List of Changes for the CY2009 – PBP and Formulary

1. The List of Chronic and Disabling Conditions has been expanded to include:
    - CVD: Chronic Heart Failure
    - CVD: Coronary Artery Disease
    - CVD: Hypetension
    - COPD: Asthma
    - Endocrine/Metabolic: Diabetes
    - Endocrine/Metabolic: Dyslipidemia
    - Endocrine/Metabolic: Obesity
    - Immune Disorders: HIV infection
    - Joint Disorders: Osteoarthritis
    - Neurologic Disorders: Ischemic stroke
    - Neurologic Disorders: Dementia
    - Renal Disorders: Chronic renal failure
    - Renal Disorders: End-stage renal disease (ESRD)
    - Status-post Organ Transplantation
    - Other
    - CVD: Cardiac Arrhythmia
    - CVD: Peripheral Vascular Disease
    - COPD: Chronic bronchitis
    - COPD: Emphysema
    - Immune Disorders: Rheumatoid Arthritis
    - Liver Disease: Chronic liver failure
    - Liver Disease: End-stage liver disease (ESRD)
    - Neurologic Disorders: Hemorrhagic stroke
    - Psychiatric Disorders: Alcoholism
    - Psychiatric Disorders: Bipolar disorder
    - Psychiatric Disorders: Drug dependency
    - Psychiatric Disorders: Major depression
    - Psychiatric Disorders: Schizophrenia
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: HPMS Chronic and Disabling conditions has been updated and these new conditions need to be reflected in the PBP
    c. Citation: 42 CFR 422.102
    d. Impact on burden: None – this data is brought to the PBP software from HPMS
    e. Location of change: Screenshot Section A – Pg. 2

2. PBP Section B-10b (transportation benefit): Added Days, Number of Days (parent variable)-Min number of days and Max number of days (child variables), and Other to "Select type of transportation for plan-approved location:"
    a. Source: 2009 Internal Requirement
    b. Reason why change is needed: to allow plans more flexibility to describe their transportation benefits.
    c. Citation: 42 CFR 422.102
    d. Impact on burden: minimal
    e. Location of change: Screenshot Section B – Pg. 108

3. For Rx Basic/Enhanced Alternative; Alternative ICL screen the options: Non-preferred Generic, and Non-Preferred Brand drug types were added to: "Please indicate which drug type this limited benefit applies to." The following validation rule was modified to check for Non-Preferred Generic and Non-Preferred Brand: If the plan has pre-ICL tiers,

Generic may be selected only if Generic is selected in one of the tiers. The equivalent rule must be in effect for Preferred Generic, Non-Preferred Generic, Brand, Preferred Brand, and Non-Preferred Brand.

a. Source: CY2009 Internal Requirement
b. Reason why change is needed: to allow plans to define drugs as non-preferred generic and non-preferred brand.
c. Citation: 42 CFR 423.120
d. Impact on burden: None
e. Location of change: Screenshot Section Rx, Pg. 19

4. Section C: the item 8b3 – X-Rays was added to OON General Base 2, OON Group Base 1, Cost Share Reduction General Base 1, and Cost Share Reduction Group Base 1.
    a. Source: CY2009 Industry Requirement
    b. Reason why change is needed: Copy data entry fields as related to Section B
    c. Citation: 42 CFR 422.101
    d. Impact on burden: None
    e. Location of change: Screenshot Section C, Pg. 2, 9, 23, 30

5. Added the following field to b-7c Base 1 and b-7i Base 1: “Do you charge the Medicare coverage limit?”
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: Question is applicable to these two categories, but not previously included
    c. Citation: 42 CFR 422.101
    d. Impact on burden: minimal
    e. Location of change: Screenshot Section B, Pg. 62 and 81

6. The label: “Even if you do not offer enhance benefits, you must complete this section for your Medicare Covered Benefits” Was added to B-14a-Base 1, B-16b-Base 1, B-17b-Base 1, and B-18a-Base 1
    a. Source: CY2009 Industry Requirement
    b. Reason why change is needed: Further clarification needed for data entry – these are Medicare-covered benefits
    c. Citation: 42 CFR 422.101
    d. Impact on burden: none
    e. Location of change: Screenshot Section B, Pg. 133, 185, 196, and 202

