CMS Part D Audit Report

Auditing Results (Public Website Version)

Date Report Generated: 9/30/2008

Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
Audit ID: 141
Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: MR06
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
Date Report Due: 6/18/2007
Element Accepted Date: 7/12/2007
Element Release Date: 8/1/2007
Element Projected Completion Date: 7/25/2007

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Plan Responsibility for Persons Employed or Contracted to Perform Marketing - The Part D sponsor must have a compensation structure that meets CMS requirements for any person directly employed or contracted to market the plan. The Part D sponsor must utilize only state licensed, certified, or registered individuals to perform marketing on behalf of the Part D sponsor, whether as an employee or under contract directly or downstream, if a state has such a marketing requirement, and it must conduct monitoring activities to ensure that individuals marketing on behalf of the Part D sponsor comply with all applicable Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines, to ensure that beneficiaries receive truthful and accurate information.

Reference:

Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

Deficiencies:

CMS reviewed policies and procedures, contracts, and compensation documents associated with marketing representatives and found that BCBSM does not meet this requirement. Documentation that BCBSM submitted does not confirm that BCBSM's marketing representatives are providing the written disclosure statement to all potential enrollees prior to or at the time of enrollment. The BCBSM samples cases for individuals who perform marketing did not meet the CMS compliance standard because CMS reviewed 10 cases out of a universe of 1582 and found 10 cases did not demonstrate that the appropriate persons were employed to perform marketing, specifically: -5 out of 10 cases did not demonstrate a compliant certification status, -4 out of 10 cases did not demonstrate a contractual relationship, -4 out of 10 cases did not demonstrate compliant incentive structure, -4 out of 10 cases did not demonstrate a provision prohibiting payments by person performing marketing to beneficiaries, -10 out of 10 cases did not demonstrate a provision for withholding/withdrawing payment if an enrollee disenrolls in an unreasonably short timeframe, -4 out of 10 cases did not demonstrate a provision requiring any person directly employed or contracted to market on behalf of the Part D sponsor provide a written disclosure statement to all potential enrollees prior to enrollment or at the time of enrollment, and -4 out of 10 cases did not demonstrate a provision for coordinating marketing.

Corrective Action Required:

BCBSM must provide CMS with evidence that marketing program monitoring activities confirm that BCBSM's marketing representatives are providing the written disclosure statement to all potential enrollees prior to enrollment or at the time of enrollment. BCBSM must also provide CMS with evidence that it has a current contract/ compensation structure in effect that includes the following provisions: - Any person directly employed or contracted to market on behalf of BCBSM must provide a written disclosure statement to all potential enrollees prior to enrollment or at the time of enrollment, and the written disclosure statement must state the following: `The person that is discussing plan options with you is either employed by or contracted with BCBSM. The person may be compensated based on your enrollment in a plan.¿ - Any coordinated marketing must be done in accordance with all applicable Part D laws, CMS policies, including CMS marketing guidelines and the prohibited activities listed in MR05, and all Federal health care laws (including civil monetary penalty laws). BCBSM must also provide CMS with evidence that it has a current employee-specific contract/compensation structure in effect that demonstrates that an actual contractual/ employment relationship exists between BCBSM and its employees, and demonstrates or includes the above provisions as well as those listed below: - A compliant incentive structure avoiding incentives toward misleading beneficiaries, cherry picking certain beneficiaries, or churning beneficiaries between plans. - A person/agency performing marketing to beneficiaries is prohibited from making payments to beneficiaries. - Payment will be withheld or withdrawn if an enrollee disenrolls in an unreasonably short time frame.

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
Audit ID: 141
Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: MR09
Audit Type: Routine
Audit Location: Desk Review
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Element Accepted Date: 7/12/2007
Element Release Date: 11/5/2007
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Provision of Notices Regarding Formulary Changes - Prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug, the Part D sponsor must provide a written notice to affected enrollees at least 60 days prior to the date the change becomes effective, or provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change at the time an affected enrollee requests a refill of the Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to the affected enrollees.

Reference:

42 CFR § 423.120(b)(5)(i-iii); § 423.120(b)(7); § 423.578(d); Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed policies and procedures and determined that they do not include the following provisions: - to notify affected enrollees in writing at least 60 days prior to the date of formulary changes, - stating that if no prior notice is given, to ensure that affected enrollees are provided with a 60-day supply of the Part D drug under the same terms as previously allowed at the time a refill is requested, and - stating that members will be notified of 'maintenance' and 'other' formulary changes. BCBSM did not meet the CMS compliance standard for the samples cases provided for beneficiaries affected by a formulary maintenance change because CMS reviewed 10 cases out of a universe of 1780 and found 10 contained EOBs that were not dated. Therefore, the beneficiaries would not know the effective date of formulary change.

Corrective Action Required:

BCBSM must revise its policies and procedures to include the following provisions: - to notify affected enrollees in writing at least 60 days prior to the date of formulary changes, - stating that if no prior notice is given, to ensure that affected enrollees are provided with a 60-day supply of the Part D drug under the same terms as previously allowed at the time a refill is requested, and - stating that members will be notified of 'maintenance' and 'other' formulary changes. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM's EOBs must be dated and contain an effective date of formulary change to meet CMS requirements, and provide documentation of this to CMS.

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: FM03
Audit Type: Routine
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Provision of Notice Regarding Formulary Changes - The Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (SPAPs), and entities providing other prescription drug coverage prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to the parties listed above.

Reference:

42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d); Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed policies and procedures and found that they do not include provisions for providing: - a notice of `maintenance' formulary changes to CMS, SPAPS, and entities providing other prescription drug coverage, - a notice of `other' formulary changes to CMS, SPAPS, and entities providing other prescription drug coverage, and - a retrospective notice to CMS, SPAPs, and entities providing other prescription drug coverage if a covered Part D drug is immediately removed from the formulary because it is deemed unsafe by the FDA or removed from the market by the manufacturer.

Corrective Action Required:

BCBSM must revise its policies and procedures to include provisions for providing: - a notice of `maintenance' formulary changes to CMS, SPAPS, and entities providing other prescription drug coverage, - a notice of `other' formulary changes to CMS, SPAPS, and entities providing other prescription drug coverage, and - a retrospective notice to CMS, SPAPs, and entities providing other prescription drug coverage if a covered Part D drug is immediately removed from the formulary because it is deemed unsafe by the FDA or removed from the market by the manufacturer. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

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Auditing Results (Public Website Version)

Date Report Generated: 9/30/2008

Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
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Element Accepted Date: 7/12/2007
Element Release Date: 8/9/2007
Element Projected Completion Date: 12/31/2007

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Notices in Network Pharmacies - The Part D sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

Reference:

42 CFR § 423.562(a)(3); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures and found they do not include a provision for sending the `Medicare Prescription Drug Coverage and Your Rights' notice to the location in the long-term care (LTC) facility designated to accept such notices, or if the network or preferred pharmacy is on-site, delivering the notice described above to the location in the LTC facility designated to accept such notices. BCBSM was unable to provide a template contract for its network Indian Health Services, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies, that contains a provision requiring I/T/U pharmacies to post or distribute notices regarding procedures for obtaining a coverage determination or requesting an exception. In addition, BCBSM was unable to provide documentation demonstrating that it conducts ongoing monitoring of its network pharmacies to ensure they are posting or distributing notices regarding procedures for obtaining a coverage determination or requesting an exception.

