

# CY2012 PBP/Formulary List of Changes

## CY 2012 PBP Changes

### General

1. The ESRD I plan type questions have been removed throughout the PBP.

SOURCE: Policy

PBP SCREEN/CATEGORY: 1a: Inpatient Hospital-Acute - Base 9, 1b: Inpatient Hospital Psychiatric - Base 9, 2: SNF - Base 6, 11a: DME - Base 2, 11b: Prosthetics/Medical Supplies - Base 3

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

PAGE(s): 9, 23, 35, 105, 108

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: ESRD I plan types will not exist for 2012.

IMPACT ON BURDEN: No Impact

2. The supplemental formulary file upload date has been updated to April 18, 2011 throughout the PBP.

SOURCE: Internal

PBP SCREEN/CATEGORY: B-15: Part C Home Infusion Bundled Services, B-20: Part C Home Infusion Bundled Services, Throughout the Rx Section.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf, and

PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

PAGE(s): PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf: 153, 198;

PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf: 2, 3, 17

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To reflect the 2012 deadline.

IMPACT ON BURDEN: No Impact

### 3. Cost Share Limitations:

Add an edit rule in PBP 2012 that includes the ALL MA cost share limitations, including the following criteria.

- Service category level deductibles and cost sharing are included in the calculation
- Both service specific max enrollee out of pocket cost AND plan level max enrollee out of pocket cost values are included in the calculation.

For purposes of illustration, CY 2011 values are used in table below. **2012 values TBD.**

Category	Voluntary	Mandatory
Physician Mental Health	45% or \$40 co-pay	45% or \$40 co-pay
Renal Dialysis – 156 visits	\$4,216 If coinsurance, then calculate percentage of \$135 (TBD for 2012).	\$4,216 If coinsurance, then calculate percentage of \$135 (TBD for 2012).
Part B Drugs-Chemotherapy	20% or \$75 co-pay	20% or \$75 co-pay
Therapeutic Radiation	20% or \$55 co-pay	20% or \$55 co-pay
Part B Drugs-Other	20% or \$50 co-pay	20% or \$50 co-pay

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DME-Equipment	N/A	20% No threshold for copayment – manual review.
DME-Prosthetics	N/A	20% No threshold for copayment – manual review.
DME-Medical Supplies	N/A	20% No threshold for copayment – manual review.
DME-Diabetes Monitoring Supplies	N/A	20%/ \$10
Home Health – 37 Days	\$1,110 If coinsurance, then calculate percentage of \$141 (TBD for 2012).	0

There is a requirement to enforce the following cost share limitations. For purposes of illustration, CY 2011 values are used in table below. **2012 values TBD.**

Service Category	Voluntary MOOP	Mandatory MOOP
Inpatient – 60 Days <sup>1</sup>	N/A	\$3,935
Inpatient – 10 Days <sup>1</sup>	\$2,231	\$1,785
Inpatient – 6 Days <sup>1</sup>	\$2,016	\$1,613
Mental Health Inpatient-60 Days <sup>1</sup>	\$2,471	\$1,977
Mental Health Inpatient-15 Days <sup>1</sup>	\$2,156	\$1,796
SNF-First 20 days <sup>2</sup>	\$100/day	\$50/day
SNF-Days 21-100 <sup>2</sup>	\$143/day	\$143/day

SOURCE: Internal

PBP SCREEN/CATEGORY: throughout

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_2010\_12\_03.pdf

Page(s):throughout

CITATION: CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To prevent plans from submitting bids that do not meet MA cost share requirements.

IMPACT ON BURDEN: Low Impact

### **PBP Section A**

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1. On the Section A-5 Screen the following 'Yes/No' questions have been added to the Section A-5 screen: 'Is your organization filing a standard bid for Section B of the PBP?', 'Is your organization filing a standard bid for Section C of the PBP?', and 'Is your organization filing a standard bid for Section D of the PBP?'

SOURCE: Internal

PBP SCREEN/CATEGORY: Section A-5

DOCUMENT: PBP\_2012\_screenshots\_section\_a\_\_2010\_12\_03.pdf

Page(s): 5

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To allow a plan to indicate that it is submitting a Fee for Service (FFS) bid.

IMPACT ON BURDEN: Low Impact for plans not submitting a FFS bid, lowers the impact for a plan that is submitting a FFS bid.

### **PBP Section B**

1. The periodicity questions throughout Section B of the PBP have been updated to include only the following options: 'Every Year,' 'Every six months,' and 'Every three months.'

