsidized part of the cost from their budgets. Instead, they have requested a specific dollar "donation" that covers part of the cost of the vaccination. These entities do not then submit a claim to Medicare on behalf of the beneficiary. Is this an acceptable practice?

No. Since the influenza virus and pneumococcal vaccine benefits do not require any beneficiary coinsurance or deductible, a Medicare beneficiary has a right to receive this benefit without incurring

any out-of-pocket expense. In addition, the entity is required by law to submit a claim to Medicare on behalf of the beneficiary.

The entity may bill Medicare for the amount that is not subsidized from its budget. For example, an entity that incurs a cost of $7.50 per influenza vaccination and pays $2.50 of the cost from its budget may bill the carrier/AB MAC the $5.00 cost which is not paid out of its budget.

C.14 Must carrier/AB MACs generate the MSN for beneficiaries for the influenza virus and pneumococcal vaccinations?

An MSN must be generated for influenza virus and pneumococcal vaccines and their administration.

C.15 Will Medicare pay for claims for influenza virus and pneumococcal vaccinations that are old?

Immunizers have at least 12 months from the date of service to file claims to the Medicare Program. All claims not submitted within 12 months, however, will be denied as being past the timely filing statute.

General Billing Procedures

(See Section D for Roster Billing procedures)

C.16 What information is needed on the CMS-1450 and CMS-1500 to bill for the influenza virus and pneumococcal vaccinations?

All data fields that are required for any Part A or Part B claim are required for the vaccines and their administration. Physicians, non-physician practitioners and suppliers should bill in accordance with the instructions within provider manuals provided by their Medicare carrier/AB MAC. Additionally, coding specific to these benefits is required.

Institutional providers should bill in accordance with the instructions within provider manuals provided by their Medicare FI/AB MAC.

C.17 If the Health Insurance Claim Number (HICN) is incorrect, will the contractor contact the provider or the beneficiary to determine the correct number?

Providers and suppliers are responsible for filling out required items on the claims forms with correct information from beneficiaries. If necessary, the "Date of Birth" column on the roster should, along with other data elements, provides sufficient beneficiary information for the contractor to resolve incorrect HICNs. However, if through other information on the claim or through beneficiary contact the contractor cannot resolve the problem, the claim will be rejected.

Health Insurance Portability and Accountability Act (HIPAA)

C.18 What is HIPAA?

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 are intended to reduce the costs and administrative burdens of health care by making possible the standardized, electronic transmission of many administrative and financial transactions, such as claims, eligibility requests and claims status inquiries. The passage of HIPAA was one of the first steps toward facilitating the electronic exchange of health care information and is expected to continue to improve the effectiveness and efficiency of the health care industry in general, by simplifying the administration of the system and enabling the efficient electronic transmission of certain health information.

C.19 Who/what is a "covered entity" for HIPAA?

Covered entities are health plans, clearinghouses and certain health care providers who transmit health information in electronic form in connection with a transaction for which standards have been adopted. These include:

- claims or equivalent encounter information;
- claim status inquiry and response;
- eligibility inquiry and response;
- referral certifications and authorizations;
- enrollment and disenrollment in a health plan;
- payments and remittance advice; and
- coordination of benefits.

If your office does not conduct any of the above standard transactions electronically and you do not have someone else conduct them on your behalf, such as a clearinghouse or billing service, you are not a covered entity.

Also, in 2010, Congress passed the Patient Protection and Affordable Care Act of 2010 (ACA), which adds some new requirements for covered entities. These new requirements may not affect influenza virus and pneumococcal vaccine billing, but they are important for other impacts. For information, visit our ACA webpage at http://www.cms.gov/Affordable-Care-Act/.

Information and guidance about HIPAA, covered entities, the standards and the requirements under this regulation may be found on the CMS website, at: http://www.cms.gov/home/regsguidance.asp .

C.20 What impact do the HIPAA requirements for the format and content of electronic transactions have on influenza virus and pneumococcal vaccine billing?

HIPAA Administrative Simplification requirements apply to all electronic transactions for which the Secretary has adopted standards, they do not apply to paper transactions. When submitted electronically,

individual claims for influenza virus and pneumococcal vaccine billing are required to comply with all HIPAA Administrative Simplification requirements. When submitted on paper rosters, influenza virus and pneumococcal vaccines are exempt from having to be submitted electronically (see C.31).

C.21 How long will paper claims for influenza virus and pneumococcal vaccine continue to be paid by Medicare?

For non-centralized billers, paper claims for Medicare-covered vaccinations are now exempt from the electronic submission requirement under a ruling published August 15, 2003.

C.22 Where can we find additional information related to HIPAA?

Information about HIPAA and its requirements is available through CMS, industry groups, associations, and other organizations. Some important websites are:

- http://www.cms.gov/home/regsguidance.asp – Website for Centers for Medicare & Medicaid Services (CMS)
- www.wpc-edi.com – this site is the source for the 4010/4010A1 implementation guides.
- www.x12.org - this site is the source for the 5010 implementation guides – also known as TR3 Technical Reports.
- www.wedi.org - this is the website for the Work Group for Electronic Data Interchange, which provides information, white papers, webinars and list serves related to all of the HIPAA regulations.

Questions regarding the HIPAA privacy and security rules should be directed to the Office for Civil Rights, 1-866-627-7748 or its website at http://www.hhs.gov/ocr/hipaa .

C.23 If a physician sees a beneficiary for the sole purpose of administering an influenza virus or pneumococcal vaccination, may they routinely bill for an office visit?

No. If a physician sees a beneficiary for the sole purpose of administering an influenza virus or PPV vaccination, the physician may only bill for the administration and vaccine. However, if a patient actually receives reasonable and medically necessary services constituting an "office visit" level of service, the physician may bill for the office visit, the vaccine and the administration of the vaccine.

C.24 May providers bill for services related to counseling and education?

No. Medicare does not pay solely for counseling and education for influenza virus and pneumococcal vaccines. If Medicare-covered services are provided during the visit in which the immunization is given, the physician may code and bill those other medically necessary services, including evaluation and management services. A frequently asked question (FAQ) section on the CMS website describes the use of these codes in detail.

C.25 For HHAs, are vaccines paid under cost reimbursement?

Yes. Medicare pays for vaccine on a cost-reimbursement basis on the cost report.

