

# CY2011 PBP/Formulary List of Changes

## **CY 2011 PBP Changes**

### General

1. All text within the PBP pertaining to Medicare and Non-Medicare coverage will be displayed in the following format: Medicare-covered or Non-Medicare-covered.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the entire PBP.

DOCUMENT: Appendix C – PBP Screenshots A, B, C, D, Rx

PAGE(s): All

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To make the PBP language consistent throughout.

IMPACT ON BURDEN: No Impact

2. All numeric fields in the PBP have a numeric validation which does not allow the user to copy and paste numeric values that contain commas, or any symbols to denote a negative value such as: negative/minus sign and parentheses. A pop up warning has been put in place to inform the user that negative values and values with a comma are not allowed when the user has copied and pasted a negative/minus sign or parentheses into a numeric field.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the entire PBP.

DOCUMENT: Appendix C – PBP Screenshots A, B, C, D, Rx

PAGE(s): All

CITATION: N/A

REASON WHY CHANGE IS NEEDED: So that a user cannot enter a negative value into the PBP.

IMPACT ON BURDEN: No Impact

3. All category descriptions are now consistent across all the Sections and Screens in the PBP.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the entire PBP.

DOCUMENT: Appendix C – PBP Screenshots A, B, C, D, Rx

PAGE(s): All

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To make the PBP and SB consistent throughout.

IMPACT ON BURDEN: No Impact

4. An edit rule has been implemented that prevents a plan from entering more than 50% coinsurance for any In-Network or Out-of-Network Medicare-Covered service category.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the entire PBP.

DOCUMENT: Appendix C – PBP Screenshots A, B, C, D

PAGE(s): All

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To ensure benefits meet appropriate cost sharing requirements.

IMPACT ON BURDEN: No Impact

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## PBP Section A

1. On the Section A-1 Screen the service area will now show in Alphabetical order by state and the counties will be in alphabetical order within each state.  
SOURCE: Internal  
PBP SCREEN/CATEGORY: Section A-1  
DOCUMENT: PBP\_2011\_screenshots\_sec\_a\_2009\_12\_9  
Page(s): 1  
CITATION: 42 CFR 422.256  
REASON WHY CHANGE IS NEEDED: To allow correctly display of service area in the summary of benefits.  
IMPACT ON BURDEN: No Impact
2. On the Section A-2 Screen the answers for the question "Special Needs Institutional Type:" have been updated to the options "Institutional," "Institutional Equivalent (Living in the Community)," and "Institutional and Institutional Equivalent."  
SOURCE: CMS  
PBP SCREEN/CATEGORY: Section A-2  
DOCUMENT: PBP\_2011\_screenshots\_sec\_a\_2009\_12\_9  
Page(s): 2  
CITATION: 42 CFR 422.256  
REASON WHY CHANGE IS NEEDED: To match the existing HPMS language.  
IMPACT ON BURDEN: No Impact
3. A new field is now present for the plan's Pharmacy Website URL (which will be populated from Contract Management in HPMS).  
SOURCE: Internal  
PBP SCREEN/CATEGORY: Section A-3  
DOCUMENT: PBP\_2011\_screenshots\_sec\_a\_2009\_12\_9  
Page(s): 3  
CITATION: 42 CFR 423.272  
REASON WHY CHANGE IS NEEDED: This field needs to be added to the PBP so the Pharmacy URL can be pulled into the SB Introductions.  
IMPACT ON BURDEN: No Impact

## PBP Section B

### **B-1: Inpatient Hospital Services**

#### B-1a: Inpatient Hospital – Acute

1. On the Base 9 screen Inpatient Acute Hospitals with a Copay or a Coinsurance will now have the question "Does cost sharing vary based on the hospital network?" enabled. If Medicare Defined Cost Sharing is offered, then regardless of copay and coinsurance the question "Does cost sharing vary based on the hospital network?" will be disabled.  
SOURCE: Internal  
PBP SCREEN/CATEGORY: 1a Inpatient Hospital-Acute – Base 9  
DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

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Page(s): 2

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: CMS needs to understand which plans have tiered hospital cost sharing.