Corrective Action Required:

BCBSM must update its policies and procedures (Part D Std Coverage Determinations.pdf) to include a provision for sending the `Medicare Prescription Drug Coverage and Your Rights' notice to the location in the LTC facility designated to accept such notices, or if the network or preferred pharmacy is on-site, delivering the notice described above to the location in the LTC facility designated to accept such notices. BCBSM must instruct the LTC facility staff to provide the enrollee (or the enrollee's appointed representative) and the enrollee's treating physician with the notice, and to place a copy of the notice in the enrollee's file at the LTC facility. BCBSM must submit to CMS a template contract for its network I/T/U pharmacies that contains a provision requiring I/T/U pharmacies to post or distribute notices regarding procedures for obtaining a coverage determination or requesting an exception. BCBSM must provide CMS with documentation demonstrating that its network pharmacies are posting or distributing notices regarding procedures for obtaining a coverage determination or requesting an exception. An example of acceptable documentation for this is results of pharmacy audits showing the number and percent of pharmacies that have undergone an audit.

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Audit Type: Routine
Audit Location: Desk Review
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Coverage Determination Policies and Procedures - The Part D sponsor must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all enrollee requests for coverage determinations (expedited and standard) regarding basic coverage and supplemental benefits, and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. These procedures must address unplanned transitions, and actions that are coverage determinations as defined in § 423.566(b). The Part D sponsor must establish and maintain efficient and convenient means for individuals (including enrollees, their appointed representatives, or their prescribing physicians) to submit oral or written requests for coverage determinations, document all oral requests in writing, and maintain the documentation in a case file. The Part D sponsor must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all enrollee requests for re-determinations, reconsiderations by the Independent Review Entity (IRE), and reviews by the Administrative Law Judge (ALJ) received both orally and in writing.

Reference:

42 CFR § 423.566(a); § 423.566(b); § 423.566(c); § 423.570(c)(1-2); PDP Solicitation; Reporting Requirements Section VII: Appeals; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals; Information

Deficiencies:

BCBSM does not meet this requirement because its policies and procedures are insufficient for consistently tracking and addressing in a timely manner oral and written requests for both standard and expedited redeterminations. CMS' review of BCBSM's system documentation, including the tracking log maintained in Microsoft Excel, indicates that BCBSM was unable to correctly document the date that oral and written requests for exceptions, coverage determinations and redeterminations were received.

Corrective Action Required:

BCBSM must revise its policies and procedures to include provisions for consistently tracking and addressing in a timely manner oral and written requests for both standard and expedited redeterminations. BCBSM must revise the system it uses to track and address, in a timely manner, enrollees' oral and written requests for exceptions, coverage determinations, and redeterminations to ensure that it correctly documents the date that requests are received by BCBSM, the disposition of the request, the date of disposition, and the date the beneficiary is notified of the disposition of the request, and provide documentation of this to CMS. BCBSM must conduct training of appropriate staff on policies and procedures and its systems for tracking, addressing, and maintaining documentation on the timely review and resolution of all enrollee requests for exceptions, coverage determinations, and redeterminations. BCBSM must submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Timely Notification of Coverage Determination Concerning Drug Benefit - In response to a drug benefit request, the Part D sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee¿s health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician¿s supporting statement. If the coverage determination was denied and the initial notification was provided orally, the Part D sponsor must send the written notice to the enrollee within 3 calendar days of the oral notice. Failure to notify the enrollee within the 72 hour timeframe constitutes an adverse coverage determination requiring the Part D sponsor to forward the enrollee¿s request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.

Reference:

42 CFR § 423.568(a); § 423.568(e); § 423.578(c)(2); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because its policies and procedures (Part D Std Coverage Determinations.pdf and Coverage Determinations and Exceptions.pdf (Policy #CE01)) do not include a provision stating that failure to notify the enrollee of its coverage determination concerning drug benefit decision within the required timeframe constitutes an adverse coverage determination, requiring BCBSM to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. Although BCBSM provided documentation to demonstrate that it has a corrective action plan (CAP) in place to address the process for forwarding requests and case files to the IRE when notice of coverage determination decisions are not made timely, this CAP was closed on 11/15/06, and BCBSM was unable to demonstrate that it meets this requirement in its request for standard coverage determinations concerning drug benefits sample cases. BCBSM does not meet the CMS compliance standard because CMS reviewed 10 sample cases regarding standard coverage determinations concerning drug benefits from a universe of 320 and found that 1 sample was misclassified. To account for this, the auditor reduced the sample size by 1 and made the sample size 9. CMS reviewed the 9 cases and found 5 did not demonstrate compliance with notifying enrollees of standard coverage determinations concerning benefits within the CMS-approved timeframes. Additionally, BCBSM did not demonstrate that it forwarded the untimely cases to the IRE, as CMS requires.

Corrective Action Required:

BCBSM must revise its policies and procedures to include a provision stating that failure to notify the enrollee of its coverage determination concerning drug benefits decision within the required timeframe constitutes an adverse coverage determination requiring BCBSM to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must notify enrollees of its decision regarding standard coverage determinations concerning benefits within the CMS-approved timeframe, and provide documentation of this to CMS.

CMS Part D Audit Report
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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Coverage Determinations Concerning Payment - The Part D sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the payment request, or, for an exceptions request, after receiving the physician's supporting statement. If the coverage determination was denied and the initial notification was provided orally, the Part D sponsor must send the written notice to the enrollee within 3 calendar days of the oral notice. For favorable determinations, the Part D sponsor must authorize payment and notify the enrollee within 72 hours after receiving the request, or, for an exceptions request, after receiving the physician's supporting statement. The Part D sponsor must also make payment (i.e., mail the payment) within 30 calendar days of the request, or, for an exceptions request, after receiving the physician's supporting statement. Failure to notify the enrollee within the 72 hour timeframe constitutes an adverse determination requiring the Part D sponsor to forward the enrollee¿s request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE. Note: This element also applies to out-of-network (OON) paper claims submitted by beneficiaries or their appointed representatives.