C.26 If a vaccine (influenza virus, pneumococcal, or hepatitis B) is administered during the course of an otherwise covered home health visit (e.g., to perform wound care), is the visit covered by Medicare? If so, how should it be billed?

Yes, the visit would be covered as normal, but the HHA must not include the vaccine or its administration in their visit charge. In this case, the HHA is entitled to payment for the vaccine and its administration under the vaccine benefit. In this situation, the HHA bills under bill type 34x and reports revenue code 0636 along with the appropriate HCPCS code for the vaccine and revenue code 0771 along with the appropriate HCPCS code for the administration.

C.27 For HHA, will interim rates be paid to home health agencies for their immunization expenses?

Yes. Provider Reimbursement Manual, Part 1, section 2406, provides for the percentage of billed charges interim payment method for cost reimbursed services by HHAs. As this section explains, the intermediary, with documentation from the HHA, estimates the annual Medicare cost-reimbursement for the vaccines furnished to beneficiaries divided by estimated charges for those drugs, applying the resulting interim rate to the vaccine charges on submitted bills. Although the lower of costs or charges provision does not apply to an HHA's Medicare prospective payments, it does apply to items or services paid on a cost basis. Therefore, should the estimated charges for the vaccines be less than estimated cost, the interim rate cannot exceed 100 percent (section 2406.6). Interim payments are to be approximated as close as possible to the reimbursement that will be made on the cost report. Therefore, an intermediary is expected to monitor the rate and make adjustments as necessary, and a provider may always furnish information to its intermediary if it can support that the actual costs are significantly different from the payment it is receiving via its interim payments. Finally, adjustment is made with a payout or recovery as necessary on final settlement (and, as appropriate, through a tentative retroactive adjustment on the submitted cost report).

C.28 How should HHAs represent the costs for vaccines and administration on their cost reports? (Further guidance is provided at B.23)

The cost of the vaccines is shown separately on the cost report (for a free-standing HHA on FORM CMS-1728, Worksheet A, line 13, Drugs, later further identified On Worksheet C between drugs to which Medicare deductible and coinsurance (D&C) apply (the osteoporosis drug) and drugs to which D&C do not apply (influenza virus and pneumococcal vaccines)). Provider documentation to support the costs incurred is no different than for any other cost claimed on the cost report or no different from what has been expected for these vaccines in the past. An HHA must have support for its costs when asked by the FI for that information. Administration of the vaccines during a visit made for reasons other than administration of a vaccine is part of the visit cost paid under the Prospective Payment System (PPS) and is not paid separately. The cost of administration made outside the context of home health visits and which is documented as necessary in administering the vaccines can be included in the drugs cost center along with the vaccine cost. Cost finding (allocation of overhead costs) is done the same as for any other cost center, whether paid via PPS or on a cost basis. Statistics for the drugs cost center will draw overhead (general service) costs as appropriate. For example, the accumulated cost

statistic draws administrative and general costs, and the square footage statistic draws capital and plant operation costs as appropriate.

C.29 Are there any specific reasonable cost limits or guidelines applied to vaccination costs that could result in payments less than an HHA's actual costs for furnishing services to Medicare beneficiaries?

Other than application of the lower of costs or charges provision, Medicare recognizes the reasonable, allowable cost for vaccines. If an HHA's intermediary believes that the HHA has unreasonably incurred cost for the vaccines—or otherwise has not been a prudent buyer –it is up to the HHA to support that it was prudent and that the costs are reasonable. If it cannot, the intermediary is expected not to recognize what it finds to be the unreasonable portion of the incurred cost.

C.30 If vaccine demand is less than that anticipated, and vaccine cannot be returned, resold or used elsewhere, may the cost of unused vaccine be considered as a reasonable cost?

No. CMS would only pay for vaccines actually administered. We would not pay for vaccines bought by hospitals or HHA but never administered. For instance, a provider may order 1,000 vaccines but only provide 700 immunizations because of lower than anticipated demand. CMS would recognize only the cost of the 700 vaccines that are administered. We would not recognize the cost of the 300 excess unused vaccines.

FI-A/B MAC

C.31 Who bills for influenza virus and pneumococcal vaccination when it is furnished to a dialysis patient of a hospital or hospital-based renal dialysis facility?

When vaccination is furnished to a dialysis patient of a hospital, the hospital bills the intermediary using bill type 12x or 13x. For dialysis patients of a hospital-based or independent renal dialysis facility, the facility bills under 72x.

C.32 What bill types for claims billed to the intermediary are applicable for influenza virus and pneumococcal vaccine benefits?

Applicable bill types are: 12x, 13x, 22x, 23x, 34x, 72x, 75x and 85x RHCs/FQHCs do not bill the intermediary for the influenza virus and pneumococcal vaccinations. Payment is made based on information provided on the cost report.

C.33 Generally, RHCs and FQHC are required to use revenue code 52x or 0900 in order to bill. How should they code for the influenza and pneumococcal vaccines and their administration on the CMS-1450?

RHCs are not required to report separate revenue lines for influenza virus or pneumococcal pneumonia vaccines on the 71x claims as the cost for these services are not included in the encounter. Costs for the influenza virus or pneumococcal pneumonia vaccines are included in the cost report and no line items are billed. Coinsurance and deductible do not apply to either of these vaccines.

As of January 01, 2011, for data collection and analysis for the PPS, FQHCs are required to report separate revenue lines for influenza virus or pneumococcal pneumonia vaccines (PPV) on the 77x claims. The charges of these vaccines and the administration shall be carved out of the office visit and reported on a separate line. The cost for these services will continue to be reimbursed through cost reporting. Coinsurance and deductible do not apply to either of these vaccines.

See MLN Matters SE1039 article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1039.pdf

C.34 For claims billed to the intermediary, are providers allowed to use therapy revenue codes on the influenza vaccine and pneumococcal claims?

Providers bill for the vaccines using revenue code 636, and for the administration using revenue code 771. If therapy services are also provided, they can be reflected on the same claim with the vaccines and their administration.

C.35 Should shared systems maintainers allow condition code "A6" or special program indicator "06" on vaccine claims?

Yes. Condition code A6 is used to indicate services not subject to deductible and coinsurance.

C.36 For inpatient hospital and SNFs that bill the intermediary or AB MAC, what revenue code is used for the administration?

All providers that bill the intermediary for the influenza and pneumococcal vaccines report the administration under revenue code 771.