IMPACT ON BURDEN: No Impact

2. For Non-network plans the question "Does cost sharing vary based on the hospital network?" will always be disabled.

SOURCE: Internal

PBP SCREEN/CATEGORY: 1a Inpatient Hospital-Acute – Base 9

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 9

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: CMS needs to understand which plans have tiered hospital cost sharing.

IMPACT ON BURDEN: No Impact

B-1b: Inpatient Hospital – Acute

1. For Non-network plans the question "Does cost sharing vary based on the hospital network?" will always be disabled.

SOURCE: Internal

PBP SCREEN/CATEGORY: 1b Inpatient Psychiatric Hospital – Base 9

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 23

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: CMS needs to understand which plans have tiered hospital cost sharing.

IMPACT ON BURDEN: No Impact

B-8: Outpatient Procedures, Tests, Labs & Radiology Services

B-8a: Outpatient Diagnostic Procedures/Lab Services

1. Minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing on the 8a Outpatient Diag Procs/Tests/Lab Services – Base 3 Screen.

SOURCE: Internal

PBP SCREEN/CATEGORY: 8a Outpatient Diag Procs/Tests/Lab Services – Base 3

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 85

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

B-8b: Outpatient Diagnostic/Therapeutic Radiation Services

1. Minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing on the 8b Outpatient Diag/Therapeutic Rad Services – Base 2 Screen.

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SOURCE: Internal

PBP SCREEN/CATEGORY: 8b Outpatient Diag/Therapeutic Rad Services – Base 2 Screen

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 88

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

B-13: Blood, Acupuncture, OTC, Meal Benefit & Other

B13c: OTC

1. The question “Does this cover all of the FSA Feds OTC list?” has been changed to “Does this cover all of the CMS OTC list?”

SOURCE: Internal

PBP SCREEN/CATEGORY: 13c OTC – Base 2

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 124

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: The updated wording is needed to reflect the CMS OTC list that is used, not the FSA Feds List.

IMPACT ON BURDEN: No Impact

2. The referral and authorization questions have been removed from the 13c OTC – Base 2 Screen. A label has been added noting that the referral and authorization questions are not applicable for this service category.

SOURCE: Internal

PBP SCREEN/CATEGORY: 13c OTC – Base 2

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 124

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Referral and authorization questions are not applicable for this service category.

IMPACT ON BURDEN: No Impact

B-13e: Other

1. B13e has been updated from "Other" to "Other 1."

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the B13e Section of the PBP

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 129-131

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Another Other section has been added to the PBP, so changing this to Other 1 distinguishes the two sections from one another.

IMPACT ON BURDEN: No Impact

B-13f: Other 2

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2. "13F Other 2" has been added as a new category in Section B of the PBP. It mirrors the updated format of Section B13e.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the B13f Section of the PBP

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 132-134

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: The users wanted another Other section in the PBP.

IMPACT ON BURDEN: Low Impact on those that want to add another benefit, No Impact for those that do not want to add another benefit to their plan.

### B-14: Preventative Services

#### B-14b: Immunizations

1. If a plan indicates it is offering supplemental benefits, then minimum/maximum copay and coinsurance questions will be enabled for separate office visit cost sharing on the 14b Immunizations – Base 2 Screen.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14b Immunizations – Base 2

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 141

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

#### B-14c: Physical Exams

1. If a plan indicates it is offering supplemental benefits, then minimum/maximum copay and coinsurance questions will be enabled for separate office visit cost sharing on the 14c Physical Exams – Base 3 Screen.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14c Physical Exams – Base 3 Screen

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 145

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

#### B-14d: Pap/Pelvic

1. On the 14d Pap/Pelvic – Base 4 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14d Pap/Pelvic – Base 4

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 150

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CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-14e: Prostate Screening

1. On the 14e Prostate Screening – Base 3 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14e Prostate Screening – Base 3

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 154

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-14f: Colorectal Screening

1. On the 14f Colorectal Screening – Base 4 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14f Colorectal Screening – Base 4

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 159

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-14g: Bone Mass Measurement

1. On the 14g Bone Mass Meas. – Base 2 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14g Bone Mass Meas. – Base 2

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 162

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-14h: Mammography

1. On the 14h Mammography – Base 3 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14h Mammography – Base 3

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 166

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CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-14i: Diabetes Monitoring

1. On the 14i Diabetes Monitoring – Base 2 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 14i Diabetes Monitoring – Base 2

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 169

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-16: Dental

#### B-16b: Comprehensive Dental

2. The benefit “Emergency Services” has been changed to “Non-routine Services.”

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout section B-16b in the PBP

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 184-189

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Emergency is a technical term in Original Medicare and does not refer to routine dental services that require near-immediate attention.

