DEPARTMENT OF HEALTH & HUMAN SERVICES
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To: All Part D Plan Sponsors

From: Amy Larrick Chavez-Valdez
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Subject: Medicare Part D Coverage of Multi-Ingredient Compounds

The purpose of this memorandum is to clarify current CMS policies with respect to Part D coverage of multi-ingredient compounds. The U.S. Department of Health & Human Services Office of the Inspector General (OIG) issued a Report: *Questionable Billing for Compounded Topical Drugs in Medicare Part D,* OEI-02-16-00440 on August 7, 2018 highlighting that Medicare Part D spending associated with topical compounds (such as creams and ointments) was 24 times higher in 2016 than in 2010. While multi-ingredient compounds account for a very small fraction of overall Part D spending, this level of growth has prompted questions of possible fraud, waste, and abuse. CMS will incorporate training on fraud schemes into ongoing training programs and is encouraging sponsors to continue efforts to ensure medical necessity of Part D compounds through the use of utilization management tools and when considering exception requests. CMS continues to receive questions that indicate additional guidance surrounding multi-ingredient compounds is needed to help inform appropriate coverage of these products, and is providing in this memo a summary of current policies.

Multi-ingredient compounds are products extemporaneously prepared by pharmacies to provide drug therapies that are not commercially available as FDA-approved finished products in the same dose, formulation, and/or combination of ingredients. Multi-ingredient compounds may be covered under Part D only if they contain at least one ingredient that independently meets the definition of a Part D drug (Part D drug ingredient) and do not contain any ingredients covered under Part B as prescribed and dispensed or administered as part of the compound. Multi-ingredient compounds meeting both criteria are referred to as Part D compounds. In addition, Part D coverage of Part D compounds is limited to only the ingredient costs associated with the Part D drug ingredients and any dispensing fees, which can include labor costs associated with mixing the compound. See 42 CFR §423.120(d)

On-Formulary vs. Off-Formulary

Like other Part D drugs, Part D compounds may or may not be included on a plan's formulary. However, Part D plan sponsors do not submit Part D compounds to CMS during formulary submission because there are no unique identifiers, such as the RxNORM concept unique identifier (RXCUI) codes used for other Part D drugs, for specific Part D compounds.

Nonetheless, Part D sponsors are still responsible for choosing which, if any, Part D compounds are included on their formularies. Part D sponsors may include all, some, or no Part D compounds on their plan formulary. For example, sponsors may choose to:

- Include **all Part D compounds** on their formulary, with or without utilization management requirements.
- Include **all parenteral nutrition and IV home infusion Part D compounds** on their formulary, but not topical Part D compounds (i.e. coverage for topical products by approved exception only).
- Include **selected parenteral nutrition, IV home infusion, and/or topical Part D compounds** on their formulary (i.e. coverage for non-formulary Part D compounds by approved exception only).
- **Not include any Part D compounds** on their formulary (i.e. coverage for any Part D compounds by approved exception only). However, in cases such as on-formulary intravenous medications requiring preparation prior to infusion, CMS generally would expect the compounded products to continue to be treated as formulary drugs.

Similar to other Part D drugs, if a beneficiary receives a prescription for a Part D compound that is not on their plan's formulary, they may request a formulary exception from the plan sponsor (as outlined in 42 CFR 423.578).

A Part D compound is distinct from its ingredients for purposes of on- or off-formulary placement. Part D compounds with multiple Part D drug ingredients are treated as a single claim and all Part D ingredients must be treated the same way for purposes of coverage. For example, a Part D sponsor can treat an entire compound as off formulary, even though it contains three Part D drug ingredients that are all on the sponsor's formulary. Alternatively, a Part D sponsor can treat an entire compound as on-formulary, even though it contains three Part D drug ingredients that are not on the sponsor's formulary. If a Part D sponsor decides to include a specific compound on its formulary, all the Part D drug ingredients must be considered on-formulary for purposes of covering the Part D compound. For example, if a Part D compound contains two Part D drug ingredients that are on-formulary and one Part D drug ingredient that is off-formulary, the sponsor cannot consider the Part D compound as on-formulary and require a formulary exception for the off-formulary ingredient. See 42 CFR 423.120(d)(1)(iii)

Utilization Management

Consistent with CMS utilization management (UM) policies for other Part D drugs, Part D sponsors may implement prior authorization and quantity limit requirements for coverage of on-formulary Part D compounds. Similar to on/off-formulary placement, Part D compounds are distinct from their ingredients for purposes of UM requirements. Therefore, Part D sponsors may establish UM requirements for a Part D compound that may or may not be the same as any of the UM requirements that are in place for the Part D drug ingredients of the compound when dispensed separately. Part D sponsors will need to evaluate the individual Part D drug ingredients included in the Part D compound to determine whether the Part D compound as a whole should be covered. Although sponsors cannot pay for non-Part D drug ingredients included in the Part D compound, we do not prohibit Part D sponsors from also taking into

consideration the non-Part D drug ingredients included in the compound when determining whether the Part D compound as a whole should be covered.

Medically-Accepted Indications

With the exception of Part D drugs used in anticancer chemotherapeutic regimens, §1860D-2(e)(4) of the Social Security Act generally defines a Part D "medically-accepted indication" (MAI) to mean an indication supported by the FDA-approved label or the Part D compendia. By definition, however, Part D compounds are not FDA approved. There are no FDA-approved labels and no off-label indications supported in the Part D compendia for any Part D compounds. Consequently, if a Part D sponsor requires a coverage determination to determine the MAI for a Part D compound, the sponsor needs to evaluate the MAI for the Part D drugs in the compound on an ingredient by ingredient basis. CMS does not expect sponsors to find support for the specific combination of Part D drug ingredients in the Part D compound, only that the Part D drug ingredients would be supported for the intended indication if they were being used alone for that indication. As with all MAI determinations, it is up to the Part D sponsor to evaluate the FDA label and Part D compendia citations for each Part D drug ingredient, including determining whether, or to what extent, to take into consideration the support, or lack thereof, for specific routes of administration provided in the label or compendia citations. As with any Part D drug that a sponsor believes has a high likelihood of a non-Part D covered use (i.e. non-MAI for any or all Part D drug ingredients), Part D sponsors may require a coverage determination during any applicable transition period to confirm the MAI. See section 30.4.8 of Chapter 6 of the Prescription Drug Benefit Manual.

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