C.37 What bill types do hospitals and SNFs that bill the intermediary or AB MAC report for inpatients that receive this benefit?

Medicare hospitals bill for the vaccines under bill type 12x for their inpatients and SNFs bill for the vaccines under bill type 22x.

PART B – Carrier/AB MACs

C.38 What should be entered in item 11 of the CMS-1500 when Medicare is known to be the secondary payer?

For all influenza vaccination claims submitted to a carrier/AB MAC, item 11 (Insured's Policy Group or FECA Number) of the preprinted CMS-1500 should show "NONE."

C.39 Sometimes an entity receives donated vaccine or receives donated services for the administration of the vaccine. In these cases, may the provider bill Medicare for the portion of the vaccination that was not donated?

Yes.

Diagnosis and Procedure Codes

C.40 What are the specific codes that must be used?

Providers are responsible for submitting the correct codes on their claims. The code should be chosen based on the description of the drug and the age of the patient. Codes are not interchangeable.

The following codes are used for influenza virus vaccinations:

Table 1: CPT/HCPCS Codes and Descriptions for Influenza Virus Vaccinations

CPT/HCPCS Code	Description
90654 effective 5/10/2011	Influenza virus vaccine, split virus, preservative free, for intradermal use
90655	Influenza virus vaccine, split virus, preservative free, for children 6-35 months of age, for intramuscular use.
90656	Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years and above, for intramuscular use.
90657	Influenza virus vaccine, split virus, for children 6-35 months of age, for intramuscular use.
90660	Influenza vaccine, live, for intranasal use.
90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increase antigen content, for intramuscular use. (High Dose)
Q2034 effective 7/1/2012	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)
Q2035 effective 1/1/2011	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and above, for intramuscular use (Afluria)
Q2036 effective 1/1/2011	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and above, for intramuscular use (Fluluval)
Q2037 effective 1/1/2011	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and above, for intramuscular use (Fluvirin)
Q2038 effective 1/1/2011	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and above, for

	intramuscular use (Fluzone)
Q2039 effective 1/1/2011	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and above, for intramuscular use (Not Otherwise Specified)
G0008	Administration of influenza virus vaccine.

For the most recent code/price information, visit http://www.cms.gov/McrPartBDrugAvgSalesPrice/10_VaccinesPricing.asp#TopOfPage

Table 2: Diagnosis Code and Descriptions for Influenza Virus Vaccinations

Diagnosis Code	Description
V04.8	Influenza vaccination with dates of service prior to 10/01/2003
V04.81	Influenza vaccination with dates of services 10/1/2003 and later
V06.6	Influenza and pneumococcal (Effective October 1, 2006, providers must report diagnosis code V06.6 on claims when the purpose of the visit was to receive both vaccines during the same visit

The following codes are used for pneumococcal vaccinations:

Table 3: CPT/HCPCS Codes and Descriptions for Pneumococcal Vaccinations

CPT/HCPCS Code	Description
90669	Pneumococcal conjugate vaccine, polyvalent, for children under 5 years, for intramuscular use
90670	Pneumococcal conjugate vaccine, 13-valent, for intramuscular use
90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, for use in individuals 2 years or older, for subcutaneous or intramuscular use
G0009	Administration of pneumococcal vaccine when no physician fee schedule service on the same day

Table 4: Diagnosis Codes and Descriptions for Pneumococcal Vaccinations

Diagnosis Code	Description
V03.82	Pneumococcal Vaccination
V06.6	Pneumococcal and influenza (Effective October 1, 2006, providers must report diagnosis code V06.6 on claims when the purpose of the visit was to receive both vaccines during the same visit

C.41 If a beneficiary receives both an influenza virus and pneumococcal vaccine on the same day, will Medicare pay twice for the administration fee?

Yes, as long as you indicate the appropriate codes for administration. Providers not roster billing may put both vaccines and their administration on the same form.

C.42 May other charges be listed on the same bill with the influenza virus and pneumococcal vaccinations?

For normal billing procedures (not roster billing), other charges may be listed on the same bill as influenza virus and pneumococcal vaccinations. However, there must be separate coding for the additional charge(s).

C.43 If we choose not to roster bill and only bill on the UB-04, will Medicare track the usage from the revenue code?

Medicare will track using HCPCS and revenue codes on the UB-04

C.44 As a provider, if I choose not to roster bill and only bill on the UB-04, will Medicare track the usage from the revenue code 771?

HCPCS codes would be used to track vaccine services regardless of whether they are billed on a roster or UB. The intermediary/AB MAC converts all rosters to UBs. The revenue code alone would not provide sufficient information to identify the vaccine.

C.45 I noticed on a recent Medicare bulletin that vaccines are no longer reimbursed under OPPS, but are reimbursed according to reasonable cost. How will the reimbursement be calculated?

Each provider is assigned an interim rate which is applied to charges for items subject to reasonable cost reimbursement and that is the amount that is payable on an interim claim by claim basis. Final payment is then made via the cost settlement.

D. Mass Immunizers/Roster Billers

Note: Although these questions primarily concern mass immunizers, they may apply to any entity immunizing Medicare beneficiaries.

Definition

D.1 What is a mass immunizer?

As used by CMS, the term "mass immunizer" is defined in the following manner:

- A mass immunizer generally offers influenza virus and/or pneumococcal vaccinations to a large number of individuals (the general public or members of a specific group, such as residents of a retirement community).

- A mass immunizer may be a traditional Medicare provider or supplier such as a hospital outpatient department or may be a nontraditional provider or supplier such as a senior citizen's center, a public health clinic, community pharmacy or supermarket.

- A mass immunizer submits claims for immunizations on roster bills.

- Mass immunizers must accept assignment.

Enrollment Requirements

Note: This enrollment process currently applies only to entities that will (1) bill a carrier/AB MAC; (2) use roster bills; and (3) bill only for influenza virus and/or PPV vaccinations.

D.2 Do providers and suppliers that want to mass immunize and submit claims to Medicare on roster bills have to enroll in the Medicare program?

Yes. Providers and suppliers must enroll in Medicare even if mass immunizations are the only service they will provide to Medicare beneficiaries.

