



News Flash – PQRI Tool Kit Available

The Centers for Medicare & Medicaid Services (CMS) is pleased to announce that the 2007 Physician Quality Reporting Initiative (PQRI) Tool Kit is now available. To access the Tool Kit, visit the PQRI web page at <http://www.cms.hhs.gov/PQRI> on the CMS website, then go to the PQRI Tool Kit section. To access all of the other resources you need to assist in successful reporting, go to the Educational Resources section of the previously mentioned website.

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Reimbursement for Vaccines and Vaccine Administration Under Medicare Part D

Provider Types Affected

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

Provider Action Needed

This Special Edition *MLN Matters* article describes the Centers for Medicare & Medicaid Services (CMS) policy regarding provider reimbursement for Part D vaccines and vaccine administration in 2007 and 2008 under the Medicare Prescription Drug Benefit (Part D). In addition, the article outlines various approaches that Part D plans may implement to ensure beneficiaries have adequate access to Part D vaccines.

Background

With the advent of the Medicare Part D program, there is now broader reimbursement available to providers for vaccines administered to Medicare beneficiaries. Some vaccines are covered under Medicare Part B and others under Part D. The Part B program covers most of the vaccines indicated for the Medicare population, with the immunizer administering the vaccine and billing the Part B contractor (Medicare carrier or Part A/B Medicare Administrative Contractor

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or A/B MAC) for both the vaccine and its associated administration. The Part D program generally covers those vaccines not available under Part B; however, unlike Part B, the immunizer may or may not be able to directly bill the Part D Sponsor for the vaccine and its administration, but instead may need to work with the beneficiary and his/her Part D plan to facilitate reimbursement. The first step is for the provider to understand which vaccines are available under the two different programs so he/she can assist the beneficiary in obtaining the vaccines needed to maintain and improve his/her health.

Coverage of Vaccines Under the Part B Program

Medicare Part B currently covers the following immunizations:

- Pneumococcal pneumonia vaccine;
- Influenza virus vaccine;
- Hepatitis B vaccine for individuals at high or intermediate risk; and
- Other vaccines (e.g. tetanus toxoid) when directly related to the treatment of an injury or direct exposure to a disease or condition.

If a vaccine is covered under Part B, it will continue to be covered under Part B regardless of the changes to Part D vaccine administration reimbursement in 2007 and 2008 discussed later in this article.

Coverage of Vaccines under the Part D Program

The Part D program will generally cover those vaccines not available for reimbursement under Medicare Parts A or B when administration is reasonable and necessary for the prevention of illness.

Part D plans identify covered drugs and vaccines through the use of formularies. However, a new preventative vaccine may not be specifically listed on the Part D plan's formulary. This does not mean the vaccine is not available for reimbursement. The provider can contact the Part D plan about coverage and any supporting information that might be necessary to facilitate vaccine coverage for the beneficiary (Part D plan contact information is located at the end of this article).

To facilitate greater access to Part D vaccines, CMS has directed that starting in 2008 all Part D plans' formularies must contain all commercially available vaccines (unless excluded due to available reimbursement under Part B, e.g., influenza or pneumococcal vaccines as discussed above).

Example of identifying vaccines covered under Part B or Part D

Hepatitis B vaccine provides a useful illustration of how a provider could approach vaccine reimbursement under Medicare Part B or D. **Part B covers Hepatitis B**

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vaccine for intermediate and high risk patients. A beneficiary meeting the intermediate or high risk coverage criteria could obtain the Hepatitis B vaccination series from their physician and the physician would submit a claim to the Medicare Part B contractor. For the beneficiary who did not satisfy the appropriate Part B risk criteria, he or she could still obtain the Hepatitis B vaccine from their physician; however, any potential reimbursement would be available from the beneficiary's Part D plan instead of the Part B contractor. Facilitation of Part D vaccine reimbursement is discussed later in this article.

Coverage of Vaccine Administration Under the Part B Program

The Tax Relief and Health Care Act (TRHCA), effective January 1, 2007, provided for reimbursement of vaccine administration associated with Part D vaccines. Pharmacies and physicians can use a newly instituted G code (G0377) to bill Part D vaccine administration to local Medicare Part B contractors. Normal Part B beneficiary deductible and coinsurance requirements apply and **reimbursement for this code is only effective for calendar year 2007.**

Payment for the actual Part D covered vaccine is the responsibility of the beneficiary's Part D plan. In other words, in 2007 Medicare Part B will not pay for the Part D vaccine (i.e. low risk Hepatitis B vaccine), just the Part D vaccine administration.

For additional information on Part B reimbursement of Part D vaccine administration in 2007 see the *MLN Matters* articles MM5443 and MM5459, published in December, 2006:

- MM5443 is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5443.pdf> and
- MM5459 is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5459.pdf>.

Coverage of Vaccine Administration Under the Part D Program

TRHCA modified the definition of a Part D drug to include "for [Part D] vaccines administered on or after January 1, 2008, **its administration.**" Consequently, beginning on January 1, 2008, the Part D program will cover vaccine administration costs associated with Part D vaccines. **Thus, the coverage available in 2007 under Part B will cease and reimbursement will be available solely under Part D.** CMS interprets this new statutory requirement to mean that the Part D vaccine administration costs are a component of the negotiated price for a Part D-covered vaccine. In other words, the negotiated price for a Part D vaccine will be comprised of the vaccine ingredient cost, a dispensing fee (if applicable), sales tax (if applicable) and a vaccine administration fee. This interpretation recognizes the intrinsic linkage that exists between the vaccine and

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its corresponding administration, since a beneficiary would never purchase a vaccine without the expectation that it would be administered.