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B in the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf,

PBP\_2012\_screenshots\_section\_c\_\_2010\_12\_03.pdf, PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf: 2, 15, 31, 41-42, 45, 49, 52, 54, 57, 60, 64, 66, 68, 71, 74, 76, 79, 81, 85, 88, 91, 94, 97, 99, 101, 102, 104, 106, 109, 111, 113, 119, 122, 125, 129-133, 140, 144, 147, 150, 185; PBP\_2012\_screenshots\_section\_c\_\_2010\_12\_03.pdf: 13-14, 17, 26;

PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf: 13-14, 20, 24, 28, 31-32.

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Eliminates the option of offering a periodicity over 1 year.

IMPACT ON BURDEN: No Impact

2. The on-screen label that reads 'You must include total cost sharing to the beneficiary' has been moved so that it is before the Medicare-covered cost sharing data entry for the applicable service categories.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B in the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 64, 79, 82, 85, 88, 91, 95, 111, 133, 141, 144

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To clarify the intent of the cost share question that now follows.

IMPACT ON BURDEN: No Impact

3. The minimum and maximum data entry questions for coinsurance and copay have been removed and replaced with a single data entry point for the following categories: 'B-5: Partial Hospitalization,' 'B-7c: Occupational Therapy Services,' 'B-13a: Acupuncture,' 'B-13d: Other 1,' and 'B-13e: Other 2.'

SOURCE: Internal

PBP SCREEN/CATEGORY: Sections B-5: Partial Hospitalization, B-7c: Occupational Therapy Services, B-13a: Acupuncture, B-13d: Other 1, and B-13e: Other 2

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 52-53, 64, 114, 123, 126

CITATION: 42 CFR 422.256

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REASON WHY CHANGE IS NEEDED: There is no need for minimum and maximum cost sharing in these sections.  
IMPACT ON BURDEN: Lessens Impact

4. An edit rule has been implemented which will prohibit plans from entering both a coinsurance AND copayment for certain Medicare-covered and Supplemental Services.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B of the PBP

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 2-9, 12-13, 16-23, 27-28, 31-35, 38-39, 42-43, 46-47, 49-50, 52-55, 57-58, 61-62, 66, 69, 72, 74, 77, 85-86, 97-98, 102-104, 106-107, 111, 114, 117, 120, 123, 126, 133-137, 141-142, 144-145, 147-148, 150-151, 156-157, 162-163, 166-167, 171-172, 175-176, 180-181, 185-186, 189, 191, 193, 195, 197

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Eliminates the option of offering a periodicity over 1 year.

IMPACT ON BURDEN: Low Impact

5. The following label has been added to certain sections of the PBP: 'Tiered Cost Sharing for Medical Benefits is not allowed. Cost sharing tiers may not be based on the provider group an enrollee selects within an MA plan. (See Chapter 4, Section 10.10). Basing a plan's cost sharing on the physician group a member selects has the effect of creating multiple MA plans within one MA plan, and therefore conflicts with the uniformity of premium and cost sharing requirement (see 42 CFR section 422.100(d)(2)).'

SOURCE: Internal

PBP SCREEN/CATEGORY: 1a Inpatient Hospital-Acute – Base 10, 1b Inpatient Hospital Psychiatric – Base 10, 8a: Outpatient Diagnostic Procedures/Tests/Lab Services – Base 4, 8b: Outpatient Diagnostic/Therapeutic Radiation Services – Base 3, 11a DME – Base 2, 11b Prosthetics/Medical Supplies – Base 3, 11c Diabetic Supplies and Services – Base 2

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 10, 24, 84, 87, 105, 108, 110

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To inform a plan that it cannot offer Tiered Cost Sharing.

IMPACT ON BURDEN: No Impact

6. The separate office visit cost share questions have been updated to read 'separate physician/professional service' instead of 'office visit' where these questions are applicable.

SOURCE: Internal

PBP SCREEN/CATEGORY: B-8a: Outpatient Diagnostic Procedures/Tests/Lab Services – Base 3, B-8b: Outpatient Diagnostic/Therapeutic Radiation Services – Base 2, B17a: Eye Exams – Base 3

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 83, 86, 167

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Physician/professional service is a more accurate description.

IMPACT ON BURDEN: No Impact

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

1. The following question has been removed for Inpatient Hospital Services: 'Does the cost sharing vary based on hospital network'

SOURCE: Policy

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

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 9

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CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Eliminates discriminatory cost sharing based on hospital network location.

