Essential Health Benefits (EHB) Rx Crosswalk Methodology

Pursuant to 45 CFR 156.122, to offer EHB, health plans must cover at least the greater of: (1) one drug in every United States Pharmacopeia (USP) therapeutic category and class; or (2) the same number of drugs in each USP category and class as the state's EHB-benchmark plan. We clarified in the *Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule* ("*EHB Rule*") that, for purposes of satisfying this requirement, drugs must be chemically distinct to be counted as more than one drug.

Issuers will need to know the extent of drug coverage in the state's EHB-benchmark plan in order to comply with this requirement. This document summarizes the process CMS uses and will continue to use to classify and categorize drug products covered by state EHB-benchmark plans. The process produces a count of distinct drug entities by state. CMS collected a list of trade-standard 11-digit National Drug Codes (NDCs) to identify the individual drug products covered by the EHB-benchmark plan's drug list. The NDCs identify the drug product, its package size and type, and its manufacturer, distributor, reseller, or labeler. While NDCs are an industry-standard identification code, they do not provide the information needed to count, group and classify chemically distinct drugs for the purposes of EHB.

CMS converts NDCs to general drug identification numbers by matching the NDCs with the National Library of Medicine's RxNorm database (http://www.nlm.nih.gov/research/umls/rxnorm/). That matching produces lists of drugs identified by "RxNorm Concept Unique Identifiers," or RxCUIs. RxCUIs group chemically identical drugs into a single code number regardless of manufacturer or packaging size and type. CMS used the December 3, 2012 release of RxNorm as the source for newly approved drug RxCUIs and their associated NDCs.

After producing the list of RxCUIs, CMS groups therapeutically similar RxCUIs into one or more unique therapeutic categories and classes (such as "antiviral, anti-hepatitis agents"). These therapeutic categories and classes come from version 5 of the Medicare Model Guidelines developed by the United States Pharmacopeial Convention. To create a crosswalk of RxCUIs to categories and classes, CMS updated and expanded the USP Model Guidelines – CMS Formulary Reference File (FRF) Alignment file ("Alignment file").[1]

Next, CMS groups RxCUIs for identical active-ingredient chemical entities with different dosage strengths (*e.g.*, ibuprofen tablets 400 mg vs. ibuprofen tablets 800 mg) or routes of administration (*e.g.*, topical ointment vs. transdermal patch) into a higher-level grouping of chemically-distinct covered drugs. To create a crosswalk of RxCUIs to categories and classes, CMS used the USP Model Guidelines – CMS Formulary Reference File (FRF) Alignment file. The final product is titled the EHB Rx Crosswalk.

[1] See http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2011-03-11frf-uspmgintegratedfile.xls.

To ensure that unapproved or discontinued drugs were not included on the EHB Rx Crosswalk, CMS removed all RxCUIs that were not in RxNorm's Current Prescribable Content or not listed as currently marketed and approved prescription drugs in the FDA's Approved Drug Products database. [2] CMS also used the RxNorm database to identify over-the-counter (OTC) drugs, which were removed from the EHB Rx Crosswalk after pharmacists verified their OTC status.

The final EHB Rx Crosswalk contains 5,306 RxCUIs, representing 916 chemically distinct drugs, 50 categories, and 143 classes.

[2] See http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.