IMPACT ON BURDEN: No Impact

3. On the 16b Comp Dental – Base 6 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 16b Comp Dental – Base 6

DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 189

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### B-17: Eye Exams/Eye Wear

#### B-17a: Eye Exams

1. On the 17a Eye Exams – Base 3 Screen minimum/maximum copay and coinsurance questions have been added for separate office visit cost sharing.

SOURCE: Internal

PBP SCREEN/CATEGORY: 17a Eye Exams – Base 3

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DOCUMENT: PBP\_2011\_screenshots\_sec\_b\_2009\_12\_2

Page(s): 192

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To accurately collect the cost sharing for separate office visits.

IMPACT ON BURDEN: Low Impact

### PBP Section C

#### General

1. The word "optional" has been removed from all the group screens for all subsections in Section C. If you offer a category in Visitor/Travel, Out-Of-Network, or Point Of Service, you must also offer it in their respective Group.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C – OON – Number of Groups, POS – Number of Groups, V/T – Number of Groups - US

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 10, 24, 37

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: The groupings in Section C are not optional.

IMPACT ON BURDEN: No Impact

2. "Inpatient Acute Services" or "Inpatient Psychiatric Services" have been added to the end of each appropriate question "Do you charge the Medicare-defined cost shares? (These are the total charges for all services provided to the enrollee in the inpatient facility.)" in Section C of the PBP.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C – Visitor/Travel, Out-Of-Network, Point Of Service

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 4, 5, 6, 7, 18, 19, 20, 21, 31, 32, 33, 34

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: To clarify the type of inpatient benefit being described.

IMPACT ON BURDEN: No Impact

#### Out-of-Network

1. An error message has been added for Out-of-Network when benefits are selected in the Out-of-Network pick list but then the benefit is not selected in an Out-of-Network grouping.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C – Out of Network

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 2, 11

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure complete data entry.

IMPACT ON BURDEN: Decrease in burden

2. If any categories are chosen as an Out-of-Network benefit at least one Out-of-Network Group needs to be chosen in order to exit-validate.

SOURCE: Industry



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PBP SCREEN/CATEGORY: OON Section of the PBP  
DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 2, 38

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: CMS Policy

IMPACT ON BURDEN: Decrease in burden

3. An exit validation error has been put in place to read: "Indicate the number of Out-of-Network Groupings offered (excluding Inpatient Hospital and SNF Services)"

SOURCE: Industry

PBP SCREEN/CATEGORY: Section C – Out of Network

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 10

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Exit validation message is to clarify what data entry is missing.

IMPACT ON BURDEN: Decrease in burden

4. The PBP will not allow a user to choose "Combined for both Inpatient Hospital Acute and Inpatient Psychiatric Hospital" for the question: "Select the type of OON Inpatient Hospital Services benefit with a Deductible:" if both Inpatient Hospital Acute and Inpatient Psychiatric Hospital have not been picked from: "Select all of the Service Categories to which the Out-of-Network benefit applies:"

SOURCE: Internal

PBP SCREEN/CATEGORY: OON – Inpatient – Base 4

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 7

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure accurate data entry.

IMPACT ON BURDEN: Decrease in burden

5. A pop up message has been added to read "For Item 'Select the type of Inpatient Hospital Services benefit with a Deductible when members voluntarily pre-authorize:' Both can only be selected when Inpatient Hospital Services and Inpatient Psychiatric Services are selected as service categories."

SOURCE: Internal

PBP SCREEN/CATEGORY: OON – Inpatient – Base 4

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 7

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure accurate data entry.

