



Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting <http://www.cms.hhs.gov/NationalProvIdentStand/> on the CMS web site.

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Payment for Part D Vaccines under the Medicare Drug Benefit (Part D)

Provider Types Affected

Physicians, pharmacists, providers, health care professionals, suppliers, and their staff.

Provider Action Needed

Be aware of the coverage and payment rules related to vaccines and administration of vaccines under Part B and Part D of Medicare. This Special Edition *MLN Matters* article describes the Centers for Medicare & Medicaid Services (CMS) approach for providers to obtain payment for Part D vaccines under the Medicare Drug Benefit.

Key Information

Coverage of Vaccines under the Part B Program

Part B covers influenza vaccine, pneumococcal vaccine *and* Hepatitis B vaccine for intermediate and high risk beneficiaries, The Part B program also covers vaccines that are necessary to treat an injury or illness. For instance, should a beneficiary need a tetanus vaccination related to an accidental puncture wound, it would be covered under Part B. However, if the beneficiary simply needed a booster shot of his or her tetanus vaccine, unrelated to injury or illness, it would be covered under Part D. Medicare Part B does not cover administration of Part D vaccines

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Coverage of Vaccines under the Part D Program

Any vaccine licensed under section 351 of the Public Health Service Act is available for payment under the Part D benefit when it is not available for payment under Medicare Part B (as so prescribed and dispensed or administered).

Unlike other Part D Drugs that may be excluded when not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Part D vaccines may be excluded from coverage only when their administration is not reasonable and necessary for the prevention of illness. Therefore, although a Part D plan's formulary might not list all Part D vaccines, the beneficiary must be provided access to such vaccines when the physician prescribes them for an appropriate indication reasonable and necessary to prevent illness in the beneficiary.

Part D Payment for Vaccines in Provider Settings

Part D plans are required to provide access to vaccines not covered under Part B. During rulemaking, CMS described use of standard out-of-network requirements to ensure adequate access to the small number of vaccines covered under Part D that must be administered in a physician's office. CMS' approach was based on the fact that most vaccines of interest for the Medicare population (influenza, pneumococcal, and hepatitis B for intermediate and high risk patients) were covered and remain covered under Part B. Under the out-of-network process, the beneficiary pays the physician and then submits a paper claim to his or her Part D plan for reimbursement up to the plan's allowable charge. As there likely would be no communication with the plan prior to vaccine administration, the amount the physician charges may be different from the plan's allowable charge, and a differential may remain that the beneficiary would be responsible for paying.

As newer vaccines have entered the market with indications for use in the Medicare population, Part D vaccine in-network access has become more imperative. Requiring the beneficiary to pay the physician's full charge for a vaccine out of pocket first and be reimbursed by the plan later is not an optimal solution, and CMS has urged Part D plans to implement cost-effective, real time billing options at the time of administration. With consideration to improve access to vaccines under the Drug Benefit without requiring up-front beneficiary payment, in May 2006, CMS issued guidance to Part D sponsors to investigate alternative approaches to ensure adequate access to Part D vaccines. CMS emphasized a solution incorporating real-time processing, given that cost sharing under Part D for non-full subsidy beneficiaries can differ depending upon where the beneficiary is in the benefit (e.g., deductible, coverage gap, and catastrophic range).

CMS has outlined the following options to Part D sponsors for their consideration in a letter dated 12/1/06. (See

http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoVaccineAccess_05.08.06.pdf on the CMS website.) However, plans have the flexibility to determine

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which approach to implement to provide their members with access to vaccines. Physicians should expect to see various models develop and should be aware of both their potential existence and use by Medicare beneficiaries.

Options to Ensure Adequate Access under Part D to Covered Vaccines

In-Network Distribution Approaches

- **In-Network Pharmacy Distribution:**

A Part D plan's network pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call in a prescription, or the beneficiary could mail a prescription for the vaccine to the pharmacy. The pharmacy would fill the prescription for the vaccine, ship to the physician's office and bill the Part D plan for the vaccine. This model resembles the competitive acquisition program (CAP) being implemented by Medicare Part B in that the drug is shipped to the physician but the physician never purchases or gets paid for the drug.

- **In-Network Retail Pharmacy Access:**

Enrollees could obtain a prescription from the physician and bring it to their local network retail pharmacy for filling. In some states, it might be possible for the vaccine administration to be provided by the pharmacist. Forty-four states currently allow pharmacists to provide some type of vaccinations. Where it was safe to dispense these vaccines in the pharmacy, plans could explore utilization of their network pharmacists as a provider of adult Medicare Part D vaccines (Pediatric vaccines should continue to be provided by physicians).

Out-of-Network (OON) Approaches: Facilitated Out-of-Network Access Approaches

- **Model Vaccine Notice for Physicians (Paper Claim Enhancement):**

Part D plans would provide all enrollees with a vaccine-specific notice that the enrollees could bring to their physicians. This notice would provide information necessary for a physician to contact the enrollee's Part D plan to receive authorization of coverage for a particular vaccine, payment rates, enrollee cost-sharing to be collected by the physician, and billing instructions. The physician would follow the Part D sponsor's instructions to bill the out-of-network claim on the beneficiary's behalf.