7. In Medicare Rx Drugs: Basic/Enhanced Alternative: Alternative Deductible, the word “COINSURANCE” was added to the second and third option to the answer of : “Indicate the Out-of-Network cost sharing structure for this plan:”
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed:
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screenshot section Rx, Pg. 4

8. Disabled the Out-of-area coinsurance and copayment fields for Cost plans in Section B-12, Renal Dialysis.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: Out-of-area renal dialysis is covered by original Medicare for Cost plans.
    c. Citation: 42 CFR 422.101
    d. Impact on burden: none
    e. Location of change: Screenshot section B, Pg. 117

9. Created a date/time stamp to indicate when the PBP/BPT was completed. This date should not be overwritten when the zip file is created.
   The PBP/BPT completion information to include date, timestamp, and time zone.

   The submission PBP MDB and associated BPTs will keep the date/time stamp of when they were last modified. The date/time stamp of the ZIP file reflects the end of the PBP Upload File Creation process. The completion of the submission process is reflected by the date/time stamp on the HPMS.
   a. Source: CY2009 Internal Requirement
   b. Reason why change is needed: Informational purposes for plan and CMS
   c. Citation: N/A
   d. Impact on burden: none
   e. Location of change: N/A

10. Added an edit rule to not allow plans to choose both 1 month and 'other 'days supply for Out-of-Network benefits. The rule was added to the tier locations screen and the general locations screen.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed:
    c. Citation: 42 CFR 423. 120
    d. Impact on burden: none
    e. Location of change: Screenshot section Rx, Pg. 6, 15, 22, 28

11. Fixed a software bug related to plans that offer all enhanced benefits for 16a. When a plan selects a combination of services included in a single cost share and does not select all of the enhanced benefits, then subsequent cost share fields that are filled in are cleared upon exit validation.
    a. Source: CY2009 testing
    b. Reason why change is needed: Bug fix
    c. Citation: NA
    d. Impact on burden: none
    e. Location of change: Screenshot Section B, Pg. 178

12. Modified the smoking cessation enhanced benefit to state "additional smoking cessation". Added ‘Medicare-covered’ smoking cessation data entry fields to indicate cost sharing for the Medicare-covered smoking cessation benefit. The three percentage fields have 0 to 100 as the range of values.
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: To capture the Medicare and non-Medicare smoking cessation benefit separately.
    c. Citation: 42CFR 422. 101
    d. Impact on burden: none
    e. Location of change: Screenshot Section B, Pg. 133, 134

13. The plan name is now displayed in the Plan Status Screen.
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: Help end users
    c. Citation: NA
    d. Impact on burden: none
    e. Location of change: Screenshot Section A, Pg. 1

14. Added the local number fields to Section A-3 screens. Fields to be pre-populated from HPMS. Eight new phone number fields were added.
    a. Source: CY2009 Industry comment
    b. Reason why change is needed: Bug fix

c. Citation: NA
d. Impact on burden: none
e. Location of change: Screenshot Section A, Pg. 3

15. Added the following on-screen label after the Yes/No question for FFS cost sharing (on screens B-1a and B-1b):
These are the total charges for all services provided to the enrollee in the inpatient facility.
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: Policy clarification to better serve users
    c. Citation: 42 CFR 422.101
    d. Impact on burden: none
    e. Location of change: Screen Section B, Pg. 2, 6, 16, 20

16. Added the following language after the Yes/No question for FFS cost sharing:
These are the total charges for all services provided to the enrollee in the SNF.
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: Policy Clarification to better serve users.
    c. Citation: 42 CFR 422.101
    d. Impact on burden: none
    e. Location of change: Screen Section B, Pg. 31, 34

17. For MSA and MSA Demo balance billing questions, removed four yes/no questions from the PBP because the answer to these balance billing questions is always “yes.”
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: these fields were disabled to yes, so should be removed.
    c. Citation: 42 CFR 422. 101
    d. Impact on burden: none
    e. Location of change: Screen Section D, Pg. 12