IMPACT ON BURDEN: Decrease in burden

6. There is a new validation ensuring that PPOs are only required to offer sections 10b, 13b,13c, 13d, 13e, 13f, 16a, and 18b Out-of-Network if the In-Network benefit is Mandatory. They are not required to offer these categories if the In-Network benefit is not offered or if the In-Network benefit is Optional.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C – Out of Network

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 2

CITATION: 42 CFR 422.254

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REASON WHY CHANGE IS NEEDED: Clarifying ruleset such that PPOs will not have to offer a benefit Out-of-Network if they do not offer it In-Network

IMPACT ON BURDEN: Decrease in burden

### Point Of Service

1. If any categories are chosen as a Point of Service Benefit at least one Point Of Service Group needs to be chosen in order to exit-validate.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C – Point of Service

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 13, 24

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: CMS Policy

IMPACT ON BURDEN: Decrease in burden

2. An exit validation error has been put in place to read: “Indicate the number of Point-of-Service Groupings offered (excluding Inpatient Hospital and SNF Services)”

SOURCE: Industry

PBP SCREEN/CATEGORY: Section C – POS

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 24

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Exit validation message is to clarify what data entry is missing.

IMPACT ON BURDEN: Decrease in burden

3. An error message has been added for Point of Service plans when benefits are selected in the Point of Service pick list but the benefit is not selected in a Point of Service grouping.

SOURCE: Internal

PBP SCREEN/CATEGORY: C–POS

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 15

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure complete data entry.

IMPACT ON BURDEN: Decrease in burden

4. The PBP will not allow a user to choose “Combined for both Inpatient Hospital Acute and Inpatient Psychiatric Hospital” for the question: “Select the type of POS Inpatient Hospital Services benefit with a Deductible:” if both Inpatient Hospital Acute and Inpatient Psychiatric Hospital have not been picked from: “Select all of the Sub-service Categories that describe the POS Option:”

SOURCE: Internal

PBP SCREEN/CATEGORY: POS – Inpatient – Base 5

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 21

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure complete data entry.

IMPACT ON BURDEN: Decrease in burden

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5. A pop up message has been added to read “For Item ‘Select the type of Inpatient Hospital Services benefit with a Deductible when members voluntarily pre-authorize:’ Both can only be selected when Inpatient Hospital Services and Inpatient Psychiatric Services are selected as service categories.”

SOURCE: Internal

PBP SCREEN/CATEGORY: POS – Inpatient – Base 5

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 21

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure accurate data entry.

IMPACT ON BURDEN: Decrease in burden

### Cost Share Reduction

1. All of the cost share reduction screens have been removed from the PBP.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C – Cost Share Reduction

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): N/A - removed

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: PPOs and PFFS plans can no longer provide lower cost sharing to members

IMPACT ON BURDEN: Decrease in burden

### Visitor/Travel

1. If any categories are chosen as a Visitor/Travel benefit at least one Visitor/Travel Group from that section needs to be chosen.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section C-Visitor/Travel

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 28, 37

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure complete data entry.

IMPACT ON BURDEN: Decrease in burden

2. An exit validation error has been put in place to read: “Indicate the number of Visitor/Travel Groupings offered (excluding Inpatient Hospital and SNF Services)”

SOURCE: Internal

PBP SCREEN/CATEGORY: C-Visitor/Travel

DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): 37

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: Validation to ensure complete data entry.

IMPACT ON BURDEN: Decrease in burden

3. All foreign V/T screens have been removed from the PBP.

SOURCE: Internal

PBP SCREEN/CATEGORY: C-Visitor/Travel

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DOCUMENT: PBP\_2011\_screenshots\_sec\_c\_2009\_11\_25

Page(s): N/A - removed

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: The Foreign V/T is not longer available.

IMPACT ON BURDEN: Decrease in burden

### PBP Section D

#### Plan Deductible

1. A new differential deductible question has been added for B13f - Other 2 to the Plan Deductible (RPPO-Differential Deductible)-Base 2 screen.

SOURCE: Internal

PBP SCREEN/CATEGORY: Plan Deductible (RPPO-Differential Deductible)-Base 2

DOCUMENT: PBP\_2011\_screenshots\_sec\_d\_2009\_12\_9

Page(s): 5

CITATION: 42 CFR 422.254

REASON WHY CHANGE IS NEEDED: The new question reflects the addition of the new Category (Other 2) to the PBP.