Providers and suppliers who wish to roster bill for mass immunizations should contact the Medicare carrier/AB MAC servicing their area for a copy of the enrollment application instructions. Those entities will enroll as provider specialty type 73, Mass Immunization Roster Biller. As such, they will accept assignment on both the administration and the vaccine. Entities providing mass immunizations must enroll by filling out Form CMS-855-I at http://www.cms.gov/CMSforms/downloads/cms855i.pdf for individuals or Form CMS 855-B at http://www.cms.gov/CMSforms/downloads/cms855b.pdf to

enroll as a group. A list of carrier/AB MACs and their contact information can be found at http://www.cms.gov/ContractingGeneralInformation/Downloads/02_ICdirectory.pdf .

D.3 If a provider or supplier already has a Medicare provider number for non-immunization services that they provide (for other than DMEPOS), do they need to obtain a new provider number in order to use the roster billing process for the influenza virus and/or pneumococcal services that they provide?

No. Providers and suppliers may use their existing provider numbers and use the roster billing process as long as they provide the influenza virus and/or pneumococcal vaccine service to multiple beneficiaries and agree to accept assignment on the service. DMEPOS suppliers (in particular pharmacies) require separate enrollments and PTANs with the National Supplier Clearinghouse and their A/B MAC(s). Their non-immunization claims will still be paid by the DME-MAC(s).

A supplier must complete an 855 application to enroll as a mass immunizer to render influenza and pneumococcal vaccinations.

D.4 Does a corporate entity with numerous locations have to get a Medicare provider number for each location?

Reimbursement for the administration of the influenza virus and pneumococcal vaccines is based on the locality of the provider. Therefore, if the practice locations were in different payment localities, then it would be necessary for each to obtain a separate Medicare provider number for each practice location. The only exception to this is an entity that participates in the Centralized Billing program.

D.5 Can providers who conduct immunization activities within their community (outside of their main practice site) utilize their practice's provider number if they are operating at those sites under the auspices of their practice?

Yes.

D.6 Why enroll providers if they are going to provide mass immunizations to Medicare beneficiaries only once a year?

Although CMS wants to make it as easy as possible for providers and suppliers to immunize Medicare beneficiaries and bill Medicare, it must ensure that those providers who wish to enroll in the Medicare program are qualified providers, receive a provider number and receive the proper payment.

D.7 May a company or representative sign the applications or does it have to be the president who signs all of the applications?

Only an authorized or delegated official may sign the CMS 855B application. The authorized official can be the owner or a person with a managing interest in the organization. The authorized officials must be listed in Section 6 of the CMS 855B. The owner or authorized official for the organization is required to submit their social security number in Section 6. The owner or authorized official carries the

legal responsibility for actions taken by the organization. The authorized official can designate a delegated official to perform Medicare enrollment activities. A delegated official must be either a W2 managing employee of the organization, an individual with 5% or greater ownership interest in the organization or in a partnership with the enrolling entity. The owner or authorized official must notify Medicare of any delegated officials in Section 16 of the CMS 855B. Only the owner, authorized official or delegated official has the authority to enroll an organization or make changes to an established enrollment record. Only the owner, authorized official or delegated official may sign the CMS 855 application.

D8. Is a separate number required for each site, or can a corporation have one number?

A corporation must have one number for each payment locality. Corporations who will centrally bill can have one number. The corporation is required to complete Item 32 on the CMS-1500 paper claim form or equivalent form for electronic claims filers. The claim is paid through the use of zip codes and allowances are based on locale where services are furnished.

D.9 Do Regional Home Health Intermediaries (RHHIs) Home Health and Hospice MACs (HH&H MACs) accept roster bills from HHAs?

Yes.

D.10 If a hospital has an outpatient unit, like a pharmacy, that wishes to administer vaccines, how should it bill for the vaccine and supplies – through the hospital number or should it get a separate number?

The pharmacy is still part of the hospital, and should follow the roster billing instructions in the IOM for billing to the FI/AB MAC.

Billing Procedures

D.11 What impact does HIPAA requirements have on electronic Mass Immunizer Roster Billing?

Roster billing is a streamlined process for submitting health care claims for large groups of individuals usually for influenza and/or PPV vaccinations for which HIPAA adopted an electronic standard, the ASC X12N 837. Roster billing can be done electronically or via paper. When conducting roster billing electronically, mass immunizer providers are required to use the HIPAA-adopted ASC X12N 837 claim standard.

D.12 Can roster billing be conducted on paper?

Yes. Paper claims for Medicare-covered vaccinations are now exempt from the HIPAA electronic billing requirement under a ruling published August 15, 2003.

D.13 Is electronic billing available for roster-billed claims?

Not all contractors offer electronic roster billing software. However, if available, contractors should offer low or no-cost software for providers to use when roster billing electronically. Providers should confirm with their local carrier/AB MAC if electronic roster billing software is available.

D.14 How many beneficiaries per day must be vaccinated in order for the roster billing procedure to be used?

Generally, FOR INTERMEDIARY PROCESSED CLAIMS ONLY, five beneficiaries per day must be vaccinated in order to roster bill. However, this requirement is waived for inpatient hospitals that mass immunize and utilize the roster billing method.

Effective July 1, 1998, CARRIER/AB MAC PROCESSED CLAIMS ONLY, immunization of at least five beneficiaries on the same date is no longer required for any individual or entity to qualify for roster billing. However, the rosters should not be used for single patient bills and the date of service for each vaccination administered must be entered.

D15. Can a roster bill have different dates of service?

No.

D.16 If providers/suppliers enroll in Medicare for the purpose of roster billing for mass immunizations only, may they bill Medicare for other Part B services?

No. Providers/suppliers who wish to bill for other Part B services must enroll as a regular provider or supplier by completing the entire CMS-855.

D.17 Can mass immunizer's bill for services relating to counseling and education?

No. Mass immunizers are a provider-type created under Medicare solely to facilitate mass immunization, not to provide other services. (Physicians may bill for additional medically necessary services but not on the roster bill. See C22.)

D.18 May an individual or entity providing both influenza virus and pneumococcal vaccinations to the beneficiaries, submit a single CMS-1450 or CMS-1500 that contains the information for both the influenza virus and pneumococcal vaccinations and a single roster bill that contains the names of the beneficiaries who received both vaccinations?

No. Individuals and entities submitting claims for influenza virus and pneumococcal vaccinations must submit a separate CMS-1450 or CMS-1500 for each type of vaccination. Each CMS-1450 or CMS-1500 must have an attached roster bill listing the beneficiaries who received that type of vaccination. Each roster bill must also contain all other information required on a roster bill.