IMPACT ON BURDEN: Lessens Impact

### **B-2: Skilled Nursing Facility (SNF)**

1. Cost share limitations are being enforced in the PBP for SNF based on whether a plan is offering a Mandatory or Voluntary Maximum Out-of-Pocket (MOOP) amount. (Release 4, 4244)

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B-2: Skilled Nursing Facility (SNF) and Section D – All of the MOOP Screens

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf, and

PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf: 31-35;

PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf: 8-12, 14

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To prohibit plan users from entering cost sharing that will not be accepted by CMS review staff.

IMPACT ON BURDEN: Low Impact

### **B-3: Cardiac and Pulmonary Rehabilitation Services**

1. Comprehensive Outpatient Rehabilitation Facility (CORF) has been deleted from the PBP entirely.

SOURCE: Internal

PBP SCREEN/CATEGORY: B-3: Cardiac and Pulmonary Rehabilitation Services.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 41-44

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Rehabilitation services data entry is performed elsewhere in the PBP.

IMPACT ON BURDEN: Lessens Impact

2. Cardiac and Pulmonary Rehabilitation Services has been moved and renamed from B-9d: Cardiac Rehabilitation Services. This benefit has been broken down into three Medicare-covered components and three enhanced benefits, with benefit limit and cost sharing questions for all of these benefits as well.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-3: Cardiac and Pulmonary Rehabilitation Services.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 41-44

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Clarifies the data entry and corresponding Summary of Benefit descriptions of these rehabilitation services.

IMPACT ON BURDEN: Medium Impact

### **B-6: Home Health Services**

1. The respite benefit has been removed from B6.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-6: Home Health Services.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 54-56

CITATION: 42 CFR 422.256

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REASON WHY CHANGE IS NEEDED: Enhanced benefits will no longer be available for this category. IMPACT ON BURDEN: Lessens Impact

### **B-7: Health Care Professional Services and B-9c: Outpatient Substance Abuse**

1. The cost sharing intervals have been removed and replaced with a minimum and maximum coinsurance and copay questions.

SOURCE: Policy

PBP SCREEN/CATEGORY: Throughout B-7e: Mental Health Specialty Services, B-7h: Psychiatric Services, and B-9c: Outpatient Substance Abuse

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 69, 77, 95

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Cost Sharing intervals are not needed for these categories.

IMPACT ON BURDEN: Lessens Impact

### **B-9d: Outpatient Blood Services**

1. Outpatient Blood Services, which previously resided in B-13a, now resides in B-9d.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-9d: Outpatient Blood Services

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 97-98

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Blood Services moved to a more logical grouping with Outpatient Services, from the other supplemental services section.

IMPACT ON BURDEN: No Impact

2. On the Base 1 screen, the following label has been added: 'If blood is given as a part of an inpatient hospital stay, the cost sharing for the blood should be included in the inpatient hospital cost sharing.'

SOURCE: Internal

PBP SCREEN/CATEGORY: = B-9d: Outpatient Blood Services – Base 1

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 97

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To clarify that this benefit is only for outpatient blood Services, not inpatient services.

IMPACT ON BURDEN: No Impact

3. On the Base 1 screen the following question has been updated from: 'Indicate Coinsurance percentage for Medicare-covered Benefits' To: 'Indicate Coinsurance percentage per unit for Medicare-covered benefits.'

SOURCE: Internal

PBP SCREEN/CATEGORY: B-9d: Outpatient Blood Services – Base 1

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 97

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Clarifies the intent of the question.

IMPACT ON BURDEN: No Impact

### **B-11c: Diabetic Supplies and Services**

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1. 'Diabetes Monitoring Supplies' has been renamed to 'Diabetic Supplies and Services.' This benefit has been expanded to include two Medicare-covered components, with cost sharing questions added for both components.

SOURCE: Internal

PBP SCREEN/CATEGORY: throughout B-11c: Outpatient Blood Services

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 109-110

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To include data collection of Diabetic Therapeutic Shoes or Inserts.

IMPACT ON BURDEN: Low Impact

### **B-12: End-Stage Renal Disease**

1. Cost share limitations are being enforced in the PBP for End-Stage Renal Disease based on whether a plan is offering a Mandatory or Voluntary Maximum Out-of-Pocket (MOOP) amount.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B-12: End-Stage Renal Disease and Section D – All of the MOOP Screens

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 111

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED:

To prohibit plan users from entering cost sharing that will not be accepted by CMS review staff.

IMPACT ON BURDEN: Low Impact

### **B-13: Other Supplemental Services**

2. The title of Section B-13 has been updated to 'Other Supplemental Services' and the subcategories have been updated to the following: B-13a: Acupuncture, B13b: OTC, B13c: Meal Benefit, B-13d: Other 1, B-13e: Other 2.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B-13: Other Supplemental Services

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 113-127

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Blood Services was moved to B-9d, this change shifted the remaining categories up.