18. There was an equation that enabled the OOPC variables if the plan type was Employer Direct PDP. This equation has been removed.
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: Bug fix – employer direct PDPs should not have access to these fields
    c. Citation: NA
    d. Impact on burden: none
    e. Location of change: Screen Section D, Pg. 1-9

19. Create a new screen entitled "Part C Home Infusion Drugs" in Service Category B-15 - Medicare Part B Rx Drugs. The new screen should be located after the Notes screen. Cost plans not offering Part D drug coverage will be able to complete this data entry in Section B-20. Include the question "Does the plan provide Part D home infusion drugs as a supplemental benefit under Part C?" Only enable the screen for MA-PD plans. Add copay/coinsurance and minimum/maximum fields.
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: Allowable plan arrangement
    c. Citation: 42 CFR 423. 120
    d. Impact on burden: minimal
    e. Location of change: Screen Section B, Pg. 178

20. Deleted the "(List OTCs in Notes)" statement from the following question: "Do you pay for Over-the-Counter medications (OTCs) under the Utilization Management Program? (List OTCs in Notes)"

a. Source: CY2009 Internal comment
b. Reason why change is needed: The OTC drugs will be collected in the formulary module, not the PBP.
c. Citation: NA
d. Impact on burden: decreased burden
e. Location of change: Screen Section Rx, Pg. 1

PBP CHANGES MADE AFTER 60-DAY COMMENT PERIOD

21. The Foreign Visitor/Travel section of the PBP has been removed. In Section B-4a, under the enhanced "worldwide coverage" benefit, the following label bas been added: “This supplemental benefit includes worldwide coverage of urgent/emergent and post-stabilization care."
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: CMS Policy Change
    c. Citation: 42 CFR 422.102
    d. Impact on burden: decreased burden
    e. Location of change: VT screens removed from Section C; label added to Screen Section B, Pg. 43

22. Re-worded the selection items for the questions "In general, describe the Gap Coverage your plan offers:" and "Select the drug types in this Tier that are covered in the gap:" as follows:
    * All Formulary Generics
    * All Preferred Generics
    * Some Generics
    * All Formulary Brands
    * All Preferred Brands
    * Some Brands
    * All drugs on Formulary
    a. Source: CY2009 Internal comment
    b. Reason why change is needed: CMS change to make Summary of Benefits clearer.
    c. Citation: 42 CFR 423.120
    d. Impact on burden: decreased burden
    e. Location of change: Screen Section Rx, Pg. 19
23. Added the ability to copy prescription drug locations from Pre-ICL through the gap tiers and vice versa. Currently functionality only allows plans to copy the tier label screens.
    a. Source: CY2008 Lessons Learned
    b. Reason why change is needed: Help plans complete PBP
    c. Citation: 42 CFR 423.120
    d. Impact on burden: decreased burden
    e. Location of change: Screen Section Rx, Pg. 6

24. There are new screens in the PBP Section D for Non-Network plan types to capture general Max Enrollee out-of-pocket amounts. The “In-network,” “out-of-network,” and “combined” Section D screens will be disabled because they are no longer applicable to these plan types. These general screens will also apply to Plan Deductible and general Max Plan Benefit Coverage fields in Section D.
    a. Source: CY2009 Internal Comments
    b. Reason why change is needed: Clarification in PBP data entry
    c. Citation: 42 CFR 422.120
    d. Impact on burden: decreased burden
    e. Location of change: Screen Section D, Pg. 9

25. 800-series MA-PD cost plans are only required to complete Section A in the PBP software. That is, the data entry rules for 800-series Cost Plans should mirror 800 Series Standalone PDPs.
    a. Source: CY2009 Internal Comments
    b. Reason why change is needed: Remove unnecessary data entry
    c. Citation: 42 CFR 422.120
    d. Impact on burden: decreased burden
    e. Location of change: N/A

26. Create a new exit validation rule that if an organization answers the question “Do you offer gap coverage” with “yes” and also selects “No ICL – Full Gap Coverage” the plan must select that they cover all drugs on their formulary.
    a. Source: CY2009 Internal Comment
    b. Reason why change is needed: Reduce data entry errors in the PBP
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screen Section Rx, Pg. 19