D.19 Are the roster bills used for influenza virus and pneumococcal vaccinations identical?

No. The following reminder to providers must be printed on the pneumococcal vaccination roster bill:

WARNING: Ask beneficiaries if they have been vaccinated with pneumococcal vaccination.

Rely on patients' memory to determine prior vaccination status. If patients are uncertain whether they have been vaccinated within the past 5 years, administer the vaccine. If patients are certain they have been vaccinated within the past 5 years, do not revaccinate.

D.20 What blocks on the CMS-1500 can be preprinted for providers using roster billing for influenza and/or pneumococcal vaccine and/or administration claims?

The following blocks can be preprinted on a modified CMS-1500 form:

Preprinted CMS-1500 Item	**Description**
Item 1	An X in the Medicare block
Item 2	(Patient's Name): "SEE ATTACHED ROSTER"
Item 11	(Insured's Policy Group or FECA Number): "NONE"
Item 20	(Outside Lab?): An "X" in the "NO" block
Item 21	(Diagnosis or Nature of Illness) - Line 1: (only one code, not both) PPV: "V03.82" Influenza Virus: "V04.81"
Item 24B	Place of Service (POS) - Line 1: "60" Line 2: "60" NOTE: POS code "60" must be used for roster billing
Item 24D	(Procedures, Services or Supplies) – Line 1: Pneumococcal vaccine: or Influenza Virus vaccine: Select appropriate influenza or pneumococcal virus vaccine Line 2: (only one code, not both) pneumococcal vaccine administration: "G0009" Influenza Virus vaccine administration: "G0008"
Item 24E	(Diagnosis Code) – Lines 1 and 2: "1"
Item 24F	($ Charges): The entity must enter the charge for each listed service. If the entity is not charging for the vaccine or its administration, it should enter 0.00 or "NC" (no charge) on the appropriate line for that item. If your system is unable to accept a line item charge of 0.00 for an immunization service, do not key the line item. Likewise, electronic media claim (EMC) billers should submit line items for free immunization services on EMC *pneumococcal* or influenza virus vaccine claims only if your system is able to accept them. Item 27: (Accept Assignment): An "X" in the YES block
Item 29	(Amount Paid): "$0.00"
Item 31	(Signature of Physician or Supplier): The entity's representative must sign the modified form CMS-1500 (08-05)
Item 32	(Name and Address of Facility): Enter the name, address, and ZIP code of the location where the service was provided (including centralized

	billers
Item 32a	Enter the NPI of the service facility.
Item 33	(Physician's, Supplier's Billing Name): The entity must complete this item to include the NPI.
Item 33a	Enter the NPI of the billing provider or group.

D.21 Do providers show the charge for one service or the total for all patients in block 24F of the modified CMS-1500 (08-05)?

Providers should show the unit cost, since carrier/AB MACs will have to replicate the claim for each beneficiary listed on the roster.

D.22 What information needs to be submitted on a patient roster form that will be attached to a preprinted CMS-1500 (08-05) under the roster billing procedure?

The following should be included on the roster form: Patient Name and Address; Health Insurance Claim Number; Date of Birth; Sex; Date of Service; Signature or stamped "Signature on File;" and Provider's Name and Identification Number; and control number for the contractor.

Some carrier/AB MACs allow providers/suppliers to develop their own patient roster forms that contain the minimum data as reflected above, while others do not. Providers/suppliers should contact their carrier/AB MAC to learn their particular carrier/AB MAC's practice regarding patient roster forms.

D.23 What is the meaning of "signature on file?"

For all institutional providers that roster bill from inpatient or outpatient departments, and for all other providers outside of the institutional setting that roster bill, a stamped "signature on file" qualifies as an actual signature on a roster claim form provided that the provider has a signed authorization on file to bill Medicare for services rendered. In this situation, the provider is not required to obtain the patient signature on the roster, but instead has the option of reporting "signature on file."

D.24 May hospitals and other entities that bill intermediaries/AB MACs use the "signature on file" designation on a roster bill?

Yes. Inpatient/outpatient departments of hospitals and outpatient departments of other providers may use a signature on file stamp or notation if they have access to a signature on file in the beneficiary's record.

D.25 What would the carrier/AB MAC do if a roster bill were received incomplete or incorrect?

The carrier/AB MAC would deny or reject the claim as unprocessable.

D.26 May other services be listed along with the influenza virus or pneumococcal vaccine and administration on the modified CMS-1500 (08-05)?

No. Other covered services are subject to more comprehensive data requirements, which the roster billing process is not designed to accommodate. Other services should be billed using normal Part B claims filing procedures and forms.

D.27 What place of service code should be used for PHCs that bill carrier/AB MACs for the influenza virus and pneumococcal vaccines and their administration?

PHCs should use place of service code "60," public health or welfare agencies (federal, state, and local), if roster billing. If not roster billing, PHC POS is 71.

D.28 If a beneficiary receives influenza virus or pneumococcal vaccination shot at a mobile unit brought to a senior center or parking lot of a mall, what place of service code should be used?

A PHC-affiliated mobile unit should use POS code "71" unless vaccinations are administered in a mass immunization setting. ALL entities that administer vaccinations in a mass immunization setting should use POS code "60" (Mass Immunization Center), no matter the setting. A mobile unit not affiliated with a PHC and not acting as a mass immunization setting should use "99" (other).

D.29 In some instances, two entities, such as a grocery store and a pharmacy, jointly sponsor a vaccination clinic and each is reluctant to accept responsibility for billing. What are the criteria for determining the responsible party?

Assuming that a charge is made for both the vaccine and its administration, the entity that furnishes the vaccine and the entity that administers the vaccine are each required to submit claims. Both parties must file separately for the specific component furnished for which a charge was made.

When billing only for the administration, billers should indicate in block 24 of the CMS-1500 (08-05) that they did not furnish the vaccine. For roster billed claims, this can be accomplished by lining through the preprinted item 24 line item component that was not furnished by the billing entity or individual.

Hospital Inpatient Roster Billing

D.30 Some hospitals have concerns about reimbursement for influenza virus and pneumococcal vaccines administered during hospitalization. Are these vaccinations covered by the DRG flat rate, or reimbursed separately?

Since influenza virus and pneumococcal vaccines are covered under Part B benefit, they are not paid above the DRG but paid under Part B when billed on a 12x type of bill for inpatients vaccinated in the hospital. For both vaccines, hospitals may roster bill for the vaccine and its administration. There is no co-pay or deductible for either vaccine.