IMPACT ON BURDEN: No Burden

#### Optional Supplemental

1. A notes field has been added to each supplemental package where the option 'Other' can be selected for the question "Select the Maximum Plan Benefit Coverage periodicity:"

SOURCE: Internal

PBP SCREEN/CATEGORY: Section D – Optional Supplemental Package

DOCUMENT: PBP\_2011\_screenshots\_sec\_d\_2009\_09\_024

Page(s): 22

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To allow for more complete description of benefit if the benefit cannot properly be entered using the standard data entry fields.

IMPACT ON BURDEN: No impact

### PBP Section Rx

1. The parent/child variables have been enhanced so that if a plan chooses Enhanced Alternative, but needs to switch its answer to Basic Alternative, the variables that became enabled with Enhanced Alternative will then become disabled when it is switched to Basic Alternative.

SOURCE: Internal

PBP SCREEN/CATEGORY: Rx - General

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 1-5

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To ensure that only the correct PBP questions are enabled, depending on the Prescription Drug Plan Type.

IMPACT ON BURDEN: Decrease in burden

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2. The warning/edit rules that affect more than one variable are triggered by all the affective variables regardless of order that you answer the variables.

SOURCE: Internal

PBP SCREEN/CATEGORY: Rx - General

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): throughout software

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To ensure that all edit rules are applied, regardless of the order of data entry.

IMPACT ON BURDEN: Decrease in burden

3. An error message for Enhanced Alternative plans has been implemented stating "If reduced cost sharing is indicated Post OOP, then the org cannot select Medicare defined cost sharing."

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx – Post OOP

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 27

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Validation to ensure complete data entry.

IMPACT ON BURDEN: Decrease in burden

4. If data is altered in the Pre-ICL Tier Label screen then the pre-populated data in the corresponding fields of the Gap Tier Label screen will reflect these changes.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx – Post OOP

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): Throughout the tiers

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To ensure correct data entry.

IMPACT ON BURDEN: Decrease in burden

5. New validations have been added to the Specialty Tier fields such that if a plan is offering the standard deductible, the specialty tier coinsurance cannot be more than 25% or if a plan is offering a \$0 deductible, the specialty tier coinsurance cannot be more than 33%. For anything 25% through 33% the following guidelines must be followed:

Specialty Tier %	Deductible
25%	\$310.00
26%	\$267.70
27%	\$232.60
28%	\$196.53
29%	\$159.44
30%	\$121.29
31%	\$82.03
32%	\$41.62
33%	\$-

Please note that these %/deductible combinations are the 2010 values and are subject to change based on what is set for CY2011.

## CY2011 PBP/Formulary List of Changes

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx - Speciality Tier cost sharing

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 5

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: This is currently a manual review done by CMS that is being automated.

IMPACT ON BURDEN: No Impact on burden

6. The following question will be disabled for Defined Standard plans on the Medicare Rx General 1 Screen: "Indicate number of Tiers in your Part D benefit:"

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: A defined standard plan only has one cost share of 25% throughout its entire benefit.

IMPACT ON BURDEN: No Impact on burden

7. The following label has been removed from the Medicare Rx General 1 Screen: "Defined Standard plans should indicate the number of tiers contained in the formulary that is associated with their plan even though a defined standard plan only has one cost share of 25% throughout its entire benefit."

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: This on-screen label is no longer applicable, since defined standard plans will not be entering the number of tiers contained in the formulary.

IMPACT ON BURDEN: No Impact on burden

8. The following questions have been removed from the Medicare Rx General 1 Screen: "Is this a Part D Payment Demo?" and "Select type of Part D Payment Demo:"

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: The Part D Payment Demo is no longer allowed.

IMPACT ON BURDEN: No Impact on burden

9. The following questions have been added to the Medicare Rx General 1 Screen for all MA-PD enhanced alternative (EA) plans: "Do you have a basic Part D plan (DS, AE, BA) that provides required prescription drug coverage to beneficiaries in the service area covered by this EA plan?" and "Does this EA plan have a zero dollar Part D premium that satisfies (for this service area) the regulatory requirement at 42CFR §423.104(f)(3)(i) to provide required prescription drug coverage?" SOURCE: Internal

## CY2011 PBP/Formulary List of Changes

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 1

CITATION: 42CFR 423.104

REASON WHY CHANGE IS NEEDED: To ensure Part D sponsors are meeting regulatory requirements

IMPACT ON BURDEN: No Impact on burden

10. The PBP will allow for the entry of only 6 tiers of drugs in Section Rx.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx Section

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Number of tiers allowed on a Plan's formulary has changed from 10 to 6.