Reference:

42 CFR § 423.568(b); § 423.568(e); PDP Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (Part D Std Coverage Determinations.pdf and Coverage Determinations and Exceptions.pdf (Policy #CE01)) and found they do not include provisions stating: - that if BCBSM makes a favorable decision on a coverage determination concerning payment, it must authorize payment and notify the enrollee within 72 hours after receiving the request, or, for an exceptions request, after receiving the physician's supporting statement, - that if BCBSM makes a favorable decision on a coverage determination concerning payment, it must make payment (i.e., mail the payment) within 30 calendar days of the request, or, for an exceptions request, after receiving the physician's supporting statement, and - that failure to notify the enrollee of BCBSM's decision on a coverage determination concerning payment within the required timeframe constitutes an adverse coverage determination, requiring BCBSM to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe. Although BCBSM provided documentation to demonstrate that it has a CAP in place to address the process for forwarding requests and case files to the IRE when notice of coverage determination/redetermination decisions are not made timely, this CAP was closed on 11/15/06. BCBSM was unable to demonstrate that it meets this requirement in its request for standard coverage determinations concerning payment sample cases. Thirty percent or more of sample cases provided for WS-CD2_D, Requests for Coverage Determination Concerning Payment, were misclassified. The universe provided by BCBSM is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must revise its policies and procedures to include provisions stating: - that if BCBSM makes a favorable decision on a coverage determination concerning payment, it must authorize payment and notify the enrollee within 72 hours after receiving the request, or, for an exceptions request, after receiving the physician's supporting statement, - that when BCBSM makes a favorable decision on a coverage determination concerning payment, it must make the payment (i.e., mail the payment) within 30 calendar days of the request, or, for an exceptions request, after receiving the physician's supporting statement, and - that failure to notify the enrollee of BCBSM's decision on a coverage determination concerning payment within the required timeframe constitutes an adverse coverage determination requiring it to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe. BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-CD2_D, Requests for Coverage Determination Concerning Payment, contains misclassified cases. Based on the analysis, BCBSM is to provide to CMS the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

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Estimated Visit Start Date: 2/26/2007
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Part D Sponsor Response Received Date:
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Requirement:

Denial Notice Requirements for Coverage Determinations - If the Part D sponsor makes an adverse determination, in whole or in part, it must provide the enrollee with written notification, using approved notice language that is readable and understandable, states the specific reasons for the denial, and informs the enrollee of his or her right to a redetermination.

Reference:

42 CFR § 423.568(c-d); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet the CMS compliance standard because CMS reviewed 3 sample cases where BCBSM made an adverse standard coverage determination concerning drug benefits decision from a universe of 320 and found that in 3 of those 3 cases, BCBSM's denial notice was not compliant. The denial notice was not CMS approved, and stated that the timeframe for appeals may be extended (this is noncompliant). Over 30% of sample cases provided for WS-CD2_D, Requests for Coverage Determination Concerning Payment, were misclassified. The universe provided by BCBSM is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must notify enrollees of an adverse coverage determination decision using a CMS-approved notice template, and provide documentation of this to CMS. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-CD2_D contains misclassified cases. Based on the analysis, BCBSM is to provide to CMS the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

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Audit Type: Routine
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Estimated Visit Start Date: 2/26/2007
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Actual Visit Start Date: 2/26/2007
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Part D Sponsor Response Received Date:
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Requirement:

Decision to Accept or Deny Request for Expedited Coverage Determination; The Part D sponsor must promptly and correctly determine whether a complaint is a standard coverage determination or an expedited coverage determination. The Part D sponsor must have a means for issuing prompt decisions on expediting a coverage determination if it determines, based on the enrollee¿s request, or as indicated in the prescribing physician¿s request, that applying the standard timeframe for making a coverage determination may seriously jeopardize the enrollee¿s life, health, or ability to regain maximum function.

Reference:

42 CFR § 423.570(c)(3); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (pg. 6 of Coverage Determinations/Exceptions.pdf (Policy #CE01))and found they do not include the criteria BCBSM uses to determine if a member is eligible for an expedited review when the request comes from the member, rather than from the prescribing physician. BCBSM's policies and procedures state that physician requests for expedited coverage determinations are granted if the physician indicates the patient's condition is life threatening. However, on pg. 8 of the same document (Coverage Determinations/Exceptions.pdf (Policy #CE01)), it states that when a member requests an expedited coverage determination, FPBU staff will determine if the member is eligible for the expedited review. Although BCBSM has policies and procedures that adequately address its means for making decisions on expediting a coverage determination outside of normal business hours when a physician or pharmacy makes the request, BCBSM does not have policies and procedures in place for making decisions on expediting a coverage determination, within the appropriate timeframe, for requests received directly from its members outside of normal business hours.

Corrective Action Required:

BCBSM must revise its policies and procedures (Part D Std Coverage Determination.pdf and Coverage Determinations/Exceptions.pdf (Policy #CE01)) to include the criteria BCBSM uses for issuing prompt decisions regarding requests for expedited coverage determinations from physicians and members. These criteria, at a minimum, must state that a request for an expedited coverage determination must be granted if BCBSM determines, based on the enrollee's request, or as indicated in the prescribing physician's request, that applying the standard timeframe for making a coverage determination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. BCBSM must also develop and implement written policies and procedures for making decisions on expediting a coverage determination within the appropriate timeframe for requests from its members that are received outside of normal business hours. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

Auditing Results (Public Website Version)

Date Report Generated: 9/30/2008

Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: CD07
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
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Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Timely Notification Following Decision to Deny Request for Expedited Coverage Determination - If the Part D sponsor decides not to expedite a coverage determination, it must automatically transfer the request to the standard timeframe, provide prompt oral notice to the enrollee and prescribing physician of the decision not to expedite, and provide equivalent written notice within 3 calendar days of the oral notice.

Reference:

42 CFR § 423.570(d); § 423.572(a); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures and found they do not include a provision stating that if BCBSM denies a request to expedite a coverage determination, BCBSM must automatically transfer the request to the standard coverage determination process, give the enrollee and his or her prescribing physician, if involved, prompt oral notice of the denial, and subsequently deliver (i.e., mail) written notice to the enrollee within 3 calendar days.

Corrective Action Required:

BCBSM must develop and implement policies and procedures regarding enrollee notification following a decision to deny a request for an expedited coverage determination. These procedures must include provisions stating that if BCBSM denies a request to expedite a coverage determination, it must automatically transfer the request to the standard coverage determination process, give the enrollee and his or her prescribing physician, if involved, prompt oral notice of the denial, and subsequently deliver (i.e., mail) to the enrollee, within 3 calendar days, written notice. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

Auditing Results (Public Website Version)

Date Report Generated: 9/30/2008

Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: CD08
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
Date Report Due: 6/18/2007
Element Accepted Date: 7/12/2007
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Element Projected Completion Date: 9/30/2007

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Notice Content Requirements for Decision to Deny Request for Expedited Coverage Determination - The notice for the decision to deny a request for an expedited coverage determination must provide an explanation that the Part D sponsor must process the request using the 72 hour timeframe for standard determinations; inform the enrollee of the right to file an expedited grievance; inform the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician¿s support; and provide instructions about the Part D plan¿s grievance process and its timeframes.