D.31 If a hospital has an outpatient unit, like a pharmacy, that wishes to administer vaccines, how should it bill for the vaccine and supplies – through the hospital number or should it get a separate number?

The pharmacy is still part of the hospital, and should follow the roster billing instructions in the IOM for billing to the Fiscal intermediary/AB MAC (FI).

D.32 What is the procedure for billing inpatient vaccinations?

All instructions are in the IOM Pub 100-4, Chapter 18, and Section 10.2.
A hospital can bill for an inpatient of a hospital using a 12x bill type using the date of discharge as the date the vaccine and its administration was given. This will avoid editing in CWF. You may also roster bill in a hospital inpatient setting. There are certain criteria for that:

1. You do not have to wait until patients are discharged.

2. Roster should reflect the actual date of service.

3. Requirement to provide the vaccine to five or more patients at the same time to meet the requirement for mass immunizers will be waived when vaccines are provided to inpatients. The roster may contain fewer than 5 patients or fewer than 5 patients on the date of discharge and the roster must contain information indicating that the vaccine was provided to inpatients to avoid questioning regarding the number of patients or various dates.

E. Centralized Billing

E.1 What is centralized billing?

Centralized billing is a process in which a provider, who is a mass immunizer for influenza virus and pneumococcal immunizations, can send all such claims to a single carrier/AB MAC for payment regardless of the geographic locality in which the vaccination was administered.

To qualify for centralized billing, a mass immunizer must be operating in at least three payment localities for which there are three different carrier/AB MACs processing claims. Individuals and entities providing vaccine and administration of vaccine must be properly licensed in the State in which the immunizations are given It's the provider's responsibility to ascertain and meet all State licensure requirements for each State where they plan to provide these services.

E.2 Do I have to enroll as a different provider type to participate in the centralized billing program?

Yes. Individuals and entities that wish to participate in the centralized billing program must enroll as a Centralized Flu Provider even if they are already enrolled in Medicare as another provider type.

E.3 How are claims submitted through the centralized billing program reimbursed?

The administration of the vaccinations will be reimbursed per the Medicare Physician Fee Schedule (MPFS) for the appropriate locality. The vaccines will be reimbursed at the standard method used by Medicare Part B for reimbursement of drugs and biologicals, which is the lower of the charge or 95 percent of the Average Wholesale Price (AWP).

E.4 How can I participate in this program?

Multi-state mass immunizers interested in centralized billing must contact CMS Central Office (CO) in writing at the following address by June 1 of each year in order to participate in this program for the upcoming influenza virus season.

Division of Practitioner Claims Processing
Provider Billing Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C4-10-07
Baltimore, MD 21244
Attention: Bridgitté Davis
410-786-4573

E.5 Is there any particular information that is required in the written request to participate in the centralized billing program?

Yes. The following information must be included with the multi-state mass immunizer's request to participate in centralized billing:

- Estimates for the number of beneficiaries who will receive influenza virus vaccinations;
- Estimates for the number of beneficiaries who will receive pneumococcal vaccinations;
- The approximate dates for when the vaccinations will be given;
- A list of the states in which influenza virus and pneumococcal clinics will be held;
- The type of services generally provided by your corporation (e.g., ambulance, home health, or visiting nurse); and,
- Whether the nurses who will administer the influenza virus and pneumococcal vaccinations are employees of your corporation or will be hired by your corporation specifically for the purpose of administering influenza and pneumococcal vaccinations.
- Names and addresses of all entities operating under the corporations' application.
- Contact information for a designated contact person that will handle the day to day operations for the centralized billing program.

E.6 Is there a particular carrier/AB MAC that centralized billing claims should be submitted to?

Yes. Upon acceptance into the program as a centralized biller, you will be provided with contact information for the carrier/AB MAC that will process the claims.

E.7 Are there any specific criteria associated with centralized billing?

Yes, by agreeing to participate in the centralized billing program, providers agree to abide by the following criteria:

- A mass immunizer must be operating in at least three payment localities for which there are three different contractors processing claims.

- Individuals and entities providing the vaccine and administration must be properly licensed in the state in which the immunizations are given.

- Multi-state mass immunizers must agree to accept assignment (i.e., they must agree to accept the amount that Medicare pays for the vaccine and the administration). Since there is no coinsurance or deductible for the influenza virus and pneumococcal benefit, accepting assignment means that Medicare beneficiaries cannot be charged for the vaccination, i.e., beneficiaries may not incur any out-of-pocket expense. For example, a drugstore may not charge a Medicare beneficiary $10 for an influenza vaccination and give the beneficiary a coupon for $10 to be used in the drugstore. This practice is unacceptable.

- The contractor assigned to process the claims for centralized billing will be chosen at the discretion of CMS based on such considerations as workload, user-friendly software developed by the contractor for billing claims, and overall performance.

- The payment rates for the administration of the vaccinations will be based on the MPFS for the appropriate year. Payment made through the MPFS is based on geographic locality. Therefore, the multi-state mass immunizer must be willing to accept that payments received may vary based on the geographic locality where the service was performed.

- The payment rates for the vaccines will be determined by the standard method used by Medicare Part B for reimbursement of drugs and biologicals, which is based on the lower of the charge or 95 percent of the AWP.

- Multi-state mass immunizers must agree to submit their claims in the American National Standards Institute (ANSI) X12.837 format. Paper claims will not be accepted.

- In addition to normal roster billing instructions, multi-state mass immunizers must complete on the electronic format, the area that corresponds to Item 32 (Name and Address of Facility, including ZIP code) on Form CMS-1500 (08-05), for the contractor to be able to pay correctly by geographic locality.

- Multi-state mass immunizers must obtain certain information for each beneficiary including name, health insurance number, and date of birth, sex and signature. The assigned Medicare contractor must be contacted prior to the season for exact requirements. The responsibility lies with the multi-state mass immunizer to submit correct beneficiary Medicare information (including the beneficiary's Medicare Health Insurance Claim Number) since the contractor will not be able to process incomplete or incorrect claims.

