

#### 4. Prescription Drug Offering

##### a. Covered Discount Card Drugs

Endorsed sponsors must offer their card enrollees discounts on covered discount card drugs. Section 1860D–31(a)(4)(A) of the Act states that the term “covered discount card drug” has the same meaning given the term “covered Part D drug” in section 1860D–2(e) of the Act. Section 1860D–2(e), in turn, is based on sections 1927(k)(2)(A)(i), (A)(ii), and (A)(iii) of the Act. This definition is incorporated into § 403.802 of our regulations under the definition of “covered discount card drug.” The definition applies only to the following types of prescription drugs:

- (1) FDA-approved drugs;
- (2) Drugs used or sold prior to the enactment of the Drug Amendments of 1962 (Pub. L. 87–781); and
- (3) Drugs described in section 107(c)(3) of the Drug Amendments of 1962 and any drug for which the Secretary has determined there is a compelling justification for its medical need.

If the Secretary has determined, in the context of the Medicaid program, that there is a compelling justification for the medical need of a drug, such drug will be incorporated into our definition of “covered discount card drug” for purposes of this program.

Section 1860D–2(e) of the Act also includes in the definition of “covered discount card drug” a biological product which (1) may only be dispensed upon prescription, (2) is licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) and (3) is produced at an establishment licensed under each section to produce that product. Vaccines licensed under section 351 of the Public Health Service Act also are “covered discount card drugs.” Finally, section 1860D–2(e) of the Act includes insulin in the definition of covered discount card drug.

Necessary medical supplies associated with the injection of insulin are also included in this definition. We interpret necessary medical supplies for this purpose to include syringes, needles, alcohol swabs, and gauze. We do not consider test strips or lancets to be supplies associated with injection since these supplies are more directly related to testing.

The definition of covered discount card drug includes drugs when they are used for a medically accepted indication. The term “medically accepted indication” is defined in section 1927(k)(6) of the Act and generally means any use of a covered drug which is approved under the Federal Food, Drug, and Cosmetic Act,

or the use of which is supported by one or more citations included or approved for inclusion in any of the following compendia: American Hospital Formulary Service Drug Information; United States Pharmacopoeia-Drug Information; the DRUGDEX Information System; and American Medical Association Drug Evaluations. While we do not expect endorsed sponsors to collect diagnosis information to confirm diagnoses associated with every dispensed drug, endorsed sponsors should make an effort to responsibly comply with this provision.

Section 1860D–2(e)(2)(A) of the Act categorically excludes from the definition of “covered discount card drug” the following drugs or classes of drugs, or their medical uses, and we have no authority to alter this Congressional exclusion:

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Outpatient drugs for which the manufacturer seeks to require associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale.
- Barbiturates.
- Benzodiazepines.

Additionally, as provided in section 1860D–2(e)(2)(B) of the Act, a drug prescribed for a card enrollee that would otherwise be a covered discount card drug will not be considered a covered discount card drug if payment for that drug, as prescribed and dispensed or administered to the card enrollee, is available under Part A or Part B of Medicare (or would be available except for application of a deductible). That is, for prescribed drugs that may be payable under Medicare Part A or Part B, Medicare participating pharmacies should bill Medicare for the drug, and not the card enrollee or, in the case of transitional assistance enrollees, the endorsed sponsor, and non-Medicare participating pharmacies should refer the beneficiary to a Medicare participating pharmacy. When a pharmacy submits a claim under Medicare Part B, the rules applicable to pharmacies’ claims adjudication under Part B will apply. Only after denial of

a claim submitted under Part B may a pharmacy adjudicate a claim under the Medicare drug discount card program.

Furthermore, endorsed discount card sponsors should not reconcile any claims under the Medicare drug discount card program previously rejected under Medicare Part A or Part B when the covered discount card drug was purchased by a non-pharmacy provider to provide to the card enrollee. For example, if a physician provides a drug to a card enrollee incident to an office visit that is not covered by Medicare Part B, then endorsed sponsors may not apply transitional assistance toward the cost of such drug.

##### b. Formulary and Minimum Prescription Drug Offerings

Studies performed for the Department of Health and Human Services (BoozAllenHamilton, *Pharmaceutical Industry Scan*, August 6, 2002) have shown that one of the primary methods pharmacy benefit management companies and insurers negotiate drug discounts is through the establishment of a formulary. Through formularies that are properly structured, pharmacy benefit management companies, in consultation with a panel of physicians, pharmacists, and other health care professionals, establish clinically appropriate, safe, and cost-effective lists of covered prescription drugs. While clinical appropriateness must be foremost in the development of a formulary, a properly designed formulary can also promote lower costs for beneficiaries as pharmaceutical manufacturers compete, using, among other things, rebates, volume discounts, and generic drugs to supply the drugs that meet the formulary requirements at the lowest price. Therefore, in § 403.806(d)(1) of our regulations, we allow endorsed sponsors to establish formularies, whereby endorsed sponsors limit the set of drugs for which a discount is offered. However, even if an endorsed sponsor uses a formulary, it must permit transitional assistance enrollees to apply transitional assistance toward the cost of any covered discount card drug, including those not on the endorsed sponsor’s formulary, offered by a pharmacy contracted by the sponsor for the endorsed discount card program’s network. Our past research demonstrates that allowing sponsors to use a formulary will result in deeper discounts for card enrollees, and enhanced use of generic drugs, and we therefore have the authority to permit such formularies under section 1860D–31(h)(8) of the Act, as larger discounts and reduced prescription drug costs promote the interests of card enrollees.