

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

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**TO:** Financial Alignment Demonstration Applicants

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

**SUBJECT:** CY2013 Part D Supplemental Formulary File and Additional Demonstration Drug File Submission Requirements for Financial Alignment Demonstration Plan Applicants

**DATE:** May 3, 2012

The purpose of this memorandum is to: (1) clarify the supplemental formulary submission requirements for Financial Alignment Demonstration plan applicants; (2) provide more information about the Additional Demonstration Drug (ADD) File referenced in our March 29, 2012 guidance memorandum for organizations interested in offering Financial Alignment Demonstration plans in 2013; and (3) announce a teleconference that will be conducted on this guidance for demonstration plan applicants on May 9, 2012.

As stated in our March 29, 2012 guidance memorandum, a required part of the CMS-State joint plan selection process is the approval of a unified formulary consistent with Part D and Medicaid drug coverage requirements. The goal of the selection process is to implement the demonstration with interested organizations that can coordinate all medical, drug, behavioral health, and long-term supports and services in a manner that creates a more seamless and person-centered experience for beneficiaries. A unified formulary will provide enrollees with a more integrated, seamless experience under the demonstration.

Financial Alignment Demonstration plan applicants for 2013 were required to submit their base formularies to CMS for review in April 2012. If your Financial Alignment Demonstration plan did not submit a base formulary to CMS by the April 30, 2012 deadline you must submit a request to CMS to crosswalk your contract to a previously submitted formulary (linked to non-demonstration contracts) by May 14, 2012. **If you do not have a previously submitted non-demonstration formulary to crosswalk your Financial Alignment Demonstration contract or you did not successfully submit your base formulary to CMS by the April 30, 2012 deadline you must notify CMS immediately by sending an e-mail to the Part D formularies mailbox at [PartDformularies@cms.hhs.gov](mailto:PartDformularies@cms.hhs.gov).**

Demonstration plan applicants will be required to submit Part D supplemental formulary files in HPMS by June 8<sup>th</sup> and the Additional Demonstration Drug file by June 15, 2012. States will

have access to information in HPMS about base formularies and supplemental files submitted by demonstration plan applicants in their respective States. Both CMS and States will ensure that the integrated formulary submitted by each interested organization meets both entities' requirements. States' primary role in the joint review process will be in reviewing the supplemental files submitted by demonstration plan applicants. We expect demonstration plan applicants to work with States to ensure that their base formularies and supplemental file submissions include drugs covered under Medicaid, as well as any specific drugs States require to be included in demonstration plan formularies.

### **Supplemental Formulary File Submission**

The deadline for all organizations to submit Part D supplemental formulary files is June 8, 2012. This includes the Free First Fill File, Home Infusion File, Excluded Drug File, and Over-the-Counter (OTC) Drug File through HPMS. The Partial Gap Coverage File will not be applicable to demonstration plans because all enrollees will be full benefit dual eligible with no coverage gap. Instructions for how to populate the Free First Fill and Home Infusion files have been provided in the Formulary Training Webinar ([https://webinar.cms.hhs.gov/e39303730/event/event\\_info.html](https://webinar.cms.hhs.gov/e39303730/event/event_info.html)). In addition, demonstration plans will need to submit an ADD file to CMS by June 15, 2012. We provide additional guidance below on submission of the Excluded Drug, OTC Drug, and ADD files.

#### ***Supplemental Excluded Drug File***

Any drugs a demonstration plan intends to cover that are in Part D excluded drug categories must be submitted in the Supplemental Excluded Drug File due to CMS on June 8, 2012. Demonstration plans must include those Part D excluded drugs that are required to be covered by State Medicaid agencies (consistent with Medicaid requirements), as well as any such drugs a demonstration plan intends to offer as a Part D supplemental benefit.

Organizations should 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 detail about excluded categories of drugs in the Part D program. Part D coverage of benzodiazepines is permitted starting in 2013, as is coverage of barbiturates if used in the treatment of epilepsy, cancer, or a chronic mental health disorder.

#### ***Supplemental OTC Drug File***

Demonstration plans should only submit on the Supplemental OTC Drug File due to CMS on June 8, 2012, those OTC drugs provided under the plan consistent with Part D rules. The Part D program allows plans the option of providing OTC drugs as part of their administrative cost structure, either as (1) a part of general drug utilization management, or (2) as part of a step therapy protocol, but always at no cost to the enrollee. Organizations should refer to section 60.2 of Chapter 7 of the Prescription Drug Benefit Manual (<https://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf>) for more detail about the provision of OTC drugs under Part D.

While demonstration plans may cover OTC drugs under their integrated formulary more broadly than the Part D program allows – for example, to accommodate State Medicaid OTC drug coverage requirements – only those drugs provided consistent with Part D requirements should be included on the Supplemental OTC Drug file. Additional OTC drugs should be included in the ADD File described below.

### ***Additional Demonstration Drug (ADD) File***

If a State requires coverage of additional drugs – whether prescription or OTC drug products that cannot be captured in the base formulary, Excluded Drug file, or OTC Drug file – under its Medicaid program, demonstration plan applicants must submit an ADD file to CMS by June 15, 2012. Attached to this memorandum is a record layout of this file.

A new link will be available on the Contract Year (CY) 2013 Formulary Submission Start page to submit the ADD file. Organizations will be required to select the formulary that is associated with the ADD file. **Please note that consistent with the Part D supplemental file submissions, there must be a one-to-one relationship between additional demonstration drug and formulary files. This means that only one formulary may be associated with each submitted ADD file.** Formularies may only be selected if one or more Financial Alignment Demonstration contracts are associated with the given formulary. The ADD file must follow the ADD record layout as identified in the attached appendix and must be submitted in a .txt format. Users may upload this file as many times as they want before the deadline.

### **Webinar on Part D Supplemental Formulary File and Additional Demonstration Drug File Submissions**

CMS will be holding a webinar on this guidance for demonstration plan applicants on May 9, 2012. There will be ample opportunity for organizations to ask questions about this process. For organizations that cannot join the call at the scheduled time, please note that the call will be recorded.

Demonstration plan applicants should use the following call-in information to join the call:

Call-in number: 877-267-1577  
Meeting ID: 8124

To join the webinar meeting, please access and enter as a guest at the following URL:  
**<https://webinar.cms.hhs.gov/additionalformularyfilestraining/>**.