- Multi-state mass immunizers must obtain an address for each beneficiary so that the contractor can send a MSN to the beneficiary. Beneficiaries are sometimes confused when they receive an MSN from a contractor other than the contractor that normally processes their claims, which results in unnecessary beneficiary inquiries to the Medicare contractor. Therefore, multi-state mass immunizers must provide every beneficiary receiving an influenza virus or pneumococcal vaccination with the name of the contractor selected by CMS. This notification must be in writing, in the form of a brochure or handout, and must be provided to each beneficiary at the time he or she receives the vaccination.

- Multi-state mass immunizers must retain roster bills with beneficiary signatures at their permanent location for a time period consistent with Medicare regulations. The Medicare contractor selected to process the claims can provide this information.

- Though multi-state mass immunizers may already have a Medicare provider number, for purposes of centralized billing, they must also obtain a provider number from the contractor selected by CMS to process the influenza virus and pneumococcal vaccination claims. This can be done by completing Form CMS-855 (Provider Enrollment Application), which can be obtained from that contractor.

- If a multi-state mass immunizer's request for centralized billing is approved, the approval is limited to the upcoming influenza virus season. It is the responsibility of the multi-state mass immunizers to reapply to the CMS CO for approval each year by June 1 for the year prior to the beginning of the influenza virus season for which they wish to bill. Claims submitted without approval will be denied.

- Each year the multi-state mass immunizers must contact the assigned contractor to verify understanding of the coverage policy for the administration of the pneumococcal vaccine, and for a copy of the warning language that is required on the roster bill.

- The multi-state mass immunizer will be responsible for providing the beneficiary with a record of the pneumococcal vaccination.

E.8 Are separate rosters required for each place of service as well as date of service?

Yes.

F. Medicare Advantage Plans

F.1 Can a Medicare Advantage (MA) organization require members to obtain prior authorization from their primary care provider (PCP) for influenza and pneumococcal vaccinations?

In-network: Enrollees can self-refer within the plan's network of providers for influenza vaccines, and consequently the MA organization may not require prior authorization for influenza vaccines received from network providers. Plans are not required to, and so plans may not allow, self-referral for the pneumococcal vaccine because this is a one-time vaccination and the providers need to be able to check whether it's been given before.

Out-of-network: Private Fee-for-Service, Preferred Provider Organization and Medical Savings Account types of MA plans are required to cover all services in or out of network, however a co-payment may apply. Other types of MA organizations may allow self-referral to an out-of-network provider for influenza vaccinations, typically with a co-payment. [Note: Network rules were waived for H1N1 vaccinations in 2009.]

F.2 Is the beneficiary responsible for a co-payment when influenza or pneumococcal vaccines are provided within the MA provider network?

There is no charge for the vaccine itself for either of these or for the service of giving these vaccinations. A beneficiary may be asked to pay a co-payment for the office visit, but only if other services are provided during the office visit.

F.3 Is the beneficiary responsible for a co-payment when a vaccine is provided outside of the MA provider network?

MA organizations may choose to allow vaccinations out of network and may also charge a co-payment out of network, except for Private Fee-for-Service plans that pay at Original Medicare rates. Private Fee-for-Service, Preferred Provider Organization and Medical Savings Account plans are required to cover services out of network.

F.4 What should carrier/AB MAC do if providers submit claims for beneficiaries who are enrolled in MA organizations when the vaccine is furnished by a facility or provider outside of their MA organization?

Medicare will not reimburse a non-MA provider for influenza virus or pneumococcal vaccinations for beneficiaries enrolled in an MA plan. Medicare has already paid the MA organization to provide this service. If the MA enrollee has received care out-of-network, and the plan allows that, the beneficiary who chooses to pay upfront and out-of-pocket for the vaccination should then seek reimbursement from the MA organization. Rules for out of network access vary by plan type, as described above.

G. Medicaid and CHIP

States cover all recommended immunizations for children enrolled in Medicaid and CHIP. Examples of these immunizations include flu, pneumonia, etc. Visit http://www.insurekidsnow.gov/state/index.html to visit your State's web site and find out more.

Some States also cover vaccines for adults enrolled in Medicaid. For information on what adult immunizations are covered, please refer to your State's Medicaid Manual and/or agency representative for further information.

H. Terms and Definitions

Advisory Committee on Immunization Practices (ACIP) – The ACIP develops written recommendations for the routine administration of vaccines to pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. ACIP is the only entity in the federal government that makes such recommendations.

Assignment – The doctor or person performing the service receives the Medicare payment. The provider of services accepts the amount Medicare allows as his total charge. The beneficiary is responsible for any deductible and the 20 percent coinsurance.

Assigned claim – See assignment.

Beneficiary – an individual who is entitled to Medicare Part A and/or Medicare Part B.

Billing Providers – the provider who submits a claim for payment on services he/she has performed or, in some cases, the group, such as a clinic, bills for the performing providers within the group.

Carrier/AB MAC – the company contracted with the federal government to handle the Medicare Part B program for a particular state.

Centers for Medicare & Medicaid Services (CMS) – the Federal agency that administers the Medicare, Medicaid and CHIP programs.

Centralized billing – optional program for providers who qualify to enroll with Medicare as the provider type, "mass immunizer." Additional criteria must also be met.

CMS-1450 – Paper form used to bill the fiscal intermediary/AB MAC for services provided to a Medicare beneficiary.

CMS-1500 – Paper form used to bill the carrier/AB MAC for services provided to a Medicare beneficiary.

Coinsurance – the 20 percent difference between the allowed amount and the 80 percent that is paid under the Medicare program.

Deductible – the amount that must be met each calendar year from allowed medical expenses before Medicare Part B payment will be made. This amount is the responsibility of the beneficiary.

Electronic billing software – software available for transmitting electronic claims to Medicare.

Fiscal intermediary/AB MAC (FI) – Contractor for the Centers for Medicare & Medicaid Services that processes claims for services covered under Medicare Part A and most types of claims for services covered under Medicare Part B.

Government entities (such as public health clinics) – may bill Medicare for PPV, hepatitis B, and influenza virus vaccine administered to Medicare beneficiaries when services are rendered free of charge to non-Medicare beneficiaries.

Health Care Procedure Coding System (HCPCS) – a listing of codes, modifiers, and descriptive terminology used for reporting the provision of medical supplies, materials, injections, Durable Medical Equipment (DME), prosthetic devices, and certain services and procedures to Medicare.

Health insurance claim number – the 10- or 11-digit number assigned by Medicare to each beneficiary.