Reference:

42 CFR § 423.570(d)(2); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed its policies and procedures regarding enrollee notification following a decision to deny a request for an expedited coverage determination and found that they do not include the following provisions stating that oral and written notice: -must provide an explanation that BCBSM must process the request using the 72 hour timeframe for standard determinations, -must inform the enrollee of the right to file an expedited grievance, -must inform the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support, and -must provide instructions about BCBSM's grievance process and its timeframes. The review of BCBSM's notice template for notifying beneficiaries of its decision to deny a request for an expedited coverage determination did not demonstrate that it meets the CMS requirements. BCBSM was unable to provide the appropriate notice template and instead provided the `Medicare Prescription Drug Coverage and Your Rights' notice in response to the audit team's request.

Corrective Action Required:

BCBSM must develop and implement policies and procedures regarding enrollee notification following a decision to deny a request for an expedited coverage determination that include provisions stating: -that oral and written notice must provide an explanation that BCBSM must process the request using the 72 hour timeframe for standard determinations, -that oral and written notice must inform the enrollee of the right to file an expedited grievance, -that oral and written notice must inform the enrollee of the right to resubmit a request for an expedited determination with the prescribing physicians support, and -that oral and written notice must provide instructions about BCBSM's grievance process and its timeframes. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with a CMS-approved notice template for notifying an enrollee that a request for an expedited coverage determination is denied. This notice must be consistent with the CMS-issued model notice, `Notice of Right to an Expedited Grievance'. If BCBSM does not have a template for this notice that has been approved by CMS, then it must submit one for CMS approval through the normal marketing review submission process, and provide evidence that it has done this for the purpose of this audit. BCBSM must also conduct training of appropriate staff on the use of this template and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report
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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

Findings: Not Met
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Contract Number: S5584
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Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Audit Location: Desk Review
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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
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Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Timely Notification of Expedited Coverage Determination - The Part D sponsor must make its expedited coverage determination and notify the enrollee of its decision (adverse or favorable), as expeditiously as the enrollee¿s health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician¿s supporting statement. If the decision is adverse and the Part D sponsor first notifies the enrollee of the determination orally, the Part D sponsor must mail written confirmation to the enrollee within 3 calendar days of the oral notification. Failure to notify the enrollee within the 24 hour timeframe constitutes an adverse determination requiring the Part D sponsor to forward the enrollee¿s request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.

Reference:

42 CFR § 423.570(e); § 423.572(a-b); § 423.572(d); § 423.578(c)(2); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed policies and procedures (Part D Std Coverage Determination.pdf and Coverage Determinations/Exceptions.pdf (Policy #CE01)) for enrollee notification when an expedited coverage determination is forwarded to the IRE, and found that policies and procedures do not include the following provisions: - that BCBSM must make an expedited coverage determination and notify the enrollee (and/or other applicable party) of its decision (adverse or favorable), as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement. Although BCBSM provided policies and procedures that address this requirement, none of the policies reviewed specifically included the `as expeditiously as the enrollee's health condition requires' provision, and none were clear that both the decision AND the enrollee notification must take place within the 24 hour timeframe. - that if a decision on an expedited coverage determination is adverse and BCBSM first notifies the enrollee of the determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. - that failure to notify the enrollee of its decision on an expedited coverage determination within the required timeframe constitutes an adverse coverage determination, requiring BCBSM to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe. Although BCBSM provided documentation to demonstrate that it has a CAP in place to address the process for forwarding requests and case files to the IRE when notice of coverage determination decisions are not made timely, this CAP was closed on 11/15/06, and BCBSM was unable to demonstrate through sample cases that it meets this requirement. -that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE because it failed to provide timely notice of a decision on an expedited coverage determination.

Corrective Action Required:

BCBSM must revise its policies and procedures to include the following provisions: - that BCBSM must make an expedited coverage determination and notify the enrollee (and/or other applicable party) of its decision (adverse or favorable), as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement, - that if a decision on an expedited coverage determination is adverse and BCBSM first notifies the enrollee of the determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification, - that failure to notify the enrollee of its decision on an expedited coverage determination within the required timeframe constitutes an adverse coverage determination, requiring BCBSM to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe, and - that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE because it failed to provide timely notice of a decision on an expedited coverage determination. BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Audit Type: Routine
Audit Location: Desk Review
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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Notice Content Requirements for Expedited Coverage Determination - The notice of any expedited coverage determination must state the specific reasons for the determination in understandable language. If the determination is not completely favorable, the notice must also: (i) include information concerning the enrollee¿s right to a redetermination; (ii) describe both the standard and expedited redetermination processes, including the enrollee¿s right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeals process; and (iii) comply with any other requirements specified by CMS.

Reference:

42 CFR § 423.572(c); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed its policies and procedures and found that they do not address the requirements for oral notification of an enrollee following an adverse decision on an expedited coverage determination. Specifically, BCBSM's policies and procedures do not include the following provisions: - that the oral notice must provide the specific reason for the denial and take into account the enrollee's presenting medical condition, disabilities, and special language requirements, if any, - that the oral notice must provide information regarding the right to appoint a representative to file an appeal on the enrollee's behalf, and -that the oral notice must provide a description of both the standard and expedited redetermination processes and timeframes, including conditions for obtaining an expedited redetermination, and the rest of the appeals process.

Corrective Action Required:

BCBSM must develop and implement policies and procedures that include a provision stating that if oral notice is provided for an adverse decision on an expedited coverage determination, the notice must satisfy the following requirements: - states the specific reason for the denial and takes into account the enrollee's presenting medical condition, disabilities, and special language requirements, if any, - provides information regarding the right to appoint a representative to file an appeal on the enrollee's behalf, and - provides a description of both the standard and expedited redetermination processes and timeframes, including conditions for obtaining an expedited redetermination, and the rest of the appeals process. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: CE01
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Exceptions Procedures and Criteria (Tiered Cost-Sharing) - The Part D sponsor must establish and maintain reasonable and complete exceptions procedures, subject to CMS¿ approval, for exceptions requests to the Part D sponsor¿s tiered cost-sharing structure. The exceptions procedures must address situations where a formulary¿s tiering structure changes during the year, and an enrollee is using a drug affected by the change. The Part D sponsor must grant an exception for non-preferred drugs when medically necessary and consistent with the prescribing physician¿s statement that meets CMS criteria. The Part D sponsor¿s tiered cost-sharing exceptions process and exception criteria must meet CMS requirements including for unplanned transitions.