IMPACT ON BURDEN: No Impact on burden

11. If a MA-PD plan answers yes to 'Do you pay for OTCs under the utilization management program' on the Medicare Rx General 2 Screen, then the attestation statement "Per the CY2009 Call Letter, an MAO cannot offer the same OTC drug under both its Part C supplemental benefit and its Part D benefit. I attest any OTC drugs that are covered under Part C are separate and distinct from OTC drugs covered under Part D." will be enabled with a radio button. The user will not be able to exit validate without clicking the enabled attestation radio button.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx Section

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To clarify policy on OTC drugs for MA-PD plans.

IMPACT ON BURDEN: Minor Impact on burden

12. The following question will be enabled on the Medicare Rx General 2 Screen: "Do you offer OTCs as a part of a formal Step Therapy Protocol submitted for review and approval by CMS?"

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To clarify if the organization is offering a formal step therapy protocol for OTCs or a general utilization management strategy.

IMPACT ON BURDEN: Minor Impact on burden

13. The following label has been added to the Medicare Rx General 2 Screen to explain the question "Do you offer OTCs as a part of a formal Step Therapy Protocol submitted for review and approval by CMS?": "A Step Therapy protocol is one that requires the use of the OTC product prior to receiving a prescription formulary drug. This is in contrast to a general utilization management strategy that offers OTCs as alternatives to prescription formulary drugs but without a requirement to try the OTC first. All OTC drugs used in either a Part D Step Therapy Protocol or a general utilization management strategy

## CY2011 PBP/Formulary List of Changes

should appear in an OTC supplemental file. However, only those OTCs used in a formal Step Therapy Protocol must be documented in the Step Therapy Criteria text files submitted with the formulary files.”

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To help clarify the question “Do you offer OTCs as a part of a formal Step Therapy Protocol submitted for review and approval by CMS?”

IMPACT ON BURDEN: No Impact on burden

14. The following questions have been removed from the Medicare Rx General 2 Screen: "Do you offer free Generics up to a maximum amount?" and "Enter maximum amount of free Generics:"

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Question is no longer needed in the PBP.

IMPACT ON BURDEN: Decreased Impact on burden

15. The following label has been removed from the Medicare Rx General 2 Screen: "Scenario 2: If your plan offers a \$0 copay for the first fill of a limited number of generic medications, you should only answer 'yes' to the question 'Do you offer a free first fill for any drugs?' and indicate these specific medications in a flat file which will be uploaded through the Formulary Submission Module on June 8, 2009."

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Label is no longer applicable

IMPACT ON BURDEN: No Impact on burden

16. The following question has been added to the Medicare Rx General 2 Screen: “Do you prorate cost sharing for partial fills of new prescriptions to provide a 'trial supply' of a new medication?” This question will be enabled for Enhanced Alternative, Basic Alternative, and Actuarially Equivalent Standard plans.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To determine which plans prorate for partial fills ofr beneficiaries trying new medications.

IMPACT ON BURDEN: Minor Impact on burden for Enhanced Alternative, Basic Alternative, and Actuarially Equivalent Standard plans.



## CY2011 PBP/Formulary List of Changes

17. The following label has been added to the Medicare Rx General 2 Screen: “Prorating cost sharing refers to a reduction in the cost share of a new prescription for a new medication not previously taken by the beneficiary, for which the beneficiary is only getting a partial fill for reasons such as determining tolerability to the new medication. This does not refer to scenarios where the pharmacy is out of stock of the new medication and therefore can only supply a partial fill or the beneficiary can only afford a partial fill at the time of dispensing.”

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To clarify the prorated

IMPACT ON BURDEN: No Impact on burden

18. The response for the question “Do you offer national prescription coverage?” on the Medicare Rx General 2 Screen has been changed from “Yes, the beneficiary can use this plan to get their prescription drugs in any of the 50 states” to “Yes, the beneficiary can use this plan to get their prescription drugs nationally”

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 2

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 2

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To clarify that the definition of national coverage includes more than the 50 US states.

