

Formulary Changes During the Plan Year
Operational Frequently Asked Questions
Last Updated May 5, 2006

Question 1

Q: Are plan sponsors required to submit a formulary file each month to HPMS for review and approval?

A: Plan sponsors are only required to submit a formulary file to HPMS when changes such as enhancements or approved negative formulary change requests previously submitted to CMS, are to be incorporated into the files.

Question 2

Q: How often may Part D sponsors update their HPMS formulary flat files?

A: Part D sponsors may update their HPMS formulary flat files on a monthly basis beginning in February 2006 for an effective date of March 1, 2006. Updated formulary flat files will always be submitted one month prior to the intended effective date and will always contain the complete formulary file, not just the formulary changes. Negative formulary changes that are subject to the 60-day notice rule must have been previously approved (see Question 8) before an upload may occur. For example, a negative change with an effective date of March 1, 2006 would require all applicable parties to be notified on or before January 1, 2006 in order to satisfy the 60-day rule requirements.

Question 3

Q: When will the monthly update periods occur for the HPMS formulary flat file?

A: HPMS Formulary flat file submissions will occur between the 1st and 7th of each month, beginning in February 2006.

Question 4

Q: When uploading my monthly formulary update, what option in HPMS do I choose?

A: When uploading monthly formulary changes, plan sponsors should use the “Update” option in HPMS to send their complete formulary file and attachments (see Question 13).

Question 5

Q: Do plan sponsors need to complete the effective date field when uploading monthly formulary changes to HPMS?

A: Prior to the implementation of Part D, the effective date for all HPMS formulary submissions was automatically defaulted to January 1, 2006. However with each subsequent formulary flat file upload, completion of the “effective date” field will be required. The effective date indicates the projected date that the proposed change will become effective.

Question 6

Q: What is the process for enhancing the formulary such as adding new drugs, improving the cost-sharing status of a drug, or removing utilization management restrictions after January 1, 2006?

A: Enhancements to the formulary do not require at least a 60-day notice to CMS. Enhancements should be included in the formulary flat file during the first available monthly update period.

Question 7

Q: What is the process for adding a new generic drug and changing the status of the corresponding brand drug (e.g. deleting the drug or moving it to a higher cost-share tier)?

A: The addition of any new generics should be included in the formulary flat file during the first available monthly update period. This addition is not subject to any waiting period, assuming that the utilization management edits of the generic mirror those of the existing formulary brand agent. However, any corresponding negative change to the brand drug is subject to the 60-day notice rule. Plan sponsors should submit their proposed change via the Negative Formulary Change Request Template at least 60-days prior to the effective date of the change. If approved, the proposed change should then be reflected in the formulary update submitted in the month preceding the proposed effective date. For example, if the brand drug will be removed from the formulary on May 1, 2006, then the proposed negative formulary change request template should be sent to CMS on or before March 1, 2006. The proposed negative change would be submitted as part of the formulary flat file between April 1 and April 7, 2006.

Question 8

Q: What is the process for making a negative formulary change such as removing a drug from the formulary or changing the cost-sharing status of a drug to a less favorable position?

A: Removing a drug from the formulary or moving a drug to a less favorable tier is subject to the 60-day notice rule. In the absence of the formulary addition of a new generic equivalent or withdrawal from market, clinical justification for proposed negative formulary changes may be required. Plan sponsors should submit their proposed change via the Negative Formulary Change Request Template at least 60-days prior to the effective date of the change. Once explicit approval from CMS is granted, the proposed change should then be submitted as part of the monthly formulary updates in the month preceding the proposed effective date. For example, if a drug will be removed from the formulary on May 1, 2006, then the proposed negative change template should be sent to CMS on or before March 1, 2006. The proposed negative change should be reflected in the formulary update submitted as part of the formulary flat file between April 1 and April 7, 2006.

Question 9

Q: Can I submit negative formulary changes to my HPMS formulary file without prior CMS approval of the changes?

A: Only those negative changes that were previously approved by CMS may be submitted with the HPMS formulary upload. If there are additional negative changes submitted that did not receive prior approval, the entire HPMS formulary file will be rejected and the implementation of any previously approved changes may be delayed. The formulary must be submitted with only enhancements and approved negative formulary changes.

Question 10

Q: Can I delete NDCs from my HPMS formulary file during the monthly upload period if I still have other NDCs for the same drug in my formulary file?