Reference:

42 CFR § 423.578(a)(1-2); § 423.578(a)(4); PDP Solicitation and EP Attestation Addendum; Reporting Requirements for Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions; Prescription Drug Benefit Manual; Chapter 18 ¿

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures and found they do not include a provision clearly stating that: - if BCBSM makes a request for additional supporting medical documentation from a prescribing physician, to support a request for a tiering exception, then it must clearly identify the type of information that must be submitted. - BCBSM must grant a tiering exception when it determines that the preferred drug for treatment of the enrollee's condition would not be as effective for the enrollee as the requested drug and/or would have adverse effects. The case files BCBSM submitted for this audit lacked consistent documentation of requests (phone calls) to physicians for information in support of exceptions requests, and therefore, BCBSM was unable to demonstrate that it includes a clear description of the information needed during its calls to the prescribing physician.

Corrective Action Required:

BCBSM must develop and implement policies and procedures that include the following provisions stating that: - if BCBSM makes a request for additional supporting medical documentation from a prescribing physician, to support a request for a tiering exception, then it must clearly identify the type of information that must be submitted. - BCBSM must grant a tiering exception when it determines that the preferred drug for treatment of the enrollee's condition would not be as effective for the enrollee as the requested drug and/or would have adverse effects. BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report
Auditing Results (Public Website Version)

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Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

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Audit Type: Routine
Audit Location: Desk Review
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Exceptions Procedures and Criteria (Non-Formulary Drugs) - The Part D sponsor must establish and maintain exceptions procedures, subject to CMS¿ approval, for receipt of an off-formulary drug. The Part D sponsor must grant an exception for a non-formulary Part D drug whenever it determines that the drug is medically necessary, consistent with the prescribing physicians¿ statement that meets CMS criteria, and that the drug would be covered but for the fact that it is an off-formulary drug. The Part D sponsor¿s formulary exceptions process and exception criteria must meet CMS requirements including for unplanned transitions.

Reference:

42 CFR § 423.578(b); § 423.578(b)(1); § 423.578(b)(2); § 423.578(b)(5); PDP Solicitation and EP Attestation Addendum; Reporting Requirements for Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions; Prescription Drug

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures and found that they do not adequately address how BCBSM processes requests for non-formulary exceptions (or more specifically, given Blue Cross Blue Shield of Michigan's open formulary, a request for an exception to a drug's utilization tools, including dose restrictions, step therapy requirements, and therapeutic substitution requirements). BCBSM's exceptions policies and procedures currently address only tier exceptions. BCBSM's policies and procedures do not contain provisions: - stating that an enrollee, an enrollee's appointed representative, or an enrollee's prescribing physician shall be permitted to file a request for a non-formulary exception, - stating that if BCBSM makes a request for additional supporting medical documentation, then it must clearly identify the type of information that must be submitted, and - stating BCBSM must grant a formulary exception when it determines that one of the three factors listed below has been demonstrated, and the drug would be covered but for the fact that it is an off-formulary drug (or more specifically given BCBSM's open formulary, a drug subject to utilization tools). (1) All covered Part D drugs on any tier of BCBSM's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects, or (2) The number of doses available under a dose restriction for the prescription drug: (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or, (b) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or (3) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements: (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or (b) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee. The case files submitted for this audit lacked consistent documentation of requests (phone calls) to physicians for information in support of exceptions requests, and therefore, BCBSM was unable to demonstrate that it includes a clear description of the information needed during its calls to the prescribing physician.

Corrective Action Required:

BCBSM must develop and implement policies and procedures that include the following provisions: - stating that an enrollee, an enrollee's appointed representative, or an enrollee's prescribing physician shall be permitted to file a request for a non-formulary exception, - stating that if BCBSM makes a request for additional supporting medical documentation, then it must clearly identify the type of information that must be submitted, - stating BCBSM must grant a formulary exception when it determines that one of the three factors listed below has been demonstrated, and the drug would be covered but for the fact that it is an off-formulary drug (or more specifically given BCBSM's open formulary, a drug subject to utilization tools). (1) All covered Part D drugs on any tier of BCBSM's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects, or (2) The number of doses available under a dose restriction for the prescription drug: (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or, (b) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or (3) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements: (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or (b) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee. BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

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Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
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Requirement:

Approval of Tiering and Non-Formulary Exceptions Requests - Following approval of a request for a tiering or a non-formulary exception, the Part D sponsor cannot require an approval for a refill or a new prescription following the initial prescription, provided that (i) the enrollee¿s prescribing physician continues to prescribe the drug; (ii) the drug continues to be considered safe for treating the enrollee¿s disease or medical condition; and (iii) the enrollment period has not expired. For tiering exceptions, the Part D sponsor must permit enrollees to obtain an approved non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier. For approved non-formulary exceptions, the Part D sponsor has the flexibility to determine what level of cost-sharing applies to all non-formulary drugs approved under the exceptions process, so long as the designated level is one of its existing cost-sharing tiers.

Reference:

42 CFR § 423.578(c)(3); § 423.578(c)(4)(i-ii); EP Attestation Addendum; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures regarding exceptions and found that they do not address the requirement that a Part D sponsor cannot require an approval for a refill or a new prescription following the initial prescription, provided that: -the enrollee's prescribing physician continues to prescribe the drug, -the drug continues to be considered safe for treating the enrollee's disease or medical condition, and -the enrollment period has not expired. Thirty percent or more of sample cases provided for WS-CD2_D, Requests for Coverage Determination Concerning Payments, were misclassified. The universe provided by BCBSM is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must update its Coverage Determinations/Exceptions.pdf (Policy #CE01), and any other applicable policies that specifically address non-formulary exceptions, to include a provision stating that its enrollees are not required to request an approval for a refill or a new prescription following the initial prescription for, at a minimum, the remainder of the plan year. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-CD2_D, Requests for Coverage Determination Concerning Payments, contains misclassified cases. Based on the analysis, BCBSM is to provide to CMS the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

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CAP Accepted Date: 7/12/2007

Requirement:

Complaint Categorization (Grievances vs. Coverage Determinations) - The Part D sponsor must promptly and correctly determine and inform the enrollee whether a complaint is subject to its grievance procedures or its coverage determination procedures.