IMPACT ON BURDEN: No Impact

### **B13b: OTC**

1. All periodicity questions have been updated on the Base 1 screen to include only the following options: 'Every Year,' 'Every six months,' 'Every three months,' and 'Every month.'

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B-13b: OTC

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 116

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Users will no longer be able to enter in 'other' for any periodicities throughout the PBP.

IMPACT ON BURDEN: No Impact

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### **B-13d: Other 1 and B-13e: Other 2**

On the Base 1 screen for both categories, the following question has been changed from blue to red:  
'Enter name of Service (Optional): '

SOURCE: Internal

PBP SCREEN/CATEGORY: 13d: Other 1 – Base 1, B13e: Other 2 – Base 1

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 122, 125

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: The information provided for this field will now be used to generate sentences in the Summary of Benefits.

IMPACT ON BURDEN: No Impact

### **B-14: Preventive Services**

1. The Preventive Services Category has been revised to include Preventive Services that must be offered at Zero Dollar Cost sharing. As a result, the number of sub-categories has been reduced from ten (10) to the following five (5): '14a: Medicare-covered Zero Cost-Sharing Preventive Services,' '14b: Supplemental Preventive Health Benefits,' '14c: Supplemental Education/Wellness Programs,' '14d: Kidney Disease Education Services,' and '14e: Diabetes Self-Management Training.'

SOURCE: Policy

PBP SCREEN/CATEGORY: Throughout Section B-14: Preventive Services

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 128-149

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Preventive services must be offered at zero dollar cost sharing.

IMPACT ON BURDEN: Significantly lessens Impact

### **B-14a: Medicare-covered Zero Cost-Sharing Preventive Services**

1. B-14a consists of the following Attestation statement and a list of the Medicare-covered services that must be offered at zero dollar cost sharing: 'An "Attestation" statement along with a list of Medicare-covered Preventive Services has been added to 14a. The statement reads 'I attest that there is no coinsurance, copayment, or deductible for the following In-Network Medicare-covered Preventive Services'. Organizations must check the box beside the statement to indicate they cover the following Medicare-covered Preventive Services at Zero Dollar Cost-Sharing'

SOURCE: Policy

PBP SCREEN/CATEGORY: B-14a: Medicare-covered Zero Cost-Sharing Preventive Services

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 128

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Medicare covered preventive services must be offered at zero dollar cost sharing.

IMPACT ON BURDEN: Lessens Impact

### **B-14b: Supplemental Preventive Health Benefits**

1. 14b consists of the following enhanced benefits only (No Medicare-covered Benefits) with cost sharing data entry for each one: 'Other Immunizations,' 'Additional Physical Exams,' 'Additional Pap Smears,' 'Additional Pelvic Exams,' 'Additional Prostate Exams,' 'Additional Colorectal Exams,' and 'Additional Mammography Exams.'

SOURCE: Policy

PBP SCREEN/CATEGORY: B-14b: Supplemental Preventive Health Benefits



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DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 129-138

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: The enhanced benefits that may be offered from the Medicare-covered preventive services that must be offered at zero dollar cost sharing are now combined in one section.

IMPACT ON BURDEN: Lessens Impact

2. Physician/Professional Services cost sharing data entry has been included for Mammography and Colorectal screenings only.

SOURCE: Internal

PBP SCREEN/CATEGORY: B-14b: Supplemental Preventive Health Benefits – Base 8, & Base 9

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 136-137

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: These are the only two enhanced benefits for which separate cost sharing may apply.

IMPACT ON BURDEN: Lessens Impact

### **B-14c: Supplemental Education/Wellness Programs**

1. B-14c now consists of the following enhanced benefits only (No Medicare-covered Benefits), with cost sharing data entry for each one: 'Written Health Education Materials, incl. Newsletters,' 'Nutritional Benefit,' 'Additional Smoking Cessation,' 'Membership in Health Club/Fitness Classes,' and 'Nursing Hotline.'

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-14c: Supplemental Education/Wellness Programs

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 139-143

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: The Medicare-covered Preventive services offered at zero dollar cost sharing was moved to section B-14a, and B-14b is their enhanced benefits. These additional enhanced benefits logically follow in this section.

IMPACT ON BURDEN: No Impact

### **B-14d: Kidney Disease Education Services**

1. 14d now consists of Medicare-covered Kidney Disease Education Services with no enhanced benefits, along with minimum/maximum cost sharing data entry.

SOURCE: Policy

PBP SCREEN/CATEGORY: Throughout B-14d: Kidney Disease Education Services

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 144-146

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Created data entry screens for this Medicare-covered service.

