

## **60.2 - Access to Vaccines**

**(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)**

Part D vaccines may be dispensed and administered in different settings (e.g., by pharmacists in pharmacies, by physicians in physician offices) depending on factors such as State laws regarding the administration of vaccines and product administration complexity. While access to Part D vaccines via a network pharmacy is likely the best method for improving enrollees' access to Part D vaccines, Part D sponsors must ensure that enrollees have adequate access to Part D vaccines in physician offices when those Part D vaccines are appropriately dispensed and administered in physician offices. Such access is considered OON access because sponsor networks are defined as pharmacy networks only.

CMS recognizes, however, that the process of upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan described for OON purchases in section 60.1 may be less feasible in the case of enrollees who require OON access to a vaccine in a physician's office. As new vaccines come on the market with indications for use in the Medicare population, network Part D vaccine access will become more critical. To address this issue, CMS offers a range of in-network and facilitated OON approaches, described in sections 60.2.1 and 60.2.2 below, for improving access to Part D vaccines appropriately administered and dispensed by a physician without requiring upfront beneficiary payment and subsequent reimbursement by Part D sponsors. Part D sponsors are not limited to these approaches and are encouraged to pursue the implementation of any cost-effective, real-time billing option at the time of vaccine administration. Additionally, Part D sponsors may consider adopting alternative approaches, depending upon the vaccine and its respective cost, storage requirements, and complexity of administration. Sponsors electing to implement one or more of the options discussed below must still meet their obligation to generally provide OON access when appropriate – including through upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan.

The administration of a Part D-covered vaccine is included in the definition of a “Part D drug,” effective January 1, 2008. Consequently, the Part D program covers vaccine administration costs associated with Part D vaccines. For more information, refer to section 10.14 of [chapter 6](#).

### **60.2.1 - In Network Vaccine Distribution Approaches**

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While CMS is in no way limiting Part D sponsors to any specific approach to ensuring access to Part D vaccines, CMS believes that an in-network, real time solution is the best method to improve vaccine access. In addition to the in-network options listed below, Part D sponsors could reduce the burden of copayment collection by establishing a benefit design with zero cost-sharing on vaccines.

#### **1. 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-eight States currently allow pharmacists to provide some type of vaccinations. Where it is safe to dispense these vaccines in the pharmacy, Part D sponsors 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, however.

#### **2. In Network Pharmacy Distribution**

A Part D sponsor’s network pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call or fax 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, deliver or ship to the physician’s office, and bill the Part D sponsor for the vaccine. This model resembles the competitive acquisition program being implemented by Medicare Part B in that the drug is shipped to the physician but the physician never purchases or is reimbursed for the drug.

### **60.2.2 - Facilitated OON Access Approaches**

**(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)**

While the following options are OON arrangements between physicians and Part D sponsors, CMS expects that these and similar options will reduce the need for up-front beneficiary payment by facilitating other forms of payment arrangements between physicians and Part D sponsors, increasing access beyond the current regulatory OON requirements and avoiding the incurring of significant OON costs by beneficiaries or CMS as part of the low-income subsidy.

#### **1. Model Vaccine Notice for Physicians (Paper Claim Enhancement)**

Under this option, Part D sponsors 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 billing instructions. If the Part D sponsor authorizes payment, the physician would then bill the Part D sponsor using the physician standard claim form or ASC X12 electronic format (which Part D sponsors must accept) and would receive payment directly from the Part D sponsor. Alternatively, physicians could access this information directly by calling the sponsor's prior authorization line.

## 2. Web-Assisted Electronic Physician Billing

Using a commercially-developed Web-based system based on the real-time NCPDP standard, physicians could electronically request OON reimbursement from Part D sponsors on behalf of beneficiaries for vaccines dispensed and administered in the physician's office. The physician would agree to accept Part D sponsor payment as payment in full as a condition of using the system.