Reference:

42 CFR § 423.564(b); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (GV01_Categorizing of Complaints.pdf and GV01PandP_GA07 - Part D Complaints.pdf) and found that they do not include provisions for promptly and correctly categorizing complaints as inquiries, grievances, or coverage determinations. Specifically, a definition of 'Inquiry' was not included in the documentation provided. While a definition of 'Appeals' was included, it was incorrect as it more accurately described 'Coverage Determinations'. Finally, there was no separate section or definition pertaining to 'Coverage Determinations'. CMS requested documentation that demonstrates that BCBSM has a means of informing enrollees whether their complaints are subject to grievance procedures or coverage determination procedures. However, BCBSM attested in a memo that it does not have means by which to do so, and that it would develop a corrective action plan to address this deficiency. Additionally, CMS requested BCBSM's CMS-approved notice template for informing enrollees about inquiries involving excluded drugs, and BCBSM was unable to provide this notice template. Four samples out of the 15 standard grievances samples provided were misclassified and, to account for this, the auditor reduced the sample size by 4 and made the sample size 11. CMS reviewed 11 samples from a universe of 320 and found that 3 did not demonstrate that enrollees were informed whether their complaint was subject to grievance or coverage determination procedures, resulting in non-compliance with CMS requirements. Over 30% of sample cases provided for WS-CD2_D, Requests for Coverage Determination Concerning Payment,were misclassified. The universe provided by BCBSM was not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must revise its grievance policies and procedures (GV01_Categorizing of Complaints.pdf, GV01PandP_GA07 - Part D Complaints.pdf) as follows: -include a definition of 'Inquiry' and a correct definition of 'Appeals,' -replace all current incorrect references to 'Appeals' with 'Coverage Determinations,' and -include policies and procedures to inform enrollees whether their complaints are subject to grievance or coverage determination procedures. BCBSM must provide documentation to CMS that it has a means of informing enrollees of complaint categorization (e.g., phone script and notice template). BCBSM must conduct training of its Customer Service staff, Grievance staff, and any other appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with a CMS-approved notice to inform enrollees about inquiries involving excluded drugs (i.e., a notice consistent with the CMS-issued model notice, `Notice of Inquiry Regarding an Excluded Drug'). If BCBSM does not have a notice template that has been approved by CMS (i.e., a notice consistent with the CMS-issued model notice, `Notice of Inquiry Regarding an Excluded Drug'), then it must submit one for CMS approval through the normal marketing review submission process, and provide evidence that it has done this for the purpose of this audit. BCBSM must conduct training of appropriate staff on the use of this notice template and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must inform enrollees, and provide CMS with documentation of this notification, of whether their complaint is subject to grievance or coverage determination procedures, per CMS requirements. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-CD2_D contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

CMS Part D Audit Report

Auditing Results (Public Website Version)

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Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
Auditing Element: GV02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Grievance Policies and Procedures - The Part D sponsor must establish and maintain policies and procedures for tracking and addressing the timely hearing and resolution of all oral and written enrollee grievances including but not limited to the following: fraud and abuse, enrollment/disenrollment, benefit package, pharmacy access/network, marketing, customer service, confidentiality/privacy, and quality of care. The Part D sponsor must also maintain records of such grievances.

Reference:

42 CFR § 423.562(a)(1)(i); § 423.564(a-b); § 423.564(g); PDP Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals; Reporting Requirements for Section V: Grievances

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (GV02_GA08 - Part D Grievance.pdf and GV02_GV03_GV04_GV05_PandP_PR04 - Part D Processing Grievance R.pdf) and found that they do not include provisions: - for tracking, addressing, and maintaining records of grievances. Specifically, they do not include provisions for tracking and maintaining, at a minimum, the date of receipt, disposition of the grievance, and the date that the enrollee was notified of the disposition. - for quarterly reporting of all data requested in Part D Reporting Requirements Section V: Grievances. Finally, CMS requested documentation that demonstrates that BCBSM has systems for logging or capturing enrollees' grievances in a centralized location. However, its systems are not fully compliant. While BCBSM's Excel Tracking Log includes columns for: 'Corporate Date Received', 'Member Last Name', 'Member First Name', 'Decision', 'Resolved Date', and 'Resolution Notification Type', it does not include columns to track and maintain 'Mode of Receipt of Grievance', 'Subject of Grievance', and 'Date the Enrollee was Notified of the Disposition'. Although the Excel Tracking Log provided by BCBSM does include a column called 'Resolved Date', it is unclear if this date indicates the actual date the enrollee was notified of the disposition.

Corrective Action Required:

BCBSM must revise its policies and procedures to include the following provisions: - tracking and maintaining, at a minimum, the date of receipt, disposition of the grievance, and the date that the enrollee was notified of the disposition, and - quarterly reporting of all data requested in Part D Reporting Requirements Section V: Grievances. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. Finally, BCBSM must include and use the following columns in its Excel Tracking Log: 'Mode of Receipt of Grievance', 'Subject of the Grievance', and 'Date the Enrollee was Notified of the Disposition', and provide documentation of this to CMS. BCBSM must conduct training of appropriate staff on the use of the Excel Tracking Log and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

Auditing Results (Public Website Version)

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 5/4/2007
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Element Release Date: 8/2/2007
Element Projected Completion Date: 9/30/2007

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Grievance Process Training - The Part D sponsor will train relevant staff and subcontractors on its grievance policies and procedures.

Reference:

PDP Solicitation

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (GV03_1 Training of Staff.pdf) and found they do not include provisions for training relevant staff on grievance policies and procedures. Additionally, CMS requested documentation that demonstrates that BCBSM has and implements training on grievance policies and procedures. However, BCBSM was unable to provide this documentation.

Corrective Action Required:

BCBSM must revise its policies and procedures to include a provision for training relevant staff on grievance policies and procedures. In addition, BCBSM must provide CMS with documentation that demonstrates that it has and implements a formal training program regarding its grievance policies and procedures. BCBSM must conduct training of appropriate staff to ensure they are aware of this addition to the policies and procedures, and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Audit Type: Routine
Audit Location: Desk Review
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
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Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Timely Notification of Grievance Disposition - The Part D sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee¿s health status, but no later than 30 days after the date the Part D sponsor receives the oral or written grievance (or an additional 14 days if an extension is requested by the enrollee or justified by the Part D sponsor). If the Part D sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

Reference:

42 CFR § 423.564(e)(1-2); PDP Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (GV02_GV03_GV04_GV05_PandP_PR04 - Part D Processing Grievance R.pdf) and found that they do not include the following provisions: - the 30-day timeframe for processing a grievance may be extended by 14 days or less if the enrollee requests the extension or if BCBSM justifies a need for additional information and documents how the delay is in the interest of the enrollee, and - the enrollee must immediately be notified in writing when BCBSM extends the deadline for processing a grievance. Four samples out of the 15 standard grievances samples provided were misclassified and, to account for this, the auditor reduced the sample size by 4 and made the sample size 11. CMS reviewed 11 samples from a universe of 320 and found that 3 did not demonstrate compliance with grievance adjudication since the documentation did not demonstrate that enrollees were notified of grievance resolution within the CMS-approved timeframes.

Corrective Action Required:

BCBSM must revise its policies and procedures to include the following provisions: - the 30-day timeframe for processing a grievance may be extended by 14 days or less if the enrollee requests the extension or if BCBSM justifies a need for additional information and documents how the delay is in the interest of the enrollee, and - the enrollee must immediately be notified in writing when BCBSM extends the deadline for processing a grievance. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must notify enrollees of grievance resolution, and document this notification, within the CMS-approved timeframe, and provide CMS documentation of this.