IMPACT ON BURDEN: Low Impact

### **B-14e: Diabetes Self-Management Training**

1. 14e now consists of Medicare-covered Diabetes Self-Management Training with no enhanced benefits, which previously resided in 14i and was named Diabetes Monitoring.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-14 e: Diabetes Self-Management Training

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

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Page(s): 147-149

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: This service was shifted up in the PBP because other categories were merged into B-14a, and B-14b.

IMPACT ON BURDEN: No Impact

### **B-15: Medicare Part B Rx Drugs and B-20: Prescription Drugs**

1. Cost share limitations are being enforced in the PBP for Medicare Part B Rx Drugs based on whether a plan is offering a Mandatory or Voluntary Maximum Out-of-Pocket (MOOP) amount.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section B-15: Medicare Part B Rx Drugs and Section D – All of the MOOP Screens

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 150-151

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To prohibit plan users from entering cost sharing that will not be accepted by CMS review staff.

IMPACT ON BURDEN: Low Impact

### **B-16: Dental, B-17: Eye Exams/Eye Wear, B-18: Hearing Exams/Hearing Aids**

1. All periodicity questions have been updated throughout the Dental, Eye Exams/Eye Wear, and Hearing Exams/Hearing Aids sections of the PBP to include the following options: 'Every three years,' 'Every two years,' 'Every Year,' 'Every six months,' 'Every three months,' and 'Other.'

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-16: Dental Section of the PBP, B-17: Eye Exams/Eye Wear, and B-18: Hearing Exams/Hearing Aids Sections.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf,

PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf: 154-156, 159-161, 165, 168-171, 174-175, 178-180; PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf: 34-36, 39-41, 45, 48-51, 54-55, 58-60

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: To allow plan users a three year option.

IMPACT ON BURDEN: Low Impact

2. The following field has been added for Dental and Hearing Benefits: 'Does the Maximum Plan Benefit Coverage amount apply to In-network services only OR does it apply to both In-network and Out-of-network services?'

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-16a: Preventive Dental – Base 2, B-16b: Comprehensive Dental – Base 3, B-18a: Hearing Exams – Base 2, B-18b: Hearing Aids – Base 2

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 155, 161, 175, 179

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Clarifies if the Maximum Plan Benefit Coverage amount applies In-Network or both In and Out-of-network.

IMPACT ON BURDEN: Low Impact

3. The separate office visit cost sharing questions have been removed for dental services, Eye Exams, and Eye Wear.

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SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout B-16: Dental, and B-17: Eye Exams/Eye Wear Sections of the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_b\_\_2010\_12\_03.pdf

Page(s): 154-173

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: A separate office visit cost is not applicable for this category.

IMPACT ON BURDEN: Lessens Impact

### **PBP Section C**

1. Separate 'Physician/Professional Services' data entry questions have been added to the Section C groups. Only a Copayment or a coinsurance may be chosen for these fields and these fields will be enabled if any of the following are chosen: '8a: Outpatient Diagnostic Procedures and Test and Lab Services,' '8b: Outpatient Diagnostic and Therapeutic Radiological Services,' '14b: Supplemental Preventive Health Services,' '16b: Comprehensive Dental,' or '17a: Eye Exams.'

SOURCE: Internal

PBP SCREEN/CATEGORY: On the Group screens in Section C of the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_c\_\_2010\_12\_03.pdf

Page(s): 12, 26

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Separate Physician/Professional Services are only applicable to these categories, this change allows users to provide cost sharing information Out-of-Network, since it is present In-Network.

IMPACT ON BURDEN: Low Impact

### **Out-of-Network**

1. A validation rule has been added which will prohibit plans from entering both a coinsurance AND copayment for any Inpatient Hospital Service, SNF stay, or OON Group that includes any of the service categories that do not allow both to be chosen In-Network.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the C-OON Section of the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_c\_\_2010\_12\_03.pdf

Page(s): 4-9, 11-12, 18-23, 25-26

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: A service cannot contain cost sharing with both a coinsurance and copayment Out-of-Network if they cannot In-Network.

IMPACT ON BURDEN: Low Impact

### **Visitor/Travel**

1. All PBP data entry for US V/T has been removed except for the following two questions: 'Do you offer a US V/T program?' AND 'Select the type of benefit the US V/T program:'

SOURCE: Policy

PBP SCREEN/CATEGORY: Throughout the C-V/T Section of the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_c\_\_2010\_12\_03.pdf

Page(s): 21

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: The other data entry is unnecessary.

