

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR BENEFICIARY CHOICES

Date: December 1, 2006

Memorandum to: All Part D Sponsors

Subject: Part D Vaccines

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

Over the last few months we have had a number of inquiries on our Part D User Calls related to Part D Vaccines, increasing access to Part D Vaccines, and the possibility of any associated vaccine administration fees. To provide a better understanding and continue our outreach on Part D vaccines, we have included a series of Question and Answers that address these incoming inquiries.

We remind Part D Sponsors that they should be actively pursuing processes that increase vaccine access for their members in line with our May 8, 2006 Part D Vaccine Access Memorandum. Part D Sponsors should also already have call center scripts and communication materials that explain to members how they can obtain Part D vaccines at either network pharmacies or their physician's office.

For questions on these Questions and Answers please contact Greg Dill at (312) 353-1754.

Web-based Vaccine Access

Q:

Is it permissible for a third party administrator to assist beneficiaries with the submission of out of network claims for vaccines administered in a physician's office?

A:

As discussed in the preamble to the final rule (FR 70 @ 4328), vaccines administered in a physician's office may be covered under our out-of-network access rules at 423.124(a)(2). Out of network ("OON") access would be permitted because a beneficiary could not reasonably be expected to obtain that vaccine through an "in-network" solution, such as at a network pharmacy. Under these OON rules, a part D enrollee may self-pay the physician for the vaccine cost and submit a paper claim for reimbursement to his or her Part D plan. This approach is consistent with how beneficiaries accessing covered Part D drugs at an out of network pharmacy will be reimbursed by Part D plans for costs associated with those drugs.

While this current out-of-network policy from a physician's office presumes that the beneficiary will submit a paper claim to the Part D plan, it is permissible for a third party administrator to assist beneficiaries with the submission of out-of-network claims for vaccines administered in a physician's office. Indeed, we are encouraged that these types of arrangements may actually provide greater access to physician-administered vaccines for beneficiaries, while also reducing the administrative burden on beneficiaries, physicians and plans for out-of-network vaccine administration.

One such third party arrangement contemplates the use of an electronic portal for physician submission of electronic out of network claims for vaccines administered in the physician's office. Under this web based scenario, physicians would electronically submit claims to Part D plans on behalf of beneficiaries for vaccines dispensed and administered in the physician's office. Rather than paying for the full cost of the vaccine and then submitting a paper claim to the Part D plan for reimbursement of the out-of-network amount, the beneficiary would pay the physician directly for the appropriate deductible and cost sharing for the vaccine [and administration fee (if any)]. The physician would assume responsibility for submitting the claim and would agree to accept Part D plan payment as payment in full. The physician does not become a network provider through use of the web-assisted process, but is assisting the beneficiary in the submission of his or her out-of-network claim to the Part D Sponsor.

Utilization of this web-assisted concept has several benefits. First, it allows the beneficiary to pay out-of-pocket only the appropriate deductible, copay or cost sharing [and administration fee (if any)] directly to the physician, thus avoiding an up-front payment of the full cost of the vaccine and the necessity of submitting for reimbursement. Second, assuming that many physicians will participate in this arrangement, it should increase access to physician-administered vaccines. Third, electronic submission of these claims will reduce the administrative burden on plans in accepting paper claims and automate the process for updating

the beneficiaries' True Out-of-Pocket (TrOOP) balance for allowable out-of-network out-of-pocket costs.

While this web portal concept has several benefits, we want to reiterate that there would be no "network" affiliation of the third party administrator to the Plan. Plans that voluntarily accept any such arrangement with the third party administrator would remain responsible for full compliance with CMS policies on out-of-network claims submission. Further, any such arrangements would need to be in compliance with the Anti-Kickback Statute and other applicable laws and regulations. However, under this scenario, an electronic claim submitted by the physician and administered by the third party would be acceptable in lieu of the out-of-network paper claim submission from the beneficiary. Under no circumstances could PDPs pay any administration fee to the physician for the out-of-network vaccine. Medicare Advantage Plans may cover vaccine administration fees for Part D vaccines with Part C supplemental benefits in line with §422.102, but no Part D funds are available for the payment of vaccine administration services.

Vaccine Administration

Q: Can a provider administering a Part D vaccine charge the beneficiary a separate administration fee?

A: Yes.

As we have stated in our July 11, 2006 memorandum

[<http://www.cms.hhs.gov/PrescriptionDrugCovcontra/HPMSGH/list.asp#TopOfPage>] there is no reimbursement available under Parts B or D for the administration of a Part D vaccine.

However, since vaccine administration services are not part of the Medicare Prescription Drug Benefit, similar to other Medicare non-covered services, providers offering administration of Part D vaccines can charge the beneficiary an administration fee directly for providing this non-covered service. Before dispensing a covered Part D vaccine for which the Provider intends to charge an administration fee, the Provider needs to notify the beneficiary in advance that the administration of the vaccine is not offered as part of the Medicare Prescription Drug Benefit and therefore, the beneficiary is responsible for the fee or charge associated with administration. The Provider should inform the beneficiary of the exact amount of the administrative fee or charge. Also, the Provider should inform the beneficiary that any fee or charge for vaccine administration falls entirely outside the Part D cost sharing structure and will not be included as part of the beneficiaries' True Out-of-Pocket (TrOOP) costs. As with all good business practices, we would expect that this notice would be provided in writing so the beneficiary is given every opportunity to understand the costs associated with vaccine administration.

Q: Can a provider bill Medicaid for administration of a Part D vaccine to a dually eligible beneficiary?

A: Yes. If the State Medicaid Agency is providing reimbursement for vaccine administration for the nondually eligible beneficiary, it also would have to provide it on behalf of the dually eligible beneficiary. If physicians do not know how to facilitate billing vaccine administration fees for these beneficiaries or want to verify the State Medicaid Policy on vaccine administration

they should contact their respective State Medicaid Agency. State Medicaid Agency information is located at the following website: <http://www.cms.hhs.gov/MedicaidGenInfo/>.