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CENTER FOR MEDICARE

TO: All Part D Sponsors

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SUBJECT: Formulary Reference File Frequently Asked Questions

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The following frequently asked questions pertain to CMS' Formulary Reference File (FRF). The FRF serves as a listing of drug products that can be included on Part D sponsors' Health Plan Management System (HPMS) formulary files that are submitted to CMS for review and approval. The information below is provided for Part D sponsors and other stakeholders in an effort to provide more information and transparency regarding the purpose, content, and methods utilized to produce the FRF.

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 to the Centers for Medicare & Medicaid Services (CMS) for review. Each row of the file represents a single drug as identified by an RxNorm concept unique identifier (RXCUI) and related fields outlined in question two below. RxNorm is a normalized drug naming system that is produced by The National Library of Medicine (NLM). RXCUIs are used on the FRF to serve as a unique identifier which can represent multiple National Drug Codes (NDCs) for similar drug products with the same brand name, active ingredient, strength and dose form (e.g., multiple package sizes and/or manufacturers can be represented by a single RXCUI).

Q2. What is the FRF format and what do the fields represent?

A2. The 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 FRF will be valid codes for 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[1]), SCD (Semantic Clinical Drug[2]), BPCK (Branded Pack), GPCK (Generic Pack), and SY (Synonym).

[1] This represents the ingredient, strength, and dose form, plus brand name.
[2] This represents the ingredient, strength, and dose form.

- **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 with one 11-digit NDC on the FRF. Medicare Plan Finder (MPF) price file submissions will be based on this NDC. Inactive or obsolete NDCs will be replaced on a regular basis.

Q3. Does the inclusion or exclusion of a particular product indicate whether CMS considers that product to be a Part D drug?

A3. No. Placement on the FRF should not be perceived as a CMS coverage determination. RXCUIs are generally included on the FRF if, based on information available at that time, at least one NDC associated to that RXCUI 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 RXCUIs on their Health Plan Management System (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 Food and Drug Administration (FDA).

Q4. What are the sources CMS uses to compile their list of drugs for review and potential addition to the FRF?

A4. CMS uses a number of sources to create an expansive database of drugs for review. Drug information is obtained from the following:

- FDA Data: Comprehensive NDC Structured Product Labeling (SPL) Data Elements File (NSDE), Orange Book, and NDC Directory.
- NLM RxNorm downloadable data (full data set is released on the first Monday of each month. During months when the first Monday is a Federal holiday, RxNorm is released on the following Tuesday).
- HPMS Medicare Coverage Gap Discount Program Participating Labeler Codes.
- NDC Databases.

Once the information from the various sources is obtained and compiled, products can then be evaluated for potential inclusion on the FRF.

Q5. What specific factors are reviewed to determine whether an RXCUI is included on the FRF?

A5. A Part D drug is defined in Title XVIII of the Social Security Act (the Act) and in the regulations (42 CFR 423.100). Only drugs that could potentially meet this definition are considered for inclusion on the FRF. While RXCUIs and other information from RxNorm is the source of the information contained on

the FRF, CMS must determine that an NDC is available and is associated to an RXCUI before the RXCUI can be included on the FRF. All of the following must be true for a product to be considered eligible for the FRF:

- The product is available only by prescription (exception for medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B as discussed in Chapter 6).
- There is an active NDC for the given product.
- An NDC must be associated to an RXCUI within RxNorm.
- NDCs for applicable drugs (e.g., those approved under New Drug Applications or licensed under Biologics License Applications) must be covered by a signed labeler agreement.
- There is an NDC listed on the NSDE file.
- The NDC does not have an End Marketing Date (EMD) beyond the current calendar year.
- There is pricing information available for an NDC.

Q6. Why does CMS produce and maintain separate FRFs for the current contract year and the upcoming contract year?