CMS Part D Audit Report

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
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Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
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CAP Accepted Date: 7/12/2007

Requirement:

Method of Grievance Response - The Part D sponsor must respond to all written grievances in writing (including facsimile). If the enrollee orally submits a grievance and requests a written response, the Part D sponsor must respond in writing.

Reference:

42 CFR § 423.564(e)(3)(i-ii); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (GV02_GV03_GV04_GV05_PandP_PR04 - Part D Processing Grievance R.pdf) and found that they do not include a provision stating that all grievances submitted in writing must be responded to in writing, and a provision stating that grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response. Four samples out of the 15 standard grievances samples provided were misclassified and, to account for this, the auditor reduced the sample size by 4 and made the sample size 11. CMS reviewed the remaining 11 samples from a universe of 320 and found that 2 did not contain documentation verifying the method BCBSM used to inform the enrollee of his/her grievance resolution.

Corrective Action Required:

BCBSM must revise its policies and procedures to include the following provisions: - all grievances submitted in writing must be responded to in writing, and - grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must document the method it uses to inform the enrollee of his/her grievances resolution, and provide documentation of this to CMS.

CMS Part D Audit Report

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Contract Number: All, Chapter: All, Element: All, Finding: Not Met, Auditor: All

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Audit Location: Desk Review
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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Grievance Response ¿ Quality of Care - The Part D sponsor must respond in writing to all grievances related to the quality of care. The response must include a description of the enrollee¿s right to file a written complaint with the Quality Improvement Organization (QIO). If a complaint is submitted to the QIO, the Part D sponsor must cooperate with the QIO in resolving the complaint.

Reference:

42 CFR § 423.564(e)(3)(iii); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (GV06_GA10 - Part D GandA explanatory data.pdf) and found that they do not include a provision that requires that all grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing, and a provision that describes BCBSM's commitment to cooperating with the QIO in resolving quality of care grievance cases.

Corrective Action Required:

BCBSM must revise its policies and procedures to include the following provisions: - all grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing, and - BCBSM is committed to cooperating with the QIO in resolving quality of care grievance cases. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Contract Number: S5584
Part D Sponsor Name: BLUE CROSS BLUE SHIELD OF MICHIGAN

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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Request for Redeterminations (Standard) - The Part D sponsor must have policies, procedures, and systems in place that allow it to accept written requests for standard redeterminations of coverage determinations filed within 60 calendar days of the notice of the coverage determination. The Part D sponsor must provide the enrollee or the prescribing physician with a reasonable opportunity to hand-deliver or present in writing, evidence and allegations of fact or law related to the issue in dispute.

Reference:

42 CFR § 423.582(a-b); § 423.586; PDP Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS requested documentation that demonstrates that BCBSM has a system in place to accept written requests from an enrollee for a redetermination within the 60 calendar day timeframe (i.e., 60 days from the date of the initial determination) and although BCBSM's Excel Tracking Log indicates that BCBSM can track and maintain various types of information regarding a redetermination, it is not clear if it can track whether or not written requests for redeterminations are made and accepted within the 60 calendar day timeframe. Over 30% of sample cases provided for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, and WS-RE2_D, Requests for Standard Redeterminations Concerning Payments, were misclassified. The universes provided by BCBSM are not representative of cases that CMS requested, and are therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must revise its Excel Tracking Log to include columns that BCBSM can use to clearly track whether or not written requests for redeterminations are made and accepted within the 60 calendar day timeframe (i.e., 60 days from the date of initial determination), and provide documentation of this to CMS. BCBSM must conduct training of appropriate staff on the use of these columns and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with an analysis and explanation of why the universes submitted for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, and WS-RE2_D, Requests for Standard Redeterminations Concerning Payments, contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause(s) as well as detailed corrective action plans to ensure that this element will be met consistently.

CMS Part D Audit Report

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Auditing Element: RE02
Audit Type: Routine
Audit Location: Desk Review
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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
CAP Release Date: 11/5/2007
CAP Accepted Date: 7/12/2007

Requirement:

Request for Redeterminations (Expedited) - The Part D sponsor must establish and maintain an efficient and convenient means for an enrollee or a prescribing physician acting on behalf of an enrollee to submit oral or written requests for expedited redeterminations, document all oral requests in writing, and maintain the documentation in a case file. The Part D sponsor must provide the enrollee or the prescribing physician with a reasonable opportunity to present in person or in writing evidence and allegations of fact or law related to the issue in dispute. Since the opportunity to submit evidence is limited, the Part D sponsor must inform the enrollee or the prescribing physician of the conditions for submitting such evidence.

Reference:

42 CFR § 423.584(c)(1); § 423.586; PDP Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf and CD02_GA09 - Part D Appeals Policy.pdf) for accepting and addressing requests for expedited redeterminations, and found they do not include a provision stating the name of a designated office and/or department to receive both oral or written requests for expedited redeterminations, and a telephone number for oral requests for expedited redeterminations. Although the Grievance and Appeals Staff's responsibility to accept and process both oral and written requests is cited in one of the documents provided that addresses redeterminations (CD02_GA09 - Part D Appeals Policy.pdf), it is not included in the document provided that addresses expedited redeterminations (RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf). In addition, a phone and fax number are provided in the former document (for redeterminations), but they are listed only under the information for written request, and are not included in the document that addresses expedited redeterminations.

Corrective Action Required:

BCBSM must revise its policies and procedures for expedited redeterminations (RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf) to include the provisions stating the name of a designated office and/or department to receive both oral or written requests for expedited redeterminations, and a telephone number for oral requests for expedited redeterminations. In addition, BCBSM must revise its policies and procedures for redeterminations (CD02_GA09 - Part D Appeals Policy.pdf) to include a phone number for both oral and written requests. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report
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Estimated Visit Start Date: 2/26/2007
Estimated Visit Start Date: 3/2/2007
Actual Visit Start Date: 2/26/2007
Actual Visit End Date: 3/2/2007
Part D Sponsor Response Received Date:
Part D Sponsor Response Due Date: 6/18/2007
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Requirement:

Timely Notification and Effectuation of Standard Redetermination Concerning Covered Drug Benefit - If the Part D sponsor makes a redetermination that is favorable for the enrollee, or affirms in whole or in part its original adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee¿s health condition requires, but no later than 7 calendar days from the date it received the request for a standard redetermination, meeting CMS requirements. For favorable redeterminations for the enrollee, the Part D sponsor must effectuate it as expeditiously as the enrollee¿s health condition requires, but no later than 7 calendar days from the date it receives the request. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D sponsor to forward the enrollee¿s request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.

Reference:

42 CFR § 423.590(a)(1-2); § 423.590(c); § 423.590(g)(1-4); § 423.636(a)(1); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (RE05_RE06_RV01_RV02_RV03_PR15 - Case Effectuation.pdf and CD02_GA09 - Part D Appeals Policy.pdf) and found that they do not include provisions: - for effectuating a favorable redetermination, concerning drug benefit, as expeditiously as the enrollee's health condition requires or within 7 calendar days from the date it received the request for a standard redetermination, and - stating that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE. Although the latter provision is included in BCBSM's 'CD02_GA09 - Part D Appeals Policy.pdf,' it is incomplete because it does not include `within 24 hours'. Furthermore, BCBSM was unable to provide CMS-approved notice templates for notifying enrollees of an adverse standard redetermination and for notifying enrollees about requesting a reconsideration. Over 30% of sample cases provided for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, were misclassified. The universe provided by BCBSM is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must revise its policies and procedures to include provisions: - for effectuating a favorable redetermination, concerning drug benefit, as expeditiously as the enrollee's health condition requires or within 7 calendar days from the date it received the request for a standard redetermination, and - stating that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE. In addition, BCBSM must add `within 24 hours' to the appropriate portion of the provision included in 'CD02_GA09 - Part D Appeals Policy.pdf.' BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with CMS-approved notice templates for a `Notice of Redetermination' and 'Notice for Request for Reconsideration'. If BCBSM does not have notice templates that have been approved by CMS, then it must submit them for CMS approval through the normal marketing review submission process, and provide evidence that it has done this for the purpose of this audit. BCBSM must conduct training of appropriate staff on the use of these templates and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

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Requirement:

Timely Notification and Effectuation of Standard Redetermination Concerning Payment - If the Part D sponsor makes a redetermination that is favorable for the enrollee, or affirms in whole or in part its adverse coverage determination, it must issue its redetermination (in writing for the adverse redeterminations) no later than 7 calendar days from the date it received the request, meeting CMS requirements. For favorable redeterminations for the enrollee, the Part D sponsor must authorize the payment within 7 calendar days from the date it receives the request for redetermination. It must then make the payment no later than 30 calendar days after the date it receives the request for redetermination. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D sponsor to forward the enrollee¿s request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.

Reference:

42 CFR § 423.590(b-c); § 423.590(g)(1-4); § 423.636(a)(2); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (RE05_RE06_RV01_RV02_RV03_PR15 - Case Effectuation.pdf and CD02_GA09 - Part D Appeals Policy.pdf) and found that they do not contain the provision stating that for favorable redeterminations concerning payment, BCBSM must authorize payment within 7 calendar days and make payment within 30 calendar days from the date it received the request for a standard redetermination. Although this provision is included in BCBSM's policy and procedure, 'CD02_GA09 - Part D Appeals Policy.pdf,' it is incorrect because it states `from date of receipt of the notice reversing the Plan determination' instead of `from the date it received the request for a standard redetermination'. Furthermore, BCBSM's policies and procedures (RE05_RE06_RV01_RV02_RV03_PR15 - Case Effectuation.pdf and CD02_GA09 - Part D Appeals Policy.pdf) do not contain the provision stating that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE. Although this provision is included in, 'CD02_GA09 - Part D Appeals Policy.pdf,' it is incomplete because it does not include the statement `within 24 hours.' Additionally, BCBSM was unable to provide CMS-approved notice templates for notifying enrollees of an adverse standard redetermination and for notifying enrollees about requesting a reconsideration. Over 30% of sample cases provided for WS-RE2_D, Requests for Standard Redeterminations Concerning Payments, were misclassified. This universe is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must revise its policies and procedures (RE05_RE06_RV01_RV02_RV03_PR15 - Case Effectuation.pdf and CD02_GA09 - Part D Appeals Policy.pdf) to include a provision stating that for favorable redeterminations concerning payment, BCBSM must authorize payment within 7 calendar days and make payment within 30 calendar days from the date it received the request for a standard redetermination. BCBSM must add the entire provision to 'RE05_RE06_RV01_RV02_RV03_PR15 - Case Effectuation.pdf.' In addition, BCBSM must replace the statement `from date of receipt of the notice reversing the Plan determination' with `from the date it received the request for a standard redetermination' in the appropriate portion of the provision included in 'CD02_GA09 - Part D Appeals Policy.pdf. BCBSM must revise its policies and procedures (RE05_RE06_RV01_RV02_RV03_PR15 - Case Effectuation.pdf and CD02_GA09 - Part D Appeals Policy.pdf) to include the provision stating that BCBSM must inform the enrollee, `within 24 hours', when the case is forwarded to the IRE. BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with CMS-approved notice templates for notifying enrollees of an adverse standard redetermination and for notifying enrollees about requesting a reconsideration. These notices must be consistent with the CMS-issued model notices, `Notice of Redetermination' and `Notice for Request for Reconsideration.' If BCBSM does not have notice templates that have been approved by CMS, then it must submit them for CMS approval through the normal marketing review submission process, and provide evidence that it has done this for the purpose of this audit. BCBSM must conduct training of appropriate staff on the use of these templates and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-RE2_D, Requests for Standard Redeterminations Concerning Payments, contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

CMS Part D Audit Report

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Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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CAP Accepted Date: 7/12/2007

Requirement:

Timely Notification of Expedited Redetermination and Request for Medical Information - If a Part D sponsor grants a request for expedited redetermination, it must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee¿s health condition requires but no later than 72 hours after receiving the request. If medical information is necessary, the Part D sponsor must make the request within 24 hours of receiving the initial request for an expedited redetermination. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D sponsor to forward the enrollee¿s request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D sponsor must also inform the enrollee, within 24 hours of the expiration of the adjudication timeframe, when the case is forwarded to the IRE.

Reference:

42 CFR § 423.584(e); § 423.590(d-e); § 423.638(a); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf and CD02_GA09 - Part D Appeals Policy.pdf) and found that they do not include a provision stating that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE. Although this provision is included in 'CD02_GA09 - Part D Appeals Policy.pdf,' it is incomplete because it does not include `within 24 hours'. BCBSM was unable to provide CMS-approved notice templates for notifying enrollees of an adverse expedited redetermination and for notifying the enrollee about requesting a reconsideration.

Corrective Action Required:

BCBSM must revise its policies and procedures to include a provision stating that BCBSM must inform the enrollee, within 24 hours, when the case is forwarded to the IRE due to BCBSM's failure to notify the enrollee of its decision within the required timeframe. Specifically, BCBSM must add the entire provision to 'RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf' and add `within 24 hours' to the appropriate portion of the provision included in 'CD02_GA09 - Part D Appeals Policy.pdf.' BCBSM must conduct training of appropriate staff on each of these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with CMS-approved notice templates for notifying enrollees of an adverse standard redetermination and for