- **Web-Assisted Out-of-Network Billing:**

Under this approach, physicians would electronically submit beneficiary out-of-network claims to Part D plans for vaccines dispensed and administered in the physician's office through a web-assisted portal. This approach would allow the beneficiary to pay out of pocket only the appropriate deductible, copay or cost sharing and administration fee (if any) directly to the physician, thus avoiding any up-front payment and repayment for the full cost of the vaccine. The physician

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would assume responsibility for submitting the claim on behalf of the beneficiary and would agree to accept Part D plan payment as payment in full.

It is important to emphasize for either OON approach, the physician does not become a network provider, but is assisting the beneficiary in the submission of his or her out-of-network claim.

CMS is working with Part D sponsors to facilitate these various approaches. CMS has also encouraged additional exploration of other possible means to coordinate the billing of vaccines in the real-time environment of the Part D benefit. CMS expects significant development in this area over the next year.

Payment for Administration of Vaccines

There is no Medicare payment for administration of Part D vaccines, so plans cannot pay for the administration of Part D vaccines in a physician's office or at a pharmacy. As mentioned previously, Medicare Part B does not cover administration of Part D vaccines. Medicare covers (under Part B) the administration of a Part B-covered "preventive" vaccine – influenza, pneumococcal, Hepatitis B for intermediate or high-risk beneficiaries – along with "medically necessary" vaccines that are directly related to the treatment of an injury or illness.

Note: *If the beneficiary has additional available payers, for example supplemental benefits offered by a Medicare Advantage Plan, the physician can investigate the potential for that payer to pay for the vaccine administration of a Part D vaccine. Similarly, physicians may be able to seek payment from the State Medicaid Agency for vaccine administration fees related to Part D covered vaccines for their dually-eligible Medicare and Medicaid patients. Each State Medicaid Agency may have a slightly different process or approach if payment is available. If physicians do not know how to facilitate billing vaccine administration fees for these dually-eligible beneficiaries or want to verify the State Medicaid Policy on vaccine administration they should contact their respective State Medicaid Agency. State Medicaid Agency information is located at <http://www.cms.hhs.gov/MedicaidGenInfo/> on the CMS website.*

If there are no other billable payers, similar to the situation for other Medicare non-covered services, providers offering administration of Part D vaccines can charge the beneficiary an administration fee directly for providing this non-covered service. Before dispensing a covered Part D vaccine for which the provider intends to charge an administration fee, the provider should notify the beneficiary in advance that the administration of the vaccine is not offered as part of the Medicare Prescription Drug Benefit and, therefore, the beneficiary is responsible for the fee or charge associated with administration. The provider should inform the beneficiary of the exact amount of the administration fee or charge. Also, the provider should inform the beneficiary that any fee or charge for vaccine administration falls entirely outside the Part D cost sharing structure and will not be included as part of the beneficiary's True Out-of-Pocket (TrOOP) costs.

Frequently Asked Questions Related to Part D Covered Vaccines

1. If I need to immunize a beneficiary with a Part D vaccine, what do I do?

The beneficiary or physician can call the Part D Plan to discuss what the cost sharing and allowable charges would be for the vaccine as part of the plan's out-

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of-network access or inquire as to the availability of any alternative vaccine access options. Plan contact information is available at <http://www.medicare.gov/MPDPF/Public/Include/DataSection/Questions/MPDPFIntro.asp> or by calling 1-800-Medicare.

2. Do I need to provide an Advanced Beneficiary Notice (ABN)?

No. Unlike traditional Medicare, Part D does not require ABNs. However, the provider should inform the beneficiary that any fee or charge for Part D vaccine administration falls entirely outside of Part B and the Part D cost sharing structure.

3. May I charge an administration fee?

Yes. The physician may charge an administration fee, however, neither the Part B carrier, nor Part D plan are responsible for payment. This fee could be billed to the beneficiary or to any supplemental insurers in accordance with the information listed above in this *MLN Matters* Article.

4. Is the Herpes zoster vaccine (Trade name Zostavax) covered under Medicare Part B or D?

Since the Herpes zoster vaccine is a preventive vaccine, it will be available for payment under Part D. Beneficiaries and providers should contact the Part D plans for more information about costs and payment for this and other preventive vaccines.

Additional Information

More information about Part D for physicians' is available on our physician website: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp#TopOfPage on the CMS website.

Flu Shot Reminder - As a respected source of health care information, patients trust their doctors' recommendations. If you have Medicare patients who haven't yet received their flu shot, help protect them by recommending an annual influenza and a one time pneumococcal vaccination. Medicare provides coverage for flu and pneumococcal vaccines and their administration. – And don't forget to immunize yourself and your staff. **Protect yourself, your patients, and your family and friends.** Get Your Flu Shot. Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. For more information about Medicare's coverage of adult immunizations and educational resources, go to CMS's website: <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0667.pdf> .

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