A6. Separate files are necessary due to the following:

1. RxNorm Changes. If there are updates to the RxNorm nomenclature, a new RXCUI is typically produced. However, since the RXCUI is the primary submission code for HPMS formulary files, updates to RXCUIs would require all Part D sponsors with the affected RXCUI(s) on their files to submit updates when changes occur. To reduce the operational burden associated with these updates, we maintain the original RXCUI on the FRF for the duration of the current contract year and update any applicable RXCUIs with the release of the following contract year's FRF.
2. Differences in Coverage Gap Discount Program Participating Labeler Codes. Depending on the effective date of manufacturers' agreements, the same product may only meet the definition of a Part D drug during one of the contract years and not the other.

Q7. When is the FRF updated during the contract year and how is it accessed?

A7. As above, CMS maintains a separate FRF for the current contract year and the upcoming contract year. The update cycles differ between the two files:

<u>Current Contract Year</u>

The FRF is typically updated on a monthly basis from January to September. The FRF is posted in the HPMS formulary submission module five business days before the monthly formulary submission windows (which occur the first three business days of the month). The updated FRF is then posted on the CMS website following the monthly submission window and can be downloaded here:

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html.

An FRF change report (CR) is also issued that highlights the most recent additions and deletions from the FRF.

Upcoming Contract Year

The initial version of the FRF is released in March, along with the Year-to-Year FRF Crosswalk file. We then issue an update to the FRF just prior to the initial HPMS formulary submission window for the upcoming contract year. A final FRF update is produced prior to a final limited summer update window for the upcoming contract year. This is the final update to the FRF until the start of the contract year.

Q8. Why are RXCUIs deleted from the FRF?

A8. An RXCUI can be removed from the FRF for a number of reasons. We routinely monitor for product-related changes that may affect our ability to maintain an RXCUI on the FRF. The following are scenarios which could lead to the deletion of an RXCUI from the FRF:

- Voluntary manufacturer product discontinuation.
- FDA-mandated product discontinuation.
- An EMD that has either passed or will occur before the next month's FRF release and there are no other available NDCs to replace the current related NDC.

Q9. What does the RXCUI 3686 (OTC-Product) represent?

A9. This RXCUI is a proxy CUI that must be used to represent Over-the-Counter (OTC) products that are 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.

Q10. How are products such as Part D covered diabetic supplies, prenatal vitamins, and fluoride preparations represented on the FRF?

A10. Diabetic supplies, prenatal vitamins, and fluoride preparations are each represented by a single proxy RXCUI (e.g., one RXCUI represents all alcohol swabs).

Q11. What process can Part D sponsors follow if they determine a covered Part D drug is not represented on the FRF?

A11. A Part D sponsor may request that a 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 20XX FRF Addition" and the FRF Addition Request template attached to this memo must be included with the email. The following template fields must be completed in order to be considered for review by CMS: RXCUI (if available), Sample NDC, Brand Name, Generic Name, Dosage Form, Route, Strength, and FDA approved application number (i.e., ANDA, NDA, BLA

number). 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.

Q12. When are FRF updates reflected on the MPF?

A12. The attached calendar illustrates the process and timelines from the time a drug is added to the FRF and when it appears in the MPF. This replicates the typical month during the plan year. However, depending on the formulary submission and approval schedule, as well as the regular MPF pricing files submission schedule, these timelines may vary. Further, since the final FRF for the upcoming contract year is issued around June, and Part D sponsors cannot update their HPMS formulary files until the first three business days of February, drugs that come to market between June and January will not display in MPF until mid-March. Typically an updated FRF is released 5 business days prior to a formulary submission window. Once CMS has released formulary approvals, sponsors submit updated pricing files based on their approved formulary during the next regular MPF submission window. MPF submission windows are scheduled every 2 weeks. We estimate FRF updates may be reflected on MPF after approximately 6-8 weeks.

Q13. Can Part D sponsors cover drugs that are not on the FRF?

A13. Yes. In the event that a sponsor has determined a drug product meets the definition of a Part D drug, the sponsor can cover the drug at point-of-sale and market the addition. However, we expect the sponsor to 1) submit an FRF add request for the missing drug, and 2) add the drug to their HPMS formulary file(s) during the next available submission window.

Q14. Who should Part D sponsors contact with questions regarding RxNorm data?

A14. 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.