DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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TO: Medicare Advantage-Prescription Drug Organizations
Cost-Based Plans
Stand-Alone Prescription Drug Plans
Employer/Union-Sponsored Group Health Plans

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

RE: Vaccine Administration

DATE: May 14, 2007

As we stated in our 2008 Final Call Letter, we received a significant number of comments in response to our Draft 2008 Call Letter language related to the statutory shift of Part D vaccine administration reimbursement from Part B to Part D in 2008. Given the extensive nature of these comments, we indicated we were taking additional time to consider them and finalize our operational guidance on administration fees for Part D vaccines. This detailed operational guidance is contained in the following attachment. Sponsors should take time to thoroughly familiarize themselves with this guidance and ensure that appropriate costs are considered in their 2008 bids.

If you have any questions on the treatment of vaccine administration under Part D, please contact Greg Dill at Gregory.Dill@cms.hhs.gov or 312 -353-1754.

Vaccine Administration under Medicare Part D in 2008

1. Relationship of vaccine administration to the vaccine:

The Tax Relief and Health Care Act of 2006 (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. The Centers for Medicare & Medicaid Services (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), 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 out-of-network in a physician's office, the physician would provide the vaccine and its administration 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.

2. Cost-Sharing Considerations:

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 copay, the copay should be applied relative to the entire negotiated price. In other words, a sponsor should not charge separate copays for the vaccine ingredient cost and its related component costs, respectively (i.e., the vaccine administration fee and dispensing fee, if applicable) since we view the vaccine and its administration as intrinsically linked. Similarly, low income subsidy eligible individuals with copays set by statute (see section 1860D-14(a)(1)(D) of the Social Security Act) will 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.[1]

3. Separate billing of the vaccine and vaccine administration:

Although CMS would prefer that all Part D vaccines be billed on one claim for both the vaccine and its administration, we recognize 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, we strongly encourage Part D sponsors to link billing of a vaccine and its administration wherever possible. Where this is not possible, and separate billing occurs, we expect 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. We plan on monitoring Part D sponsors to ensure that when separate billing does occur, there is a reasonable correlation

[1] 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 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 price for the vaccine and vaccine administration fee and the plan allowance for the vaccine and vaccine administration (see section 60.1 of Chapter 5 of the *Prescription Drug Benefit Manual* for more information).

of prescription drug event (PDE) records for vaccines dispensed to PDE records for vaccine administration.

4. Elements of vaccine administration:

Vaccine administration fees should be subject to negotiations between Part D sponsors and pharmacies. We expect that sponsors will take into consideration the elements reflected in existing 2007 Part B vaccine administration fees when establishing their own vaccine administration fees for 2008. 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.

5. Establishment of multiple vaccine administration fees:

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.

6. Other Vaccine Administration Considerations

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 plan should make payment available for a vaccine and its administration in consideration with ACIP recommendations.

7. Claims processing considerations:

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, for vaccines administered on or after January 1, 2008, 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.[2] In other words, the pharmacy

[2] 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'') prohibition (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), or any other applicable Federal or State law or regulation.

should submit the vaccine and its administration, if they are involved with the administration, as a single claim and not as two separate claims. CMS will look to NCPDP to issue 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 will be added to the PDE in 2008 for Part D sponsor submission of vaccine administration. This specific vaccine administration field will allow 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 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 NDC would still be identified, but the vaccine ingredient cost and dispensing fee would be set to zero dollars. The format will be published shortly on www.csscoperations.com.

8. Vaccine Administration Access

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 our out-of-network access rules 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 plan.

We remind Part D sponsors of their continuing responsibility to implement measures to increase access to Part D vaccines. While an in-network solution provides the greatest advantages to the beneficiary and the Part D program given that the beneficiary is provided access to the D sponsor's negotiated rate and real-time information on his/her applicable cost-sharing, we understand that beneficiaries will continue look to their physician for information on vaccines. Reimbursement of vaccine administration by the

Part D program only heightens the need for Part D sponsors to continue to aggressively seek and to implement processes that increase access to novel vaccines that are available now or will become available in coming years.