Health Maintenance Organization (HMO) – a health care organization that acts both as insurer and provider of comprehensive but specified medical services. A defined set of physicians provide services to a voluntarily enrolled population for a prospective per capita amount (i.e., by capitation). Prepaid group practices and individual practice associations are types of HMOs.

Limiting charge – the limit on the amount a non-participating doctor can charge on a non-assigned claim. The limiting charge is no more than 115 percent of the fee schedule amount.

Medicare Administrative Contractor (MAC) - The contracting organization that is responsible for the receipt, processing, and payment of Medicare claims. In addition to providing core claims processing operations for both Medicare Part A and Part B, they will perform functions related to: Beneficiary and Provider Service, Appeals, Provider Outreach and Education (also referred to as Provider Education and Training), Financial Management, Program Evaluation, Reimbursement, Payment Safeguards, and Information system security.

Managed Care Organization (MCO) – a health care organization that acts both as insurer and provider of comprehensive but specified medical services. A defined set of physicians provides services to a voluntarily enrolled population for a prospective per capita amount (i.e., by capitation). Prepaid group practices and individual practice associations are types of MCOs.

Mass Immunizer Roster Biller – provider who chooses to enroll in Medicare with this identifier, which demands the provider meets certain criteria and follows certain procedures when immunizing Medicare beneficiaries.

Medicare Summary Notices (MSNs) – the statement sent to the beneficiary explaining how the claim was processed and what payment amount is being made, what applied to the deductible, what services were denied and why, etc.

Medically necessary – services or supplies that:

- Are proper and needed for the diagnosis or treatment of a medical condition;
- Are provided for the diagnosis, direct care, and treatment of a medical condition;
- Meet the standards of good medical practice in the medical community of the local area; and
- Are not mainly for the convenience of the patient or doctor.

Non-assigned claim – a claim that directs payment to the beneficiary.

Non-government entities – entities that do not charge patients who are unable to pay or reduce their charges for patients of limited means, yet expect to be paid if the patient has health insurance coverage for the services provided, may bill Medicare and expect payment.

Non-participating physician/suppliers – a physician practice/supplier that has not elected to become a Medicare participating physician/supplier, i.e., one that has retained the right to accept assignment on a case-by-case basis (compare to participating physician.)

Participating physician/supplier – a physician practice/supplier that has elected to provide all Medicare Part B services on an assigned basis for a specified period of time.

Railroad Retirement Board (RRB) – an independent agency in the executive branch of the federal government. The RRB's primary function is to administer comprehensive retirement, survivor and unemployment, and sickness programs for the nation's railroad workers and their families under the Railroad Retirement & Railroad Unemployment Insurance Acts. In connection with the retirement program, the RRB has administration responsibilities under the Social Security Act for certain benefit payments for railroad workers' Medicare coverage.

Remittance Notice (RN) – the statement sent to the provider explaining how the claim was processed and what payment amount is being made, what applied to the deductible, what services were denied and why, etc.

Roster billing – (also referred to as simplified roster billing) a process developed by CMS which enables entities that accept assignment that administer the influenza and/or PPV vaccine to multiple beneficiaries to bill Medicare for payment using a modified CMS 1450, CMS-1500 claims form, or electronic software provided by Medicare carrier/AB MAC.

I. Centers for Medicare & Medicaid Services 2012-2013 Flu Coordinators

Table 5: Flu Coordinator Contact Information

CMS Flu Contacts and States Covered	Name	E-mail address	Phone
Region 1 (CT, MA, ME, NH, RI, VT)	Barbara Manning	Barbara.manning@cms.hhs.gov	617-565-9435
Region 2 (NJ, NY)	Norma Harris	Norma.harris@cms.hhs.gov	212-616-2342
Region 2 (PR, VI)	Maria Martinez	Maria.Martinez@cms.hhs.gov	787-771-1404
Region 3 (DE, DC, MD, PA, VA, WV)	Monique Scott	Monique.Scott@cms.hhs.gov	215-861-4508
Region 4 (AL, GA, FL, KY, MS, NC, SC, TN)	Teresa Zayas	Teresa.Zayas@cms.hhs.gov	404-562-7500
Region 5 (IL, MN, MI, OH, WI)	Ashley Setala	Ashley.Setala@cms.hhs.gov	312-886-9598
Region 6 (AR, LA, NM, OK, TX)	Sylvia Garcia	Sylvia.Garcia@cms.hhs.gov	214-767-1525
	Melissa Scarborough	Melissa.Scarborough@cms.hhs.gov	214-767-4407
Region 7 (IA, KS, MO, NE)	William Buck	William.buck@cms.hhs.gov	816-426-6313
Region 8 (CO, MT, ND, SD, UT, WY)	Michael Fierberg	Michael.Fierberg@cms.hhs.gov	303-844-1592
Region 9 (AZ, CA, HI, NV)	Sharon Yee	Sharon.Yee@cms.hhs.gov	415-744-2935
Region 10 (AK, ID, OR, WA)	Andrew Tartella	Andrew.Tartella@cms.hhs.gov	206-615-2412

Reviewers:
Barbara Cebuhar, CMS Office of Public Engagement, 202-260-1020
Andrew Kroger, MD, Centers for Disease Control and Prevention
Lisa Grohskopf, MD, Centers for Disease Control and Prevention
Abigail Shefer, MD, Centers for Disease Control and Prevention
Carol Bazel, CMS, Center for Medicare
Pat Gill, CMS, CMS, Center for Medicare
Bridgitte Davis, CMS, Center for Medicare
Juliette Jenkins, CMS, Office of Clinical Standards and Quality

Kathy Bryant, Center for Medicare
Anne Hauswald, Center for Medicare
Prabath Malluwa-Wadu, Center for Medicare
Marc Hartstein, CMS, Center for Medicare
Cheryl Gilbreath, CMS, Center for Medicare
Denise Buenning, CMS, Office of e-Health Standards and Services
William Ruiz, CMS, Center for Medicare
Antoinette Johnson, CMS, Center for Medicare
Whitney May, CMS, Center for Medicare
Renee Hildt, CMS, Center for Medicare
Mary Beth Hance, Centers for Medicaid, CHIP and Survey and Certification
Eric Sontag, Center for Medicaid, CHIPP and Survey and Certification
Brian Reitz, CMS, Office of Information Systems
Barry Bromberg, CMS, Office of Information Systems
Mike Collett, CMS, Office of Information Systems
Mark Klischer, CMS, Office of Information Systems