IMPACT ON BURDEN: Lessens Impact

### **PBP Section D**

## CY2011 PBP List of Changes

1. All of the Non-Medicare pick lists in Section D have been updated to include all of the PBP categories that have a supplemental component.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout Section D of the PBP.

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 1-3, 7-13

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Updates the pick lists with the new structure of the PBP.

IMPACT ON BURDEN: No Impact

2. On the Plan Deductible (Combined) and (In-Network) Screens, a validation has been added ensuring that B14a is not included in their Medicare-covered deductible.

SOURCE: Policy

PBP SCREEN/CATEGORY: Deductible (Combined) and (In-Network) screens

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 1-3

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Prevents a plan from including the Medicare-covered preventive services offered at zero dollar in a plan's deductible.

IMPACT ON BURDEN: No Impact

3. The following label has been updated on the Max Enrollee Cost Limit (Combined) Base -1 screen: 'All MA plans must have a maximum out-of-pocket (MOOP) that covers all A/B services. For a list of the Voluntary and Mandatory Limits, please right-click on the "Is your Combined Maximum Enrollee Out-of-Pocket (MOOP) Cost at the Voluntary or Mandatory level?" question and view the Variable Help.'

SOURCE: Policy

PBP SCREEN/CATEGORY: Max Enrollee Cost Limit (Combined) - Base 1 screen

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 8

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Clarifies to users where to find guidance on the new Voluntary and Mandatory limits.

IMPACT ON BURDEN: No Impact

4. The following label has been removed from the Max Enrollee Cost Limit (Combined) Base -1 screen: 'For Regional PPOs, all Medicare Part A/B services must be included in the Maximum Enrollee Out-of-Pocket Cost.'

SOURCE: Policy

PBP SCREEN/CATEGORY: Max Enrollee Cost Limit (Combined) - Base 1 screen

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 8

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: This label is no longer applicable.

IMPACT ON BURDEN: No Impact

5. On the Max Enrollee Cost Limit screens a new edit rule has been implemented to prevent an organization from uploading a bid without entering a 2012 Maximum Out of Pocket (MOOP) Cost. This rule applies to all plan types, with the exception of 1876 COST plans and MSAs. B-only plans do not have to cover B1a, B1b, or B2 in order to meet this MOOP requirement. An organization will now indicate if it is offering a Voluntary or Mandatory MOOP. If voluntary, the value can be from \$0-\$3400 in-network and from \$0-\$5100 combined. If mandatory, the value should be from \$3401 - \$6700 in-network and from \$5101 - \$10,000 combined.

## CY2011 PBP List of Changes

SOURCE: Policy

PBP SCREEN/CATEGORY: Max Enrollee Cost Limit screens

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 8-12

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: All plans must enter a MOOP.

IMPACT ON BURDEN: Low Impact

6. A validation rule has been added which will prohibit plans from entering both a coinsurance AND copayment for any Optional Supplemental Package that includes any of the service categories that do not allow both to be chosen In-Network.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the Optional Supplemental Screens in the PBP

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 21-62

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: If both a coinsurance and copay cannot be chosen In-Network, they cannot be chosen in an Optional package.

IMPACT ON BURDEN: Low Impact

7. An exit validation rule has been implemented that will not allow a plan to include a PBP category in the Non-Medicare pick list if they do not offer a mandatory supplemental benefit In-Network for the given service category.

SOURCE: Policy

PBP SCREEN/CATEGORY: Throughout Section D of the PBP

DOCUMENT: PBP\_2012\_screenshots\_section\_d\_\_2010\_12\_03.pdf

Page(s): 1, 3, 8, 10, 12-13

CITATION: 42 CFR 422.256

REASON WHY CHANGE IS NEEDED: Clarifies the relationship between services that are not chosen In-Network and supplemental packages.

IMPACT ON BURDEN: Low Impact

### **PBP Section Rx**

1. On the Medicare Rx General 1 screen, the following labels have been added after the field 'Select the type of drug benefit:' 'The standard generic gap coverage benefit of 14% for 2012 and the coverage gap brand discount applies to all benefit types and should be reflected in the bid; however, this information is not entered in the PBP. Only those enhanced plans who wish to offer 'additional' gap coverage over and above the standard benefit for generics and before applying the gap coverage discount for brand drugs, should enter this information in the gap coverage section of the PBP.' and 'Excluded drug only tiers must be assigned the highest tier value(s) of all tiers offered by this plan.' Add an edit rule that organizations may ONLY offer 1 excluded drug only tier.

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To inform the plan users how the standard gap coverage benefit is applied.

IMPACT ON BURDEN: No Impact

## CY2011 PBP List of Changes

2. The following question has been added on the Medicare Rx General 1 screen: 'Are any of your tiers an excluded drug only tier?'

