DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES

DATE: December 15, 2021

TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez, Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Dispensing Fees and Enrollees with Institutionalized Level of Care Needs

The Centers for Medicare & Medicaid Services (CMS) has received questions from industry regarding allowable Part D dispensing fee costs for enrollees with institutional level of care needs. The purpose of this guidance is to clarify that under the definition of dispensing fees at 42 CFR 423.100, Part D dispensing fees can include additional costs for specialized services typically provided in the institutional care setting, such as delivery and special packaging, for enrollees residing in their homes with institutionalized level of care needs. This clarification of CMS's interpretation of the regulatory definition of dispensing fees does not establish any new requirement. We remind Part D sponsors that, consistent with section 1860D-11(i) of the Social Security Act, CMS is prohibited from interfering with the negotiation of dispensing fees. Therefore, such negotiation of Part D dispensing fees for enrollees residing in their homes with institutionalized level of care needs remains a matter solely between Part D sponsors and pharmacies, consistent with 42 CFR § 423.100 and Chapter 5, § 20.7, of the Prescription Drug Benefit Manual.

42 CFR §423.100 defines the Part D dispensing fee to mean "only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee." The definition further specifies that such pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with 42 CFR § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

CMS stated in the preamble of the final rule titled “Medicare Program; Medicare Prescription Drug Benefit; Final Rule,” published in the Federal Register on January 28, 2005 (70 FR 4193, 4235) and Chapter 5, § 20.7, of the Prescription Drug Benefit Manual that "reasonable" pharmacy costs are costs that are appropriate for *the typical beneficiary in that pharmacy setting*.

Our guidance states that while it would be appropriate for Part D plans to reimburse long-term care (LTC), mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies (where the term “delivery” would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale) because the typical retail customer does not require home delivery. While retail pharmacies may offer home delivery services, Part D plans do not reimburse those pharmacies for these costs, and the delivery cost is borne by the beneficiary.

Chapter 5 also provides two additional examples of what constitutes a distinct pharmacy setting for purposes of illustrating reasonable pharmacy costs for a typical beneficiary in such settings. The first example states that costs associated with shipping from retail pharmacies to beneficiaries in remote or frontier areas would be allowable dispensing fee costs because a typical beneficiary in remote and frontier areas with limited or no access to roads would require delivery of drugs via postal or freight shipping. The second example, most relevant to this discussion, states that costs associated with specialized services such as special packaging and delivery for “residents of non-LTC facilities (e.g., assisted living facilities (ALFs) and other forms of congregate residential settings) with the same level of care need as residents of LTC facilities” would be allowable dispensing fee costs because it is reasonable to assume that the typical enrollee residing in a non-LTC facility setting who meets the same level of care need as a beneficiary in an LTC facility would require the provision of dispensing related services such as unit-dose packaging and home delivery that are provided by LTC pharmacies to the residents of LTC facilities

While our existing guidance provides only ALFs and other congregate residential settings as examples where costs associated with specialized services, such as special packaging and delivery, are reasonable pharmacy costs for the typical enrollee that meets the same level of care need as an enrollee in a long-term care facility, the same logic holds for enrollees residing in their homes with the same level of care needs. Therefore, CMS clarifies that such additional costs are reasonable pharmacy costs for these enrollees residing in their homes. Part D sponsors continue to have the flexibility to establish their own policies for determining which enrollees residing in non-institutionalized settings, including their own homes, meet this threshold.

Questions concerning this memo may be directed to PartDPolicy@cms.hhs.gov.