DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: All Part D Plan Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

RE: Release of the CY 2010 Formulary Reference File

DATE: March 26, 2009

The purpose of this memo is to announce the release of the CY 2010 Formulary Reference File (FRF). The CY 2010 FRF is currently available in the CY 2009 HPMS Formulary Submission Module and will be available in the CY 2010 module upon its release. Part D sponsors must utilize the National Library of Medicine (NLM) RxNorm Concept Unique Identifiers (RXCUIs) contained on the FRF for purposes of CY 2010 Part D formulary submissions, which must be made through the Health Plan Management System (HPMS). The following questions and answers describe the use of RxNorm RXCUIs and the CY 2010 FRF in more detail.

Q1. What is the Formulary Reference File (FRF)?

A1. The FRF is a listing of drugs that Part D plan sponsors must utilize in the submission of Part D formularies. Each row of the file represents a single drug identified by an RXCUI code and related fields outlined in question 3 below. The RXCUI used on the FRF serves as a unique identifier which can represent multiple NDCs for similar drug products with the same active ingredient, strength and dose form (e.g. multiple package sizes and/or manufacturers can be represented by a single RXCUI).

Q2. Does the inclusion or exclusion of a particular product indicate whether CMS considers that product to be a Part D drug?

A2. No. Placement on the FRF should not be perceived as a CMS coverage determination. RXCUI codes are generally included on the FRF if, based on information available at that time, the represented drug product may satisfy the definition of a Part D drug. However, Part D sponsors are ultimately responsible for making coverage determinations and should not necessarily include or exclude a drug product from coverage based solely on the presence or absence of an RXCUI on the FRF. Sponsors should only include CY 2010 RXCUI codes on their HPMS formulary files if they consider them to represent Part D drugs. For any questions regarding drug product approvals, CMS encourages Part D sponsors to contact the FDA.

Q3. What is the CY 2010 FRF format and what do the fields represent?

A3. The CY 2010 FRF is comprised of the following fields:

- **RXCUI** – The RXCUI on the FRF represents a unique proxy identifier for each drug record on the FRF. Only RXCUIs contained on the CY 2010 FRF will be valid codes for CY 2010 formulary submissions. For the purposes of the FRF, each RXCUI represents a unique branded name product (where applicable), clinical name, strength, and dose form of a drug product.
- **Term Type (TTY)** – This field contains the TTY for the RXCUI. The possible values for the FRF include SBD (Semantic Branded Drug), SCD (Semantic Clinical Drug), BPCK (Branded Pack), GPCK (Generic Pack), and SY (Synonym).
- **RxNorm Description** – This field provides a description of the drug represented by the SBD, SCD, BPCK or GPCK for a given RXCUI which includes the ingredient, strength, dosage form and where applicable the brand drug name.
- **Related Brand Name (BN)** – This field contains the brand name that is related to a given RXCUI. This field will be null for products that do not have a branded name.
- **Related Semantic Clinical Drug Component (SCDC)** – The field contains the active ingredient(s) and strength(s) for each RXCUI.
- **Related Dose Form (DF)** – This field contains the dose form for each RXCUI.
- **Related NDC** – Each FRF RXCUI is associated to one 11-digit NDC. Medicare Prescription Drug Plan Finder (MPDPF) price file submissions will be based on this NDC. Inactive or obsolete NDCs will be replaced on a regular basis. This process will be outlined in more detail in the 2010 Plan Year Pricing Data Requirements that will be released at a later date.

Q4. What are the differences between the FRF for CY 2009 and CY 2010?

A4. The main difference between the CY 2009 and CY 2010 files is the use of the RXCUI code on the CY 2010 FRF as the unique drug identifier. The CY 2010 FRF will include a related NDC for each RXCUI; however, this NDC will only be used for purposes of pricing file submissions and specialty tier placement determinations. Unlike the FRF proxy NDCs used in previous contract years, the CY 2010 related NDC can be updated during the contract year to address a change in status to inactive or obsolete under circumstances where an alternative active NDC for a given RXCUI exists.

The CY 2010 FRF is based on the CY 2009 FRF. CY 2009 FRF proxy codes were mapped to RXCUI codes in the RxNorm data along with the associated TTY, Primary Description, Related Brand Name, Related Semantic Clinical Drug Name and Related Dose Form. As in previous years, products for which no active NDCs were available or that were otherwise considered obsolete were removed from the file. In some instances, multiple CY 2009 NDCs were linked to a single RXCUI code. When duplications were identified, one representative NDC was selected as the related NDC for the RXCUI code.

Q5. What does the RXCUI 3686 (OTC-Product) represent?

A5. This RXCUI is a proxy CUI that must be used to represent Over-the-Counter (OTC) products that are used as prerequisite (step 1) drugs in applicable step therapy groups. If the PBP(s) to which a formulary will be associated will indicate payment of OTCs as part of utilization management, and these OTCs are part of your documented step therapy program, you must include this CUI on your formulary file. The CUI must be entered as a step 1 drug for each applicable step therapy group. The specific OTC products that are represented by this CUI

must be included in the step therapy criteria text file for each applicable group description. In addition, these OTC products must also be included in your OTC supplemental file submission.

Q6. How are products such as Part D covered diabetic supplies, prenatal products, and fluoride preparations represented on the CY 2010 FRF?

A6. Similar to the CY 2009 FRF, diabetic supplies, prenatal products, and fluoride preparations will each be represented by a single RXCUI code (e.g. one RXCUI code represents all alcohol swabs).

Q7. Will there be a crosswalk available between the current CY 2009 and CY 2010 FRF?

A7. The current CY 2009 FRF already includes RXCUI codes for each FRF proxy code. CMS will also provide a crosswalk between CY 2009 Proxy NDCs and CY 2010 CUI codes. The crosswalk between CY 2009 proxy NDCs and CY 2010 RXCUIs may be one to one, one to many, or many to one depending on their relationship.

Q8. What if a drug cannot be found on the Formulary Reference File?

A8. In the event that a drug eligible for Part D coverage does not appear on the FRF and is available on the market, a sponsor may request that the drug be considered for inclusion in the FRF by submitting an email to the Part D formularies mailbox (PartDformularies@cms.hhs.gov). The subject line of the email should read "Request for CY 2010 FRF Addition" and the attached CY 2010 FRF Addition Request template must be included with the email. The following template fields must be completed in order to be considered for review by CMS: Sample NDC, Brand Name, Generic Name, Dosage Form, Route, Strength, and FDA approved application number (i.e. ANDA, NDA, BLA number). An RXCUI code for the requested drug must also be included unless one is not available in the most current version of the RxNorm downloadable data. CMS will only consider FRF addition requests that are submitted by Part D sponsors, that are consistent with the instructions outlined above, and that include completed templates.

Q9. How often will the CY 2010 Formulary Reference File be updated during the contract year?

A9. As in previous contract years, the FRF will be updated prior to each formulary submission window. The FRF updates will continue to include a change report that will illustrate the differences between the previous month's FRF and the newest FRF version. Examples of monthly changes will include the addition of RXCUIs to account for newly available products and the deletion of RXCUIs that represent drugs no longer available on the market. In the event that a CY 2010 FRF RXCUI becomes obsolete in RxNorm files, the RXCUIs and/or descriptions should remain unchanged on the FRF throughout the 2010 contract year.

Q10. Who should Part D sponsors contact with questions regarding RxNorm data?

A10. More information on RxNorm can be found via the following link:
http://www.nlm.nih.gov/research/umls/rxnorm/index.html
For additional questions, emails can be sent to: rxnorminfo@nlm.nih.gov.