IMPACT ON BURDEN: No Impact on burden

19. For EA plans indicating they are offering reduced cost share pre-ICL a new validation has been added so that they either 1) cannot select that they are offering the Medicare-Defined part D coinsurance amount pre-ICL, or 2) if the plan selects they have cost share tiers and have coinsurance pre-ICL, at least one coinsurance amount must be less than 25%.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx Section

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s):

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To ensure organizations are answering questions consistently throughout the PBP.

IMPACT ON BURDEN: No Impact on burden

20. On the Alternative-Pre-ICL Tier Label Screens the question- “Tier Includes:” answers have been modified to “Part D Drugs Only,” “Excluded Drugs Only,” and “Both Part D and Excluded Drugs,”

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Pre-ICL Tier Label Screens

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 6

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To clarify which drugs are being covered in the given tier.

## CY2011 PBP/Formulary List of Changes

IMPACT ON BURDEN: No Impact on burden

21. On the Alternative-Pre-ICL Tier Label Screens if the plan indicates that the tier includes Part D Drugs Only or includes both Part D and Excluded drugs then the question “Injectable Drug Only Tier?” will be enabled.

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Pre-ICL Tier Label Screens

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 6

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: CMS previously has not been able to determine which tiers are injectable only tiers.

IMPACT ON BURDEN: Minor Impact on burden

22. The tier names will now be standardized based on the drug type(s) selected in the tier.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section Rx Tiers

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 6

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Provides consistent description of tiers across organizations and helps beneficiaries compare plans.

IMPACT ON BURDEN: No Impact on burden

23. There is a new validation for tier drug types to allow for a general description of generic and/or brand coverage or a specific preferred/non-preferred description of generic and/or brand coverage, but not both.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section Rx Tiers

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 6

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Because the Tier names are now being standardized.

IMPACT ON BURDEN: No Impact on burden

24. The Limited Gap questions and their labels have been removed from the Alternative - ICL screen.

SOURCE: Internal

PBP SCREEN/CATEGORY: Section Rx Gap Tiers

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 22

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Confusion as to what this benefit is; no plans offered the benefit in previous years.

IMPACT ON BURDEN: Decrease on burden

25. The following questions and associated labels have been removed from the Alternative-Gap Coverage Screen: “Describe the gap coverage your plan offers for Generic drugs:” and “Describe the gap coverage your plan offers for Brand drugs:”

## CY2011 PBP/Formulary List of Changes

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Gap Coverage

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 23

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: The gap coverage will be determined based on the number of drugs covered in the formulary during the gap phase of the benefit.

IMPACT ON BURDEN: Decrease on burden

26. The following question has been added to the Alternative - Gap Coverage Screen to identify which tiers offer gap coverage: "Select the tiers that include gap coverage (select all that apply)." The plan may only enter gap tier information for the tiers selected on this page. All unselected tiers will be disabled in the subsequent gap tier screens.

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Gap Coverage

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 23

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To identify which tiers offer gap coverage

IMPACT ON BURDEN: Minor impact on burden

27. The following question will be enabled on the Alternative - Gap Coverage Screen if a plan answered 'yes' to "Do you offer Gap Coverage" AND if the plan identified that for any tier they were covering a combination of Part D drugs and Excluded drugs on a single tier: "Are you offering any excluded drugs as part of your gap coverage?"

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Gap Coverage

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 23

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To help clarify if both Part D and excluded drugs are being offered on the tier, or if only Part D covered drugs are being covered.

IMPACT ON BURDEN: Minor increase on burden

28. The questions "Is the member cost share for any drugs in this tier less than 100%?" and "Are all drugs on this tier covered through the gap?" on the Alternative – Gap Tier Coverage Screens have been merged into the single question "To what extent are Pre-ICL covered drugs on tier #[prepopulate number] covered through the gap?" The answers for this question are "All drugs on this tier are covered through the gap (Full Tier Gap Coverage)" or "Some drugs from this tier are covered through the gap (Partial Tier Gap Coverage).

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Gap Tier Coverage Screens

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 23

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Re-worded the question and simplified the possible answers.

