Essential Health Benefits (EHB) Rx Crosswalk Methodology for Plan Year 2016

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 Pharmacopeial (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 used 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 collects 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 converted 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 a list of drugs identified by RxNorm Concept Unique Identifiers (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 to map NDCs to their associated RxCUIs.

After producing the list of RxCUIs, CMS grouped therapeutically similar RxCUIs into one or more unique therapeutic categories and classes (such as "Antivirals, 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 the original EHB Rx Crosswalk, CMS updated and expanded the USP Model Guidelines – CMS Formulary Reference File (FRF) Alignment file ("Alignment file").[1]

Next, CMS grouped RxCUIs for identical active ingredient chemical entities with different dosage strengths (*e.g.*, metformin tablets 500 mg vs. metformin tablets 850 mg) or routes of administration (*e.g.*, topical ointment vs. transdermal patch) into a higher-level grouping of chemically distinct covered drugs.

To ensure that unapproved or discontinued drugs are not included on the EHB Rx Crosswalk, CMS removes all RxCUIs that are 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 uses the RxNorm database to identify over-the-counter (OTC) drugs that did not have an associated prescription drug NDC, which are removed from the EHB Rx Crosswalk after pharmacists' verification.

CMS performed the most recent update to the EHB Rx Crosswalk by using the November 3rd, 2014 version of the RxNorm database and repeating the conversion, categorization, and removal processes described above where differences were found. This allowed CMS to map retired RxCUIs to their reassigned RxCUIs; add drugs that have been newly approved; add new strengths, brand names, or generic forms of RXCUIs; and delete any discontinued drugs.

The updated 2016 EHB Rx Crosswalk contains 5,663 RxCUIs, representing 1,015 chemically distinct drugs, 50 categories, and 143 classes.

1. See http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40

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