

10.14 - Vaccine Administration

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Since January 1, 2008, the Part D program *covers* vaccine administration costs associated with Part D vaccines. CMS interprets this 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), and a vaccine administration fee. This interpretation recognizes the intrinsic linkage that exists between the vaccine and 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 *outside of the plan's Part D pharmacy network*, the *provider* would *supply* the vaccine, *administer it*, and then bill the beneficiary for the entire charge, including all components. The beneficiary would, in turn, submit a paper claim to the Part D sponsor for reimbursement for both the vaccine ingredient cost and administration fee.

10.14.1 - Elements of Vaccine Administration

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Vaccine administration fees should be subject to negotiations between Part D sponsors and pharmacies. CMS expects that sponsors will take into consideration the elements reflected in existing Part B vaccine administration fees when establishing their own vaccine administration fees. For example, Part B considers the immunizing professional's time in physically delivering the vaccine to a beneficiary, the resources encompassing the supplies (syringe, gauze, band-aid, alcohol prep pad, etc.), the indirect costs of the office, and professional liability.

10.14.2 - Establishment of Multiple Vaccine Administration Fees (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors 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. CMS plans to retrospectively review vaccine administration fees to look for outliers and potentially discriminatory practices that would impact beneficiary access to Part D vaccines.

10.14.3 - Other Vaccine Administration Considerations (Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors may implement drug utilization management tools to determine if a vaccine is necessary; however, in the absence of any information showing previous immunization (i.e., claims data), the Part D sponsor should make payment available for a vaccine and its administration consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.