IMPACT ON BURDEN: Decrease on burden

## CY2011 PBP/Formulary List of Changes

29. The following labels have been added to the Alternative – Gap Tier Coverage Screens to go along with the new question “To what extent are Pre-ICL covered drugs on tier #[prepopulate number] covered through the gap?”: “The gap coverage supplemental file may not include any drugs from a tier that is fully covered in the gap.” and “A gap coverage supplemental file must include formulary drugs from a tier that is partial covered in the gap. Excluded drugs covered in the gap cannot be included on the gap coverage supplemental files.”

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Gap Tier Coverage Screens

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 26

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To explain the new question “To what extent are Pre-ICL covered drugs on tier #[prepopulate number] covered through the gap?”

IMPACT ON BURDEN: No impact on burden

30. A character limit maximum of 225 has been added to the Section Rx Notes field.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx - Notes

DOCUMENT: PBP\_2011\_screenshots\_Medicare\_Rx\_Drugs\_2009\_12\_9

Page(s): 35

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Organizations should not need more than 225 characters to enter any additional benefits not collected in the standardized PBP data entry.

IMPACT ON BURDEN: No impact on burden

### **CY 2011 Formulary Changes**

#### Formulary File Record Layout Changes:

1. The permissible values for Tier Level have been changed from 1 – 10 to 1 – 6.

SOURCE: Internal

DOCUMENT AND PAGE NUMBER: CY 2011 Plan Formulary File Record Layout 091109

Page(s): 1

CITATION: 42 CFR 423.120

REASON WHY CHANGE IS NEEDED: Number of tiers allowed in a formulary has changed from 10 to 6.

IMPACT ON BURDEN: No Impact

#### Step Therapy Record Layout Changes:

1. A new field, ST\_Change\_Criteria\_Indicator has been added. Permissible values are: 0 – No changes from Cy2010, 1 – Includes Changes.

SOURCE: Internal

DOCUMENT AND PAGE NUMBER: CY 2011 Plan Step Therapy Record Layout 091109

Page(s): 1

CITATION: 42 CFR 423.120

REASON WHY CHANGE IS NEEDED: Improve the efficiency of the desk review process.

IMPACT ON BURDEN: Increase in burden

## CY2011 PBP/Formulary List of Changes

### Over the Counter Record Layout Changes:

1. UM\_Type Field has been added. Valid Values are 0 (General Drug UM) or 1 (Step Therapy).  
SOURCE: Internal  
DOCUMENT AND PAGE NUMBER: CY 2011 Plan Over the Counter Record Layout 091509  
Page(s): 1  
CITATION: 42 CFR 423.120  
REASON WHY CHANGE IS NEEDED: Identification of OTCs that are part of a step therapy protocol will ensure coordination with the step therapy criteria reviews. This coordination will reduce the number of OTC step therapy criteria review concerns plans receive and reduce erroneous OTC supplemental file submissions.  
IMPACT ON BURDEN: Increase in burden

2. Step\_Therapy\_Total\_Groups, Step\_Therapy\_Group\_Desc, and Step\_Therapy\_Step\_Value fields have been added. The Step Therapy information must match the information provided in the formulary submission.  
SOURCE: Internal  
DOCUMENT AND PAGE NUMBER: CY 2011 Plan Over the Counter Record Layout 091509  
Page(s): 1  
CITATION: 42 CFR 423.120  
REASON WHY CHANGE IS NEEDED: Identification of OTCs that are part of a step therapy protocol will ensure coordination with the step therapy criteria reviews. This coordination will reduce the number of OTC step therapy criteria review concerns plans receive and reduce erroneous OTC supplemental file submissions.  
IMPACT ON BURDEN: Increase in burden

### Excluded Drug Record Layout Changes:

1. The permissible values for Tier\_Level have been changed from 1 – 10 to 1 – 6.  
SOURCE: Internal  
DOCUMENT AND PAGE NUMBER: CY 2011 Plan Excluded Drugs Record Layout 091109  
Page(s): 1  
CITATION: 42 CFR 423.120  
REASON WHY CHANGE IS NEEDED: Number of tiers allowed in a formulary has changed from 10 to 6.  
IMPACT ON BURDEN: No Impact