

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

TO: All Part D Sponsors

FROM: Amy K. Larrick, Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: July Limited Update Window for CY 2016 Formulary Submissions

DATE: July 13, 2015

CY 2016 Formulary Timelines and Processes

CMS is currently in the process of granting conditional approvals for CY 2016 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 2016 formulary review process. Given those constraints, organizations must understand that those organizations with limited formulary issues will receive the first negotiation calls and as a result be more likely to be eligible for the July 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 July 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 2016 Part D contract. Part D sponsors that fail to meet formulary submissions and resubmission deadlines during the 2016 contract year formulary approval process may face a CMS determination that we cannot approve their 2016 Part D bids. Organizations that failed to meet CY 2016 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 2016 Part D formulary by August 21, 2015 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 2016 formulary no later than 5:00 P.M. EDT on September 2, 2015. 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 2016.

July Limited Update Window for CY 2016 Formulary Submissions

Only sponsors that have received prior CMS conditional formulary approval will be permitted to submit an update during the July update window. Part D sponsors will have the opportunity to make limited updates, as outlined in the CY 2016 Call Letter (see below), to their conditionally approved CY 2016 formulary submissions from 12:00 A.M. ET July 29, 2015 through 5:00 P.M. ET July 31, 2015. This will be the only opportunity to make maintenance negative changes to your CY 2016 formulary submission(s) prior to March 1, 2016. An updated CY 2016 Formulary Reference File (FRF) will be available within the CY 2016 HPMS formulary submission module on July 23, 2015. Only RXCUIs added to this file can be added to the HPMS formulary submission during the limited update window.

The July update window cannot be used for making significant changes to conditionally approved formulary submissions. Consistent with the CY 2016 Call Letter, changes must be limited to: 1) the addition of RXCUIs that are new to the July 23, 2015 release of the CY 2016 FRF; and 2) the submission of maintenance negative changes to brand drugs (deletion, tier increase, or the addition of prior authorization or step therapy), only if the equivalent generic is new to the July 23, 2015 FRF and is added to your corresponding formulary file. The generic offset must be added to the formulary to the same category and class as the affected brand equivalent, and must also be added to the same or lower tier than the brand. Any applicable utilization management requirements included with the generic offset cannot be more restrictive than the affected brands. 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.**

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. 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.

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, 2015. 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 significant numbers 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).