

## **60.3 - Vaccine Administration**

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

### **60.3.1 - Vaccine Administration Cost-Sharing Considerations**

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Since the vaccine administration fee is a component of a vaccine's negotiated price, any cost-sharing applied to a vaccine should be applied relative to the negotiated price of the vaccine and its related component costs. If a sponsor structures its vaccine cost-sharing as coinsurance, including 100 percent cost-sharing in any applicable deductible or coverage gap, the coinsurance should be applied relative to the entire negotiated price (including the vaccine administration fee). Similarly, if a sponsor structures its vaccine cost-sharing as a copayment, the copayment should be applied relative to the entire negotiated price. In other words, a sponsor should not charge separate copayments for the vaccine ingredient cost and its related component costs, respectively (i.e., the vaccine administration fee and dispensing fee, if applicable), since CMS views the vaccine and its administration as intrinsically linked. Similarly, low income subsidy eligible individuals with copayments set by statute (see section 1860D-14(a)(1)(D) of the Social Security Act) will pay only one copayment for a vaccine and all related charges. Thus, for example, a low income subsidy eligible individual entitled to \$1.05/\$3.10 copayments 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.<sup>3</sup>

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<sup>3</sup> In cases involving defined standard coverage and out-of-network vaccine administration, cost-sharing for a vaccine is based on the usual and customary price for both the vaccine ingredient cost and vaccine administration fee. This is because, given the cost-sharing requirements for defined standard coverage – under which the cost-sharing between the deductible and initial coverage limit must always be 25 percent of the actual cost of a drug at the point of sale – Part D sponsors offering defined standard coverage may not charge enrollees any out-of-network differential. However, sponsors offering other benefit designs (e.g., actuarially equivalent standard coverage, basic alternative coverage, or enhanced alternative coverage), may require enrollees being administered a vaccine out-of-network (e.g., in a physician's office) to be responsible for any cost-sharing that would have otherwise applied had the drug been purchased at a network pharmacy, and also any differential between the provider's usual and customary

### **60.3.2 - Separate Billing of the Vaccine and Vaccine Administration** (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Although CMS prefers that all Part D vaccines be billed on one claim for both the vaccine and its administration, CMS recognizes there are circumstances that might require vaccine administration to be billed and reimbursed separately from the vaccine. For example, a Part D vaccine might have very specific storage conditions that would impede most physicians' offices from maintaining a ready inventory for their patients. It might be more efficient for the physician to have a pharmacy dispense and deliver the vaccine for administration. The pharmacy will submit the vaccine ingredient cost and dispensing fee to the Part D sponsor for reimbursement and the physician will bill the beneficiary for the administration. Part D sponsors should establish processes necessary to separately reimburse the pharmacy for the vaccine ingredient cost/dispensing fee and the beneficiary for physician's administration charge.

CMS has concerns about separate billing of Part D vaccines and vaccine administration fees because it provides an opportunity for both inappropriate and duplicate billing of administration fees. Separate billing is more challenging for Part D sponsors to process and track, and there is greater potential for programmatic fraud and abuse when the vaccine and its administration are not linked at time of reimbursement. Consequently, CMS strongly encourages Part D sponsors to link billing of a vaccine and its administration wherever possible. Where this is not possible, and separate billing occurs, CMS expects Part D sponsors to closely scrutinize the separate claims to ensure the beneficiary has received reimbursement for both elements and that the sponsor has neither over- nor underpaid for both the vaccine and the vaccine administration fee. CMS plans on monitoring Part D sponsors to ensure that when separate billing does occur, there is a reasonable correlation of prescription drug event (PDE) records for vaccines dispensed to PDE records for vaccine administration.

### **60.3.3 - Claims Processing Considerations** (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors will implement a process that helps ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) vaccine billing requirements. Under the Tax Relief and Healthcare Act of 2006 (TRHCA), a "covered Part D drug" is defined to include the vaccine and the administration of the vaccine. For purposes of billing for vaccines, Part D vaccine administration therefore is unique. As defined by statute, the "drug" incorporates both the vaccine and its administration. Consequently, billing of the Part D drug vaccine must be conducted using the NCPDP 5.1 standard for both the vaccine and its administration. When the administration is performed by the pharmacy or facilitated by the pharmacy through an established relationship with physician or immunizer, the administration will be included in one standardized field in the billing transaction as part of the vaccine prescription request to the Part D sponsor.<sup>4</sup> In other words, the pharmacy should submit the vaccine and its administration, if

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price for the vaccine and vaccine administration fee and the plan allowance for the vaccine and vaccine administration (see section 60.1).

<sup>4</sup> Relative to the establishment of relationships between pharmacies and immunizers, the parties must ensure that such arrangements do not violate the physician self-referral ("Stark")

they are involved with the administration, as a single claim and not as two separate claims. NCPDP has issued formal guidance regarding the standardized field to be used for vaccine administration in the billing transaction.

When administration is billed separately from the dispensing of the vaccine, Part D sponsors or their subcontracted PBM should review existing claims for the presence of a vaccine charge. Should no vaccine charge be present in their claims history, the Part D sponsor should work with the beneficiary to ensure the beneficiary did not forget to submit a paper receipt for the vaccine and that appropriate reimbursement has been paid. For example, a sponsor could generate a letter to an enrollee whenever it receives a claim for a vaccine but does not receive a claim for vaccine administration within a certain time period.

A new, unique vaccine administration field has been added to the PDE elements for Part D sponsor submission of vaccine administration. This specific vaccine administration field allows a one-to-one claim to PDE relationship. For instance, if a sponsor receives a single claim from a network pharmacy inclusive of the vaccine and its administration it will need to attribute the vaccine ingredient cost, dispensing fee (if applicable), and administration to the appropriate fields of the PDE for submission to CMS. If separate billing by a pharmacy for the dispensing of the vaccine and by a physician for its administration occurs, the sponsor will submit one PDE based on the pharmacy claim inclusive of the vaccine and dispensing fee and a separate PDE based on the out-of-network claim from the beneficiary inclusive of the vaccine administration costs attributable to physician's administration. For this second separate PDE, the vaccine ingredient National Drug Code (NDC) would still be identified, but the vaccine ingredient cost and dispensing fee would be set to zero dollars. The format will be published on [www.csscoperations.com](http://www.csscoperations.com).

#### **60.3.4 - Vaccine Administration Access**

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Part D sponsors will allow any provider so authorized by State law to administer a Part D vaccine. Where it is safe to dispense and administer vaccines in a pharmacy, sponsors could explore utilization of their network pharmacists as providers of adult Medicare Part D vaccines (pediatric vaccines should continue to be provided by physicians). Out-of-network vaccines administered in a physician's office or by other non-network providers may be covered under the out-of-network access rules detailed in section 60.2, where a Part D enrollee may self-pay for the vaccine cost and its administration and submit a paper claim for reimbursement to his or her Part D sponsor.