27. Removed the pre-populated question "Does your plan offer a drug Formulary?" from the General Rx Screen 1.
    a. Source: CY2009 Internal Comment
    b. Reason why change is needed: Unnecessary question
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screen Section Rx, Pg. 1

28. When a PBP user copies plan information to a different plan/contract, do not default the user of the plan back to the Super User. Currently users have to go in and re-assign the plans several times because of this.
    Added a third radio button under PBP plan copy step three. The third radio button should be "Retain current plan assignment" or something that indicates the plan users will remain the same.
    a. Source: CY2008 Lessons Learned
    b. Reason why change is needed: Help with data entry
    c. Citation: N/A
    d. Impact on burden: reduces burden
    e. Location of change: N/A

29. After login, do not allow PBP user to proceed to the PBP Management screen without first setting a data back-up path. The establishment of a back-up path is mandatory. The File path screen will now appear if a) a backup path has not been specified, or b) the backup path specified is invalid.
    a. Source: CY2009 Internal Comment
    b. Reason why change is needed: Require users to save a back-up of their current files
    c. Citation: N/A
    d. Impact on burden: none
    e. Location of change: N/A

30. Revise the language for the Out-of-Network Cost Sharing Structure field as follows:
    - In-network copay/coinsurance (no differential)*
    - In-Network Copay/Coinsurance plus a differential between the OON billed charge and the In-Network allowable
    - In-Network Copay/Coinsurance with Limited Days Supply

    "*If a plan chooses this option and does not utilize either a differential in cost sharing or a

differential in days supply for out of network coverage, CMS' expectation is that the plan is monitoring for appropriate out of network use with either a post authorization process or alternate review tool."
    a. Source: CY2009 Internal Comment
    b. Reason why change is needed: Further clarify PBP Question
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screen Section Rx, Pg. 12

31. Every service category offered out network must appear in at least one cost share group in the Section C OON screens. Edit rule: Check that all service categories displayed in the group-level Section C category picklist are selected at least once in at least one group throughout the total number of groups defined by the plan. This edit rule will be implemented upon exit validation from Section C.
    a. Source: CY2009 Internal Comment
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 422.120
    d. Impact on burden: none
    e. Location of change: Screen Section C, Pg. 10

32. Baselined Requirement: Reduce the in area and out of area coinsurance and copayment fields to one general coinsurance and copayment field for all Medicare Advantage plan types.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 422.101
    d. Impact on burden: none
    e. Location of change: Screenshot section B, Pg. 117

33. Add new min/max coinsurance and copayment fields for new "In-Area, Network Urgent Care" benefit in Service Category B - 7a - PCP. Use the language "In-Area, Network Urgent Care".
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 422.101
    d. Impact on burden: minimal
    e. Location of change: Screenshot section B, Pg. 56

34. If plan offers In-network preferred and non-preferred retail pharmacy location option, then every tier must have both a preferred and non-preferred location selected. Edit Rule: If the general Part D Network Location field equals "In-Network Preferred/Non-Preferred Retail Pharmacy" then for every Pre-ICL and Gap tier the locations selected must include at least one In-Network Preferred location AND one Non-Preferred Retail Pharmacy.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Throughout Rx Screen Section

35. If plan offers Mail Order preferred and non-preferred pharmacy location option then every tier must have both a preferred and non-preferred Mail Order location selected. This is ONLY valid on tiers that the plan selects mail order as mail order is NOT required on every tier. Edit Rule: If the general Part D pharmacy location field equals "Mail Order Preferred/Non-Preferred" then every Pre-ICL and Gap tier pharmacy location field must include at least one Mail Order Preferred location AND one Mail Order Non-Preferred.
    a. Source: CY2009 Internal Requirement

b. Reason why change is needed: CMS policy
c. Citation: 42 CFR 423.120
d. Impact on burden: none
e. Location of change: Throughout Rx Screen Section

36. Long term care pharmacy location is required in the gap for plans that offer gap coverage.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Throughout Rx Gap Coverage Screens

