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CENTER FOR BENEFICIARY CHOICES

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Memorandum To: All Part D Sponsors

Subject: Increasing Part D Vaccine Access

From: Abby L. Block, Director, Center for Beneficiary Choices

As you know, Part D plans are required to provide access to vaccines not covered under Part B. During rulemaking, CMS described use of standard out-of-network requirements to ensure adequate access to the small number of inexpensive vaccines coverable under Part D, when the vaccines must be administered in a physician's office. The beneficiary would pay the physician and then submit a paper claim to their Part D plan for reimbursement up to the plan's allowable charge, possibly leaving a differential amount for which the beneficiary is solely responsible for paying. However, as newer vaccines come on the market with indications for use in the Medicare population, Part D vaccine in-network access will become more imperative.

With this in mind, we have been considering options to improve access to vaccines under the Drug Benefit without requiring up-front beneficiary payment. At this point, in advance of bid submissions, it is important that we outline additional approaches that we urge plans to implement when appropriate to improve access to vaccines. Plans are also strongly encouraged to develop additional approaches that minimize out-of-network coverage that requires out-of-pocket payment and the need for the beneficiary to submit paperwork for reimbursement.

In the attachment to this letter, we describe a range of in-network and facilitated out-of-network approaches that avoid forcing the beneficiary to pay the full cost of the vaccine at the time of the visit. Again, plans 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, plans may consider adopting several approaches depending upon the vaccine and its respective cost, storage requirements, and complexity of administration.

We would like to remind plans and providers that administration and professional fees may not be included as part of the Part D dispensing fee. Additionally, vaccine administration fees under Part B are only permitted for the administration of a Medicare-covered "preventative" vaccine – influenza, pneumococcal, Hepatitis B – along with "medically necessary" vaccines to treat illness or injury. Therefore, Part D plans may not separately pay for the administration of Part D vaccines in a physician's office.

We appreciate your continuing assistance with the implementation of Part D and look forward to your innovation in increasing vaccine access for our beneficiaries.

Attachment A. **Options to Ensure Adequate Access Under Part D to Covered Vaccines**

These are only four potential approaches to improve Part D vaccine access, and are not meant to limit plans in implementing a real-time billing process for vaccine reimbursement. In addition, these options are not meant to override the plans' obligations to provide out-of-network access when necessary.

Approach A: In Network Distribution Approaches

While we are in no way limiting plans to any specific approach, we do believe that an in-network, real time solution is the best method to increase vaccine access. In addition to the in-network options listed below, plans could reduce the burden of copay collection by establishing a benefit design with zero cost-sharing on vaccines.

1. In Network Specialty Pharmacy Distribution:

A Part D plan's specialty pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call 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, ship to the physician's office and bill the Part D plan for the vaccine. This model resembles the competitive acquisition program (CAP) being implemented by Medicare Part B in that the drug is shipped to the physician but the physician never purchases or gets reimbursed for the drug.

As a reminder Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network or specialty pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy.

2. 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-four states currently allow pharmacists to provide some type of vaccinations. Where it was safe to dispense these vaccines in the pharmacy, plans 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).

Approach B. Out of Network Approaches: Facilitated Out-of-Network Access Approaches

Physicians cannot be network providers because they generally cannot meet the required contractual terms; rather, only pharmacies can meet them. While the following options are out-of-network arrangements between physicians and plans, we expect that these and similar options will reduce the need for up-front beneficiary payment by facilitating other forms of payment arrangements between physicians and plans, increasing access beyond the current regulatory out-of-network requirements,

and avoiding the incurrence of significant out-of-network costs by beneficiaries or CMS as part of the low-income subsidy.

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

Part D plans 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 plan authorizes payment, the physician would then bill the Part D plan using the physician standard claim form or ASC X12 electronic format (which Part D plans must accept) and would receive payment directly from the Part D plan.

Alternatively, physicians could access this information directly by calling the plans PA line.

2: Web-Assisted Electronic Physician Billing:

Using a commercially-developed web-based system based on the real-time NCPDP standard, physicians would electronically bill Part D plans for vaccines dispensed and administered in the physician's office. The physician would either enter into a contract with the Part D plan to be a non-pharmacy network provider, or alternatively, agree to accept Part D plan payment as payment in full payment as a condition of using the system.

In summary, we encourage plans to adopt any of these approaches as appropriate for the given vaccine and the beneficiary's circumstances. We also welcome additional exploration of other possible means to coordinate the billing of vaccines in the real-time environment of the Part D benefit with the current batch billing processes used by physicians.