



November 2007

**Re: CMS Letter on Part D Coverage of Preventive Vaccines Provided to Medicare Beneficiaries in Skilled Nursing Facilities During a Medicare-Covered Stay**

**Dear Nursing Facility Executive/Staff:**

As part of our continuing efforts to assist customers in better understanding reimbursement issues, we attach for your information, a letter from the staff of the Centers for Medicare & Medicaid Services of the Department of Health & Human Services (CMS). The letter relates to Medicare Part D reimbursement for certain vaccines when administered to residents of skilled nursing facilities. It was sent by CMS to Ms. Wendy Krasner of Manatt, Phelps & Phillips, LLP, with whom Merck & Co., Inc. has a consulting relationship, in response to a question that we asked Ms. Krasner to submit based upon feedback that Merck representatives have received from some nursing facilities.

In summary, the question asked and the CMS response is as follows:

**Question:** Can a vaccine reimbursed under Medicare Part D be provided to a Medicare beneficiary in a nursing facility during a Part A (Medicare-covered) stay?

**Answer:** Yes. According to the attached CMS letter, Part D-covered vaccines are reimbursable for Medicare beneficiaries during a Part A stay because preventive vaccines are considered outside the scope of the Part A benefit, and no benefit category exists for Part D vaccines in Part B.

**Background**

Many health care practitioners, facilities, and stakeholders are now aware that, for Medicare beneficiaries, ZOSTAVAX® (Zoster Vaccine Live) falls under the Part D prescription benefit. This includes Medicare beneficiaries who reside in nursing facilities and other long-term care communities. Although Part D plans can reimburse ZOSTAVAX and other Part D vaccines for many nursing facility residents, it has not been clear whether Part D reimbursement is available for a vaccine administered during a Medicare Part A-covered stay. This perceived lack of clarity resulted from the belief that Medicare Part A per diem payments received by nursing facilities are generally intended to cover all services, including medications and vaccines, provided to Medicare beneficiaries during a Part A stay.

In the attached letter, however, CMS clarifies that a preventive Part D vaccine provided to a Part A resident can be separately reimbursed by the Part D plan. The CMS letter explains that preventive vaccines are outside the scope of the Part A benefit, and therefore are not covered under the Part A per diem payment. Thus, according to CMS, except with regard to vaccines that are specifically enumerated as falling within the Medicare Part B benefit category, other vaccines can be reimbursed under Part D. As stated in the letter:

[A] preventive vaccine... for which no Part B benefit category exists would be coverable under the Part D drug benefit when administered to the [skilled nursing facility's] Part A resident, rather than being covered under the Part A [skilled nursing facility] benefit.

Please keep in mind that Medicare Part D is a pharmacy benefit and thus the reimbursement process for vaccines covered under Part D is different than the process applicable to, for example, vaccines covered under Medicare Part B. In a nursing facility setting, the facility typically will have a relationship with a long-term care pharmacy in the Part D plan network. The long-term care pharmacy would generally bill the resident's Part D plan for a reimbursable vaccine, and would provide the vaccine to the nursing facility for any resident for whom a vaccine has been ordered.

### **Select Safety Information for ZOSTAVAX® (Zoster Vaccine Live)**

ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older. ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia.

ZOSTAVAX is contraindicated in persons with a history of anaphylactic/anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; with a history of primary or acquired immunodeficiency states including leukemia; lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; or with AIDS or other clinical manifestations of infection with human immunodeficiency viruses. ZOSTAVAX is also contraindicated in persons on immunosuppressive therapy. ZOSTAVAX is not indicated in women of childbearing age and should not be administered to pregnant females.

Transmission of vaccine virus may occur rarely between vaccinees and susceptible contacts.

Vaccination with ZOSTAVAX may not result in protection of all vaccine recipients.