37. At least one Out-of-Network pharmacy location is required in the gap for plans that offer gap coverage.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Throughout Rx Gap Coverage Screens

38. There is a new edit rule that plans must have a one-month day supply for In-Network Retail Pharmacy or In-Network Preferred/Non-Preferred Retail Pharmacy.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Throughout Rx Location/Day Supply Screens

39. Out-of-Network cost shares must be equal to retail pharmacy cost shares in the following scenarios:
    1. If location = In-network Retail: OON (one-month supply) cost share must match the In-Network Retail (one month supply) cost share
    OR
    2. If location = In-network Retail Preferred/non-Preferred: The OON (one-month supply) must match EITHER the In-Network Preferred (one month supply) cost share OR the In-Network Non-preferred (one month supply) cost share. This is a change to the current validations.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Throughout Rx cost share Screens

40. Long Term Care cost shares must be equal to retail pharmacy cost shares in the following scenarios:
    1. If location = In-network Retail: LTC (one-month supply) cost share must match the In-Network Retail (one month supply) cost share
    OR
    2. If location = In-network Retail Preferred/non-Preferred: The LTC (one-month supply) must match EITHER the In-Network Preferred (one month supply) cost share OR the In-Network Non-preferred (one month supply) cost share. This is a change to the current validations.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120

d. Impact on burden: none
e. Location of change: Throughout Rx cost share Screens

41. Add a new question in Section A as follows: "Do you cover Hospice Care?" Only enable this question for Part B only plans.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 422.102
    d. Impact on burden: minimal
    e. Location of change: Screenshot section A, Pg. 1

42. Change the language on the Alternative - ICL screen in the following areas:
    - Do you offer any limited gap coverage above your ICL?
    - Remove the statement in parenthesis-(Not Considered Gap Coverage)
    - Under the example, change to: This is limited Gap Coverage.

    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS policy
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screenshot Section Rx, Pg. 19

43. Change the Scenario 1 and 2 Labels on Medicare Rx General 2 Screen to reflect the new CY2009 Formulary Submission Module upload date. Date will be June 9, 2008.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: Instructional CMS item
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screenshot Section Rx, Pg. 2

44. Add the following label after the question "Do you pay for Over-the-Counter medications (OTCs) under the Utilization Management Program?":
    "If you select "Yes" to "Do you pay for Over-the-Counter medications (OTCs) under the Utilization Management Program?", you must indicate these specific medications in a flat file which will be uploaded through the Formulary Submission Module on June 9, 2008"
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: Instructional CMS item
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screenshot Section Rx, Pg. 2

45. Add the following label after the question "Does the plan provide Part D home infusion drugs as a supplemental benefit under Part C?":
    "If you select "Yes" to "Does the plan provide Part D home infusion drugs as a supplemental benefit under Part C?", you must indicate these specific medications in a flat file which will be uploaded through the Formulary Submission Module on June 9, 2008"
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: Instructional CMS item
    c. Citation: 42 CFR 423.120
    d. Impact on burden: none
    e. Location of change: Screenshot Section B, Pg. 178

46. Removed the following question from the PBP Rx Section: “Do you charge the lesser of the copayment or the cost of the drug?”
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: CMS Policy

c. Citation: 42 CFR 423.120
d. Impact on burden: none
e. Location of change: Screenshot Section Rx, Pg. 4

47. Provide detailed data entry screens for SNF services in all Section C screens (e.g., CSR, OON) similar to the SNF screens in Section B. The data entry will mirror the Section C Inpatient Hospital data entry.
    a. Source: CY2009 Internal Requirement
    b. Reason why change is needed: More detailed data entry
    c. Citation: 42 CFR 422.101
    d. Impact on burden: minimal
    e. Location of change: Screenshot Section C, Pg. 4-7