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Allows a plan that offers Medicare defined cost sharing Pre-ICL or Post OOP the ability to provide separate cost sharing for an excluded drug only tier.

IMPACT ON BURDEN: Low Impact

3. The word 'supplemental' has been added to the following question on the Medicare Rx General 1 screen: 'Does this EA plan have a zero dollar Part D supplemental 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

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Clarifies the question.

IMPACT ON BURDEN: No Impact

4. On the Medicare Rx General 3 screen the following question has been updated from: 'Do you prorate cost sharing for partial fills of a new prescription to provide a 'trial supply' of a new medication?' To: 'Do you prorate cost sharing for partial fills of a new prescription to provide a 'trial supply' of a new medication? (Only select yes if you and your processor can implement prorated cost sharing)

SOURCE: Internal

PBP SCREEN/CATEGORY: Medicare Rx General 1

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Clarifies the question.

IMPACT ON BURDEN: No Impact

5. The 'Alternative-Excluded Drugs and Pre-ICL' screen has been renamed to 'Enhanced Alternative Characteristics' and the questions have been reordered.

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Enhanced Alternative Characteristics screen

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 17

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: To provide a cleaner data entry experience for Enhanced Alternative offerings.

IMPACT ON BURDEN: Low Impact

6. The option 'reduced gap coverage cost shares' has been removed from the answers for the following question: 'Indicate the area(s) throughout the Part D benefit where the reduced Part D cost sharing is reflected (select all that apply):'

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Enhanced Alternative Characteristics screen

## CY2011 PBP List of Changes

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 17

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: This option is no longer applicable in this list, users indicate reduced gap coverage cost shares elsewhere in the PBP.

IMPACT ON BURDEN: No Impact

7. The Alternative Gap Coverage section will only be enabled if 'Yes' is answered to the question 'Do you offer additional gap coverage as part of your supplemental benefit?' on the 'Alternative-Enhanced Alternative Characteristics' screen.

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Enhanced Alternative Characteristics screen, and Alternative Gap Coverage Section

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 17, 26-33

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: The question was moved to the Alternative-Enhanced Alternative Characteristics screen.

IMPACT ON BURDEN: No Impact

8. The following label has been added to the 'Alternative – Enhanced Alternative Characteristics screen after the question 'Do you offer additional gap coverage as part of your supplemental benefit?': 'Additional gap coverage offered by enhanced alternative plans through a supplemental benefit represents coverage that is significantly greater than the standard benefit for generic drugs and provides for additional savings on brand drugs that are applied before the coverage gap discount. The additional gap coverage entered in the PBP will be inclusive of the standard benefit (14% reduction in beneficiary cost-sharing in 2012) for generic drugs, but will be in addition to the coverage gap discount for brand drugs. For example, if a sponsor enters beneficiary cost-sharing of 30% for tier 1 generic drugs in the coverage gap, the standard generic gap benefit would be satisfied and included in the 70% reduction in cost-sharing provided through the supplemental benefit. In contrast if a sponsor enters beneficiary cost sharing of 40% for tier 2 brands in the coverage gap, this supplemental benefit would be applied first to the plan-negotiated price of the brand drug, followed by the coverage gap discount of 50% to the remaining drug cost.'

SOURCE: Internal

PBP SCREEN/CATEGORY: Alternative-Enhanced Alternative Characteristics screen

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 17

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Clarifies for users what the standard Gap coverage includes.

IMPACT ON BURDEN: No Impact

9. The question 'How do you apply your cost sharing before the Initial Coverage Limit (ICL) is reached' has been moved to its own separate screen. For Actuarially Equivalent benefit types the new screen is: Actuarially Equivalent – Pre-ICL. For Basic and Enhanced Alternative benefit types the new screen is: Alternative – Pre-ICL.

SOURCE: Internal

PBP SCREEN/CATEGORY: Actuarially Equivalent – Pre-ICL, and Alternative – Pre-ICL

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 6, 18

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Clarifies the Pre-ICL data entry and mirrors the Post OOP threshold screen.

## CY2011 PBP List of Changes

IMPACT ON BURDEN: No Impact

10. A validation has been added for specialty tiers that if a plan chooses the "Lesser of Coinsurance and Copayment" cost sharing structure; and enters both a copayment and a coinsurance, the specialty tier coinsurance validations will apply, but there will be no validations applied against the copayment entered.

SOURCE: Policy

PBP SCREEN/CATEGORY: Throughout the Rx Tiers

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 10-12, 14, 16, 22-24, 31-33, 35

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Provides a guideline for proper cost share entry for Specialty Tiers.