**Before administering ZOSTAVAX, please read the accompanying Prescribing Information. For additional copies of the Prescribing Information call 1-800-672-6372, visit [zostavax.com](http://zostavax.com), or contact your Merck representative.**

Sincerely,



Patrick Liedtka  
Associate Director  
Vaccine Public Policy

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-15  
Baltimore, Maryland 21244-1850



Center for Medicare Management

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Refer to: FAHB-4

25 JUL 2007

Ms. Wendy Krasner  
Manatt, Phelps & Phillips, LLP  
700 12th St. NW, Suite 1100  
Washington, DC 20005

Dear Ms. Krasner:

I am responding to your e-mail inquiry of July 11<sup>th</sup> to Ms. Liz Richter, Director of the Center for Medicare Management (CMM), regarding coverage of preventive vaccines provided to Medicare beneficiaries in skilled nursing facilities (SNFs) during a Medicare-covered stay. The SNF consolidated billing requirement makes the SNF itself responsible for billing Medicare for virtually all services that a beneficiary receives during the course of a covered Part A stay in the facility, except for those services that appear on a statutory list of exclusions in §§1888(e)(2)(A)(ii)-(iv) of the Social Security Act (the Act). As discussed in the May 12, 1998 edition of the *Federal Register* (63 FR 26296), preventive services such as vaccines are subject to SNF consolidated billing, because they do not appear on this statutory exclusion list. However, while this places with the SNF itself the Medicare billing responsibility for any preventive services that its residents receive during a Medicare-covered stay, this does not necessarily mean that the SNF would include such services on its global Part A bill for the covered stay, as explained below.

In determining priority of payment between the various parts of title XVIII, one basically proceeds in alphabetical order: Part A is primary to Part B (see §1833(d) of the Act), and both Parts A and B are primary to Part D (see §1860D-2(e)(2)(B) of the Act). This means that Part B can cover a particular vaccine only to the extent that it isn't already coverable under Part A, and the Part D drug benefit can cover such a vaccine only to the extent that it isn't already coverable under either Part A or Part B.

Moreover, preventive services are *never* coverable as Part A SNF services; even when furnished to a beneficiary during the course of a Medicare-covered SNF stay, such services are *always* covered separately under the applicable Part B (or Part D) benefit. This is because the Part A SNF benefit is limited to coverage of "diagnostic or therapeutic" services—that is, services that are reasonable and necessary to diagnose or treat an *already-existing* condition (see §§1861(h)

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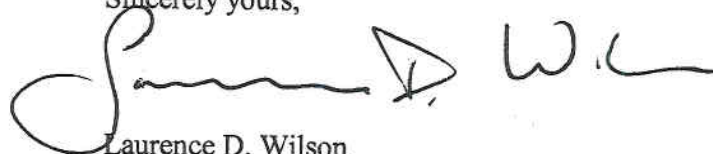
following (7), 1861(b)(3), and 1862(a)(1)(A) of the Act), whereas preventive services are those that are reasonable and necessary to ward off the occurrence of the condition altogether (see §1862(a)(1)(B) of the Act). (Screening services are similarly beyond the scope of the Part A SNF benefit, as they serve simply to check for the possible presence of a specific condition that is still in an early, asymptomatic stage (see §§1862(a)(1)(F) - (I) and (L) - (N) of the Act), rather than being reasonable and necessary to *diagnose* or *treat* an existing condition that has already manifested itself with symptoms (§1862(a)(1)(A) of the Act).)

Thus, when an SNF's Part A resident receives, for example, a preventive vaccine for pneumococcal pneumonia, hepatitis B, or influenza, the vaccine would be covered under Part B. It would not be covered under Part A (because the scope of the Part A SNF benefit does not encompass preventive services), and it also would not be covered under Part D (because Part B already includes a benefit category for these particular types of vaccines and, as discussed above, Part B is primary to Part D). Similarly, a preventive vaccine (such as poliomyelitis) for which no Part B benefit category exists would be coverable under the Part D drug benefit when administered to the SNF's Part A resident, rather than being covered under the Part A SNF benefit.

However, it is also worth noting that there are certain circumstances under which a vaccine is no longer considered to be preventive in nature, and this could affect how the vaccine is covered. For example, while a booster shot of tetanus vaccine would be considered preventive when routinely administered in accordance with a recommended schedule, it would not be considered preventive when administered in response to an actual exposure to the disease (such as an animal bite or a scratch on a rusty nail). Under the latter circumstance, such a vaccine furnished to an SNF's Part A resident would be regarded as reasonable and necessary to treat an existing condition and, accordingly, it would be included within the SNF's global Part A per diem payment for the resident's Medicare-covered stay.

I hope that you will find this information helpful. If you have any additional questions on this issue or would like to discuss it further, please contact Mr. Bill Ullman of my staff, on (410) 786-5667.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Laurence D. Wilson". The signature is fluid and cursive, with a large initial "L" and a distinct "D" and "W".

Laurence D. Wilson  
Director  
Chronic Care Policy Group

cc.: Liz Richter, CMM  
Jeff Kelman, CBC