CY2009 Formulary File Submission Changes

Formulary Flat File

CHANGES MADE AFTER 60-DAY COMMENT PERIOD ARE IN BOLD AND UNDERLINED

1. The following Field Name Labels were changed to provide clarity and uniformity:

2008 Field Name	2009 Field Name
Proxy NDC	Proxy_NDC
Tier_Level_Value	Tier_Level
Drug_Type_Label_Value	Drug_Type_Label
Quantity_Limit_Amount_YN	Quantity_Limit_YN
Prior_Authorization_YN	Prior_Authorization_Type
Specialty_Pharmacy_YN	**Limited_Access_YN**
Step_Therapy_YN	Step_Therapy_Type
Step_Therapy_Type_Group_Num	Step_Therapy_Total_Groups
Step_Therapy_Type_Group_Desc_X	Step_Therapy_Type_Group_Desc
Step_Therapy_Type_Group_Step_X	Step_Therapy_Step_Value

   a. Source: CY2009 Internal comment
   b. Reason why change is needed: To provide clarity and uniformity
   c. Citation: 42CFR 423.120
   d. Impact on burden: none

2. The Prior_Authorization_YN field was change to Prior_Authorization_Type and the valid entries are now
   0 = No Prior Authorization
   1 = Prior Authorization Applies
   2 = Prior Authorization Applies to New Starts Only
   3 = Part D vs. Part B Prior Authorization Only
   a. Source: CY2009 Internal comment
   b. Reason why change is needed: To provide addition prior authorization clarity.
   c. Citation: 42CFR 423.120
   d. Impact on burden: none

3. The Step_Therapy_YN field was change to Step_Therapy_Type and the valid entries are now
   0 = Not Part of a Step Therapy Program
   1 = Step Therapy Applies
   2 = Step Therapy Applies to New Starts Only
   a. Source: CY2009 Internal comment
   b. Reason why change is needed: To provide clarity for step therapy type.
   c. Citation: 42CFR 423.120
   d. Impact on burden: none

Free First Fill File

This file is collected at the plan level. No changes from last year.

Gap Coverage File

This file is collected at the plan level. No changes from last year.

Home Infusion Drug File

This is a new file for CY2009. This file is collected at the plan level. The file will contain only 11 digit NDCs that must contained in the associated Formulary Flat File.

a. Source: CY2009 Internal comment
b. Reason why change is needed: To provide additional information about Home Infusion drugs
c. Citation: 42CFR 423.120
d. Impact on burden: minimal

OTC Drug File

This is a new file for CY2009. This file is collected at the plan level. The file will contain the following fields:
NDC, Drug_Name, Strength, Dosage_Form, Route_of_Administration for each OTC drug covered by the plan.

a. Source: CY2009 Internal comment
b. Reason why change is needed: To provide additional information about OTC drugs
c. Citation: 42CFR 423.120
d. Impact on burden: minimal

Excluded Drugs File

This is a new file for CY2009. This file is collected at the plan level. The file will contain the following fields: **NDC, Drug_Name, Strength, Dosage_Form, Route_of_Administration, Tier, Quantity_Limit_YN, Quantity_Limit_Amount, Quantity_Limit_Days, Capped_Benefit_YN, Capped_Benefit_Quantity, Capped_Benefit_Days, Prior_Authorization_YN, Prior_Authorization_Desc, Step_Therapy_YN, and Step_Therapy_Desc** for each excluded drug covered by the plan.

a. Source: CY2009 Internal comment
b. Reason why change is needed: To provide additional information about Excluded drugs
c. Citation: 42CFR 423.120
d. Impact on burden: minimal

Prior Authorization File

****THIS IS A BRAND NEW FILE FROM THAT WAS NOT INCLUDED IN THE 60-DAY COMMENT PERIOD****

This is a new file format for CY2009. The file was previously submitted as a Word (.doc) file. The file will contain the following fields: Prior_Authorization_Group_Description, Drugs, Covered_Uses, Exclusion_Criteria, Required_Medical_Information, Age_Restrictions, Prescriber_Restrictions, Coverage_Duration, Other_Criteria.

a. Source: CY2009 Internal comment
b. Reason why change is needed: To provide additional information about Prior Authorization drugs
c. Citation: 42CFR 423.120
d. Impact on burden: minimal

**Please note: none of these changes were made based on the comments received during the 60-day comment period.