A: The monthly formulary update process allows plans to make formulary enhancements such as the addition of drugs, removal of utilization management edits, or tier reduction of a formulary drug. Also, this upload period permits the submission of a revised formulary file that incorporates the negative formulary changes that were previously approved by CMS. The monthly HPMS formulary upload process is not intended to be an opportunity for plans to “clean-up” their formulary files. The NDC that is submitted to CMS is intended to serve as a proxy for coverage of a particular drug. As such, NDC-level changes to the HPMS formulary files should be limited to only those cases where coverage for the represented drug changes. HPMS formulary files that are submitted to CMS with multiple NDC-level changes (e.g. deletion of inactive NDCs with corresponding addition of active NDCs) will be rejected. Implementation of proposed changes may only occur once an acceptable file is submitted to CMS and approved.

Question 11

Q: What is the process for adding utilization management to an existing formulary drug?

A: CMS must receive at least 60 days notice via the Negative Formulary Change Request Template when utilization management is to be added to an existing formulary drug. However, if the criterion applies only to patients newly initiated on therapy, a 60-day notice is not required to be sent to enrollees. The process for requesting and submitting these types of negative changes will otherwise mirror those outlined in Question 8. The formulary upload would also include submission of the new prior authorization or step therapy criteria in the existing respective attachment.

Question 12

Q: What is the process for removing a drug from our formulary when the drug is being withdrawn from the market due to safety reasons or manufacturer withdrawal?

A: In this instance, plan sponsors should provide CMS with immediate written notice that the drug is being removed from the formulary. The HPMS formulary flat file should be updated during the first available monthly update period. This type of change is not subject to the 60-day notification requirements.

Question 13

Q: Are we required to resubmit our supporting information attachment, prior authorization attachment and step therapy attachment with each formulary upload?

A: Plan sponsors are required to submit their supporting information attachment, prior authorization attachment, and step therapy attachment ONLY if there are any changes to the respective attachments. If there are no changes to a particular document in a particular month, then the plan sponsor should submit a Word document that indicates “No Changes” instead of the actual document that contains the notes or criteria.

Question 14

Q: Are we required to resubmit our exceptions process, transition process, and long-term care conditions of participation with each formulary upload?

A: No. Plans are not required to resubmit this information with each formulary upload.

Question 15

Q: Will plan sponsors receive written approval of their 60-day notice changes and their monthly formulary file submissions?

A: Plan sponsors will not receive written approval of their negative change requests for formulary maintenance types of changes as outlined in the *Formulary Changes During the Plan Year* clarification guidance. Since other types of formulary changes will require a more extensive review by CMS, Part D plans must not implement any proposed changes until explicit approval is received from CMS. Plan sponsors will be notified with concerns regarding proposed changes within 30 days after receipt of a 60-day notice change. CMS will not provide written notice of approval of HPMS formulary submissions. The status of your submitted formulary (approved or denied) may be viewed in HPMS and changes to the Price File data submissions should not be made until the formulary is approved in HPMS.

Question 16

Q: Can monthly updates for CY 2006 formulary be automatically added to the corresponding CY 2007 formulary?

A: No. The CY 2006 and CY 2007 formulary files must be maintained separately.

Question 17

Q: When should formulary changes be submitted to HPMS and DestinationRx in order to best synchronize formulary data?

A: In order to clarify the specific mechanism regarding the submission of formulary changes to HPMS and DestinationRx, we have provided the following process and examples. Compliance with this guidance is vital in order to synchronize formulary data provided to current Plan enrollees as well as to Medicare beneficiaries evaluating their Plan options.

Formulary Expansions:

Formulary changes that add drugs, move drugs to lower tiers or co-payment status, or delete drug utilization management tools can be submitted during the bi-weekly Wednesday data submission window closest to the effective date of the formulary change to DestinationRx using the usual FTP process. The changes must be reflected in both your Pricing File (PF) and your Formulary File (FF).

While these formulary additions do not require CMS review/approval, they must be included in the next formulary file uploaded to HPMS to ensure synchronicity of your formulary files. The HPMS formulary upload window is open during the first seven days of each calendar month.

Formulary Maintenance or Other Formulary Changes:

After receiving notice of CMS approval of a formulary change request, either through silent approval or confirmation, the change must be included in the formulary file uploaded to HPMS in the month that precedes the effective date of the change. The HPMS formulary upload window is open during the first seven days of each calendar month.

Approved formulary changes must be submitted during the bi-weekly Wednesday data submission window closest to the date in which your 60-day written notice is sent to your existing plan members. These changes must be submitted to DestinationRx using the usual FTP process and the changes must be reflected in both your Pricing File (PF) and your Formulary File (FF).