IMPACT ON BURDEN: No Impact

11. An exit validation rule has been added which will prohibit plans from entering duplicative tier names.

- Tier 1 must include the term "generic" in the tier label (with or without the qualifier preferred or non-preferred).
- If two or more separate tier labels include the term 'generic,' then at least 1 tier label must include the term 'preferred generic' and at least one of the 'generic' labeled tiers must include the term 'non-preferred generic.' The separate 'preferred generic' tier must have a lower tier number than the tier with the 'non-preferred generic' label.
- If two or more separate tier labels include the term 'brand,' then at least 1 tier label must include the term 'preferred brand' and at least one of the 'brand' labeled tiers must include the term 'non-preferred brand.' The separate 'preferred brand' tier must have a lower tier number than the tier with the 'non-preferred brand' label.

SOURCE: Internal

PBP SCREEN/CATEGORY: Throughout the Rx Tiers

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 20, 28, 36

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Eliminates confusion when two or more tiers were created with the same name.

IMPACT ON BURDEN: Low Impact

12. Platino Plan Bids: any plan that is participating in Puerto Rico Platino Program may only submit as a basic plan benefit type, that is Defined Standard, Actuarially Equivalent or Basic Alternative. A Platino Plan may not submit as an Enhanced Alternative (EA) plan.

SOURCE: Internal

PBP SCREEN/CATEGORY: General Screen

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 1

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Eliminates prohibited data entry.

IMPACT ON BURDEN: Low Impact

13. Add a new validation that no tier can have 100% cost sharing in any phase of the benefit. Also, if any tier displays as 100% OR if any organization enters "greater of" copay and coinsurance and the coinsurance is 100%, the PBP software should prohibit this.

SOURCE: Internal

PBP SCREEN/CATEGORY: Cost share tiers



## CY2011 PBP List of Changes

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): throughout

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Eliminates errors in data entry.

IMPACT ON BURDEN: Low Impact

14. Add an edit rule:

Following the question: "Is there a maximum plan benefit coverage amount for excluded drugs?" the next question asks for you to indicate the amount. This question will allow an amount of 0.00 to be entered. A number needs to be required. The edit rule must verify the value entered must be greater than 1.

SOURCE: Internal

PBP SCREEN/CATEGORY: General Screens

DOCUMENT: PBP\_2012\_screenshots\_section\_RX\_Drugs\_\_2010\_12\_03.pdf

Page(s): 3

CITATION: 42 CFR 423.272

REASON WHY CHANGE IS NEEDED: Eliminates errors in data entry.

IMPACT ON BURDEN: Low Impact

### **Formulary Changes**

#### General

1. Plans will submit updates to Formulary, Prior Authorization (PA) Criteria, and/or Step Therapy (ST) Criteria by uploading files that contain revisions only. CMS will not accept full file submissions after the initial April submission period.

SOURCE: Internal

DOCUMENT: CY 2012 Plan Formulary Submission File Record Layout

CITATION: 42 CFR 423.120

REASON WHY CHANGE IS NEEDED: Removes the need to resubmit entire formulary files for changes

IMPACT ON BURDEN: High Impact

2. For CY2011, CMS will have the option to accept/reject individual items in a formulary revision. Plans will have the ability to accept or decline the resulting approved revisions.

SOURCE: Internal

DOCUMENT: CY 2012 Plan Formulary Submission File Record Layout

CITATION: 42 CFR 423.120

REASON WHY CHANGE IS NEEDED: Provides a cleaner review approach for organizations and CMS

IMPACT ON BURDEN: Medium Impact

3. Transition Policies will be uploaded via an on-line interface.

SOURCE: Internal

DOCUMENT: CY 2012 Plan Formulary Submission File Record Layout

CITATION: 42 CFR 423.120

REASON WHY CHANGE IS NEEDED: These policies were previously received via email.

IMPACT ON BURDEN: Medium Impact

#### Supplemental

## CY2011 PBP List of Changes

4. Supplemental Files - Gap, Free First Fill, Home Infusion, Over the Counter, and Excluded Drugs - will now be associated to a formulary ID instead of to a contract/plan. All of the plans associated with the given formulary must use the same supplemental file (i.e., offer the same supplemental benefits) or not cover the supplemental benefit.

SOURCE: Internal

PBP SCREEN/CATEGORY: General Screens

DOCUMENT: CY 2012 Plan Excluded Drug, Gap, Free First Fill, Home Infusion, Over the Counter record layouts

CITATION: 42 CFR 423.120

REASON WHY CHANGE IS NEEDED: Simplification of submission

IMPACT ON BURDEN: Medium Impact