DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

TO: Financial Alignment Demonstration Applicants

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SUBJECT: Follow up on CY 2013 Part D Supplemental Formulary File and Additional Demonstration Drug File Submission Requirements for Financial Alignment Demonstration Plan Applicants

DATE: May 31, 2012

The purpose of this memorandum is to clarify issues and questions that Financial Alignment Demonstration Plan (FAD) applicants have raised following the release of our May 3, 2012 HPMS guidance memorandum entitled, "CY 2013 Part D Supplemental Formulary File and Additional Demonstration Drug File Submission Requirements for Financial Alignment Demonstration Plan Applicants." These instructions apply only to FAD applicants.

We emphasize that demonstration plan applicants must work with their respective 2013 demonstration States to ensure that their base formulary, supplemental file, and additional demonstration drug (ADD) file submissions include all drugs the State requires to be covered under Medicaid and/or specifically under the demonstration.

Attached to this memorandum are a series of FAQs to facilitate demonstration plan applicants' timely and accurate submission of supplemental formulary files. We encourage organizations that still have questions to contact both PartDBenefits@cms.hhs.gov and MMCOCapsModel@cms.hhs.gov.

Frequently Asked Questions: Financial Alignment Demonstration Plan Applicant Submission of Supplemental Formulary and Additional Demonstration Drug (ADD) Files

Q1: Which drugs should be included on the ADD file versus the base formulary or supplemental drug files?

A1: Applicants should submit or should have submitted the following:

- Drugs that meet the definition of a Part D drug on the base formulary due in April 2012; (refer to section 10 of Chapter 6 of the Prescription Drug Benefit Manual, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads//Chapter6.pdf for more information about Part D drugs). Please note that only those Part D eligible drugs that are listed on the CY2013 Formulary Reference File (FRF) may be included on the base formularies.

- Drugs that are in Part D excluded drug categories on the Supplemental Excluded Drug File due June 8, 2012 (refer to section 20.1 and Appendix B of Chapter 6 of the Prescription Drug Benefit Manual (https://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf for more information about excluded categories of drugs in the Part D program). Plans should take into consideration Part D rules when selecting an appropriate proxy NDC to submit on the Supplemental Excluded Drug File.

- OTC drugs that may be covered at $0 cost-sharing to the enrollee and consistent with Part D rules on the Supplemental OTC Drug File due June 8, 2012 (refer to section 60.2 of Chapter 7 of the Prescription Drug Benefit Manual (https://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf for more information about the provision of OTC drugs under Part D). Please note that only those proxy NDCs associated with OTC drugs that will be included in a step therapy protocol submitted for review and approval by CMS and offered at $0 cost-sharing may be submitted on the Supplemental OTC Drug File. If the base formulary associated with the demonstration contract/plan does not include the OTC RXCUI, then applicants will not submit any drugs on this file. All other OTC drugs will be submitted on the ADD file.

- Prescription or OTC drugs that the State requires to be covered, but that cannot be included in the base formulary, the Supplemental Excluded Drug File, or the Supplemental OTC Drug File must be included on the ADD File due on June 15, 2012. The submission window for the ADD file begins on June 11, 2012. The ADD file cannot be used to submit drugs that the demonstration applicant omitted from the base formulary for reasons other than that the drug was not found on the CY 2013 FRF, or that were not appropriately included on the Supplemental Excluded Drug or OTC Files during the initial submission window.

We note that drugs submitted on the Supplemental Excluded Drug File, the Supplemental OTC Drug File, and the ADD File are not considered to be Part D drugs and therefore will not be counted for purposes of the low-income subsidy and reinsurance payments to plans.

Q2: May applicants include Part B covered drugs or Part B covered non-drug products on the ADD File?

A2: No. Plans should not include Part B covered drugs or non-drug products on the ADD file. All medically necessary Part B drugs/products must be paid for by the plan and must not be included in the ADD file. Part B drugs/products should be covered consistent with the Medicare coverage rules (refer to section 10 of Chapter 4 of the Medicare Managed Care Manual, https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/index.html, for more information about Part B coverage).

Q3: May applicants include non-drug OTC products on the ADD File?

A3: Yes. The ADD File supports inclusion of non-drug OTC products as well as OTC drugs, and it is at the States' discretion whether to require their plan applicants to include this information on the ADD file. We encourage applicants to work with their respective 2013 demonstration States to ensure that it is clear whether the State expects non-drug OTC products to also to be included on the ADD file.

Q4: Must applicants submit a single proxy NDC for drugs/products on the ADD file, or must they submit individual NDCs?

A4: It is at the States' discretion whether to require their plan applicants to include one proxy NDC or multiple NDCs on the ADD file for each covered product. We encourage applicants to work with their respective 2013 demonstration States to ensure that it is clear whether the State expects submission of a single proxy NDC or multiple NDCs.

Q5: Is the review process and/or time frame for the formularies for demonstration applicants different than non-demonstration formularies? Will applicants have an opportunity to revise their formulary after it has been conditionally approved?

A5: All submitted CY2013 formularies will undergo the same review process and be subject to the same review timeframes and deadlines. Conditionally approved formularies will be eligible to participate in the formulary update window expected to be made available in mid-summer, at which time they can make those allowable changes specified in the guidance provided when the CY2013 formulary update window is announced. This includes the addition of drugs that have been included on the revised CY2013 formulary reference file.

Q6: How will the information applicants submit on the Supplemental Drug Files and the ADD File be reviewed? Will applicants have an opportunity to resubmit information originally submitted by the June 8th and June 15th deadlines?

A6: CMS will evaluate all the demonstration Supplemental Drug Files consistent with the review process and timeframes of all non-demonstration contracts. States will primarily review the Supplemental Excluded Drug File, the Supplemental OTC Drug File, and the ADD file. States will also have access to base formulary information. CMS is working with the States on developing a process for finalizing this review consistent with our overall demonstration plan approval timeline. We generally expect to communicate all issues with supplemental file submissions – including CMS outlier issues and any deficiencies found in State reviews – to applicants in early July. Directly following this communication, applicants will have a brief window (typically 2-3 business days) when they can resubmit any supplemental formulary and/or ADD files before the State and CMS complete a final review by late July.

Q7: What should applicants do about prescription drugs that were omitted from the base formulary submission? Can these be submitted on the ADD file?

A7: Only those drugs that were included on the CY2013 Formulary Reference File can be submitted on the base formulary file. Part D eligible drugs that were omitted from the base formulary (whether or not they were on the March version of the CY2013 FRF) and that are not required by the State should not be placed on the ADD file. Demonstration applicants will have an opportunity to submit these drugs on the formulary during the mid-summer formulary update window for CY 2013.

Omitted drugs that are required by the State may be placed on the ADD file, with the understanding that any Part D eligible drugs that are on the mid-summer version of the CY 2013 FRF will be added to the formulary during the mid-summer formulary update window for CY 2013. Please note that the ADD file may not be used to circumvent the formulary review process or to impose unapproved or additional restrictions on drugs that would otherwise be placed on the formulary.