In general, CMS believes that Part D vaccines, including the associated administration costs, should be billed on one claim for both in- and out-of-network situations. For example, if an in-network pharmacy dispenses and administers the vaccine in accordance with State law, the pharmacy would process a single claim to the Part D sponsor and collect from the enrollee any applicable cost-sharing on the vaccine and its administration. Alternatively, if a vaccine is administered out-of-network in a physician's office, the physician would administer the vaccine and then bill the beneficiary for the entire charge, including both components. The beneficiary would, in turn, submit a paper claim to the Part D sponsor for reimbursement of plan allowable costs for both the vaccine cost and the administration fee.

Cost-Sharing Considerations

In general, a Part D plan should not charge separate copays for the vaccine and its administration since CMS views the vaccine and its administration as intrinsically linked. If a Part D plan charges coinsurance, it should be applied relative to the entire price of both components. Low income subsidy eligible individuals with copays set by statute (see section 1860D-14(a)(1)(D) of the Social Security Act) will always pay only one copay for a vaccine and all related charges. Thus, for example, a low income subsidy eligible individual entitled to \$1.05/\$3.10 copays in 2008 would pay only \$3.10 for both the vaccine and its administration (and any applicable dispensing fee) even if the components are billed separately.

Elements of Vaccine Administration

CMS expects that Part D plans will take into consideration the elements reflected in existing 2007 Part B vaccine administration fees when establishing their own vaccine administration fees for 2008. Part D plans will have the discretion to implement either a single vaccine administration fee for all vaccines or multiple administration fees based on type of vaccine, variance in provider type, and product administration complexity. Providers should contact Part D plans regarding specific vaccine administration fees for 2008. (Part D plan contact information is listed at the end of this article.)

Part D Reimbursement for Vaccines in Provider Settings

As stated earlier, Part D plans are required to provide access to vaccines not covered under Parts A or B. During initial Part D 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 are 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

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and high risk patients) were covered and remain covered under Part B. For those that are not covered under Part B, the beneficiary would pay the physician and then submit a paper claim to his or her Part D plan for reimbursement up to the plan's allowable charge. In the absence of 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 will 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. CMS issued guidance to Part D plans to investigate alternative approaches to improve access to vaccines under the Drug Benefit without requiring up-front beneficiary payment and to ensure adequate access to Part D vaccines.

CMS outlined the following options to Part D plans for their consideration. 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 Access to Retail Pharmacies:** Enrollees could obtain a prescription from the physician and bring it to their local network retail pharmacy for filling. In some states, it will already be possible for the vaccine to be administered by the pharmacist. Forty-six states currently allow pharmacists to provide some type of vaccinations. When it is safe to dispense and administer these vaccines in the pharmacy, plans will be exploring utilization of their network pharmacists as a provider of adult Medicare Part D vaccines.
- **In-Network Pharmacy Distribution:** A Part D plan's local pharmacy or specialty pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call in a prescription, or the beneficiary could deliver or mail a prescription for the vaccine to the pharmacy. The pharmacy would fill the prescription for the vaccine, ship or deliver to the physician's office, and bill the Part D plan for the vaccine. (This model resembles the competitive acquisition program (CAP) for Medicare Part B drugs in that the

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drug is shipped to the physician, but the physician never purchases or gets reimbursed for the drug.)

Out-of-Network Approaches: Facilitated Out-of-Network Access Approaches

- **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 (vendor). This approach would allow the beneficiary to pay out of pocket only the appropriate deductible and copay or cost sharing directly to the physician, thus avoiding any up-front payment and repayment for the full cost of the vaccine. The physician 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.
- **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, reimbursement rates, enrollee cost-sharing to be collected by the physician, and instructions on how to submit the out-of-network claim on the beneficiary's behalf.

It is important to emphasize for either out-of-network 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 encourages 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.

Frequently Asked Questions

- ***If I need to immunize a beneficiary with a Part D vaccine, what do I need to 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 Part D plan's out-of-network access or inquire as to the availability of any alternative vaccine access options. Plan contact information is available at the following website:

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<http://www.medicare.gov/MPDPF/Public/Include/DataSection/Questions/MPDPFIntro.asp> and then follow the directions on the section Learn More About Plans in Your Area. You may also obtain plan contact information by calling 1-800-MEDICARE.

▪ ***Do I need to provide Advanced Beneficiary Notice (ABN)?***

No. Unlike traditional Medicare, Part D does not require ABNs.

▪ ***Can I charge an administration fee?***

Yes. Administration fees for vaccines could be handled in the following manner:

- Before January 1, 2008: When a physician administers a Part D vaccine, the physician should use HCPCS code G0377 (linked to CPT code 90471) to bill the Part B local carrier for the administration fee of the vaccine.
- January 1, 2008 and after: Part D vaccines, including the associated administration costs could be billed on one claim to the beneficiary or to the Part D plan, as stated in the preceding examples.

▪ ***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 reimbursement under Part D. Beneficiaries and providers should contact the Part D plans for more information about costs and reimbursement for this and other preventive vaccines.

Additional Information

More information about Part D for physicians' is available on the CMS prescription drug webpage for physicians, which is at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp#TopOfPage.

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