

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850



## **CENTER FOR MEDICARE**

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TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez, Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Summer Limited Update Window for CY 2018 Formulary Submissions

DATE: July 20, 2017

### **CY 2018 Formulary Timelines and Processes**

CMS is currently in the process of granting conditional approvals for CY 2018 formularies. Those organizations whose formularies still have outstanding issues will be contacted by CMS to schedule a negotiation call. CMS will make every effort to accommodate all negotiation requests within the existing time and resource constraints at this stage of the 2018 formulary review process. Given these constraints, organizations with a smaller number of formulary issues will receive the first negotiation calls and as a result are more likely to be eligible for the summer update window. CMS reminds all plans of the importance of resolving any outstanding formulary concerns in an expeditious manner. Formularies that do not receive conditional approval prior to the summer limited update window will not be eligible to take advantage of the limited update opportunity. No exceptions will be granted.

Part D sponsors must have a conditionally approved formulary to be eligible for a CY 2018 Part D contract. Part D sponsors that fail to meet formulary submission and resubmission deadlines during the CY 2018 formulary approval process may face a CMS determination that we cannot approve their 2018 Part D bids. Organizations that failed to meet CY 2018 Stage 1, 2, or 3 formulary review resubmission deadlines and those organizations whose formulary resubmissions contained negative changes will be reviewed after CMS completes its review of all other timely formulary submissions.

Any Part D sponsor that has not received conditional approval of its CY 2018 Part D formulary by August 17, 2017 will not have its plan included in the Medicare and You Handbook. Part D sponsors must resolve all outstanding issues and receive conditional approval for their CY 2018 formulary no later than 5:00 p.m. EDT on September 1, 2017. Failure to attain conditional approval by this deadline may result in the Part D sponsor not receiving a Part D contract, making it ineligible to offer Part D benefits during CY 2018.

## **Summer Limited Update Window for CY 2018 Formulary Submissions**

Only sponsors that have received prior CMS conditional formulary approval will be permitted to submit an update during the summer update window. Part D sponsors will have the opportunity to make limited updates, as outlined in the CY 2018 Call Letter (see below), to their conditionally approved CY 2018 formulary submissions from 12:00 a.m. EDT July 27, 2017 through 5:00 p.m. EDT July 31, 2017. An updated CY 2018 Formulary Reference File (FRF) is available within the CY 2018 HPMS Formulary Submission Module. Only RXCUIs added to this file can be added to the HPMS formulary submission during the limited update window.

The summer update window cannot be used for making significant changes to conditionally approved formulary submissions. Consistent with the CY 2018 Call Letter, changes must be limited to: 1) the addition of drugs that are new to the summer release of the FRF, and 2) the submission of negative changes on brand drugs, only if an equivalent generic or therapeutically similar drug is added to the summer FRF and corresponding formulary file within the same category and class, at the same tier or lower, and with no more restrictive utilization management than what was applied to the existing brand. The updated formulary submission will also require the deletion of any RXCUIs that have been removed from the updated reference file and the inclusion of any RXCUIs that are within the protected class drugs. Under no circumstances are sponsors allowed to make enhancements to existing drugs on their conditionally approved formulary or add drugs from a previous version of the FRF.

## **Prior Authorization (PA) and Step Therapy (ST) File Updates**

Changes to prior authorization (PA) and step therapy (ST) criteria files must be limited to the addition of criteria for drugs being added to the formulary and deletion of criteria for drugs that are being removed from the formulary. Updates to PA or ST group descriptions to accommodate criteria changes will not be permitted at this time but will be addressed during the PA and ST criteria review. If there are PA or ST group descriptions that need to be added based on your formulary file submission, you will submit a partial PA or ST file containing an “ADD” record for the new group description(s). PA and ST group descriptions that are being deleted based on your formulary file submission will automatically be deleted from the PA/ST files if they are deleted from the formulary (i.e. a deletion record is not to be uploaded on the partial file). You will receive a confirmation of these deletions in the “Formulary-Processing Results” email.

During the update window, Part D sponsors will select the “Revise Formulary” option in HPMS to submit their partial formulary files. Sponsors may upload and validate a formulary only once during the open window period. Following the update window, Part D sponsors must check the status of formulary approvals in HPMS. Only approved formularies can be marketed beginning October 1, 2017. Original or updated formulary submissions that have not yet been approved will be suppressed in Medicare Plan Finder. For these reasons, CMS emphasizes that Part D sponsors should not attempt to make a significant number of changes because it could delay approval of their formulary updates.

If you have any questions regarding this limited update window, please email the Part D Formularies mailbox ([PartDFormularies@cms.hhs.gov](mailto:PartDFormularies@cms.hhs.gov)).