

While we recognize the useful role of formularies in providing discounts to beneficiaries, we also want to insure that sponsors, in constructing their formularies, include, at a minimum, the types of drugs commonly needed by beneficiaries. In establishing a minimum requirement, it is not our intention to build the operating framework of a sponsor's formulary, but rather to present a floor, as we believe a minimum requirement is better than none at all. As provided in § 403.806(d)(2) of our regulations and consistent with promoting and protecting beneficiaries as specified in section 1860D–31(h)(8) of the Act, each endorsed discount card program will be required to provide a negotiated price for at least one drug in each of the lowest level categories under each of the therapeutic groupings (hereafter, collectively referred to as “categories”) representing the drugs commonly needed by Medicare beneficiaries as listed in Table 2. This minimum requirement in no way precludes sponsors from adding additional categories or differentiating the categories we provide as they construct their formularies. In fact, we anticipate that sponsors would do that through their usual process involving a pharmacy and therapeutics committee. The categories in Table 2 were structured to ensure that beneficiaries enrolling in Medicare-endorsed discount card programs will be offered discounts on many of the types of drugs most commonly needed by the Medicare population. There are a total of 209 categories (represented in italics within the table) for which card sponsors are required to offer a drug at a negotiated price. As some drugs can be classified into more than one category, a drug can be used only once to satisfy the criterion of providing a negotiated price for a drug in a category.

Moreover, under the rationale that discounts on commonly used generic drugs are also typically made available under current industry practice, and that offering discounts on generics improves beneficiary understanding of sources of prescription drug discounts, we are requiring that endorsed sponsors provide discounts on a range of generic drugs. Specifically, sponsors must provide at least one generic drug for a negotiated price in at least 55 percent of the required categories (italicized in Table 2). Fifty-five percent represents about 95 percent of those categories that include a Class A generic drug according to the FDA's Orange Book.

We believe it is important that the Medicare name be associated only with endorsed programs that offer at least the

types of drugs commonly needed by Medicare beneficiaries, while still maintaining the ability to negotiate discounts. Thus, we believe that requiring at least one drug per category, including generic drugs, strikes the proper balance between achieving drug discounts for card enrollees and offering some assurance that discounts will be available for the drugs Medicare enrollees most commonly need.

It is important to note that endorsed sponsors have the flexibility to provide negotiated prices on as many drugs as they choose beyond the minimum number and types needed to satisfy this endorsement qualification criterion, and we expect that many endorsed sponsors will choose to do so in order to make their discount cards attractive to beneficiaries.

We employed a contractor to provide technical assistance to develop the list of categories in Table 2.¹ The following set of principles served to guide a comprehensive approach to develop the list of categories:

- The category list is based on covered discount card drugs, as defined in section 1860D–2(e) of the Act, and also represents the types of drugs commonly needed by Medicare beneficiaries, as determined through analyses of survey data from the 2000 Medicare Current Beneficiary Survey, 2002–2003 Scott Levin-Verispan pharmacy data, and Food and Drug Administration information.

- One category list will set minimum requirements for discount card offerings, regardless of whether an enrollee has access to transitional assistance funds. Importantly, provided that the drug is offered at the pharmacy, enrollees with transitional assistance can use these funds to purchase covered discount card drugs for which no discount is provided.

- A given category could not contain only a single drug.

- The list is intended to wrap around rather than represent existing Medicare Part B outpatient drug coverage.² As such, drugs, biologicals, and vaccines administered in physician offices, hospital outpatient departments, dialysis centers, or provided outside of retail pharmacies were not reviewed unless they also can generally be

obtained through retail pharmacies and appeared in data sources used to identify drugs commonly used by Medicare beneficiaries.

- In compliance with section 1860D–2(e) of the Act, non-covered discount card drugs were excluded from review.

To develop the listing of therapeutic categories of drugs most commonly needed by Medicare beneficiaries, we first analyzed drug utilization and expenditure data from the 2000 Medicare Current Beneficiary Survey (MCBS), a CMS-sponsored continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries, to produce lists of the top 200 drugs used based on number of prescriptions and the top 200 drugs used based on expenditures. Separate lists were compiled for elderly enrollees and disabled enrollees to ensure that important drugs for both populations were captured.

We supplemented the list of commonly used drugs derived from the Medicare Current Beneficiary Survey by analyzing commercial datasets (Scott-Levin/Verispan Source Prescription Audit (SPA) and Physician Drug & Diagnosis Audit (PDDA)) for other commonly used drugs in the elderly populations. These data provide a comprehensive overview of the national performance of all prescription drugs dispensed by retail pharmacies for the 12-month period ending in May 2003. Utilization share percentages for people age 65 and over were applied to the data. Out of this data set, we obtained the top 200 drugs used based on number of prescriptions and the top 200 drugs used based on expenditures for the age 65 and over group. Prescription data is electronically collected on a monthly basis from approximately 35,000 U.S. retail pharmacies, including chains, independents, mass merchandisers, and food stores. It is estimated that SPA data cover approximately 70 percent of all dispensed prescriptions in the U.S. The Scott-Levin PDDA database includes data from approximately 365,000 office-based physicians in 29 specialties. Finally, to ensure that our list of commonly used drugs included new drugs and excluded retired and over-the-counter drugs (where over-the-counter drug is defined in our regulations at § 403.802 to mean non-prescription drug), we consulted current Food and Drug Administration (FDA) materials, including the FDA's “Additions/Deletions for Prescription and OTC Drug Product Lists” for June 2002 through July 2003.

After the list of drugs commonly needed by Medicare beneficiaries was

¹ Contract 500–02–0024 Modification #3, AMS, subcontracted to Navigant Consulting and Independent Pharmaceutical Consultants, Inc. *Identification of Baseline Therapeutic Categories for the Medicare Drug Discount Card Program*. December 5, 2003.

² Medicare coverage of outpatient drugs under Part B is principally for certain drugs and biologicals used in dialysis, cancer treatment, organ transplantation, certain vaccines and drugs used with DME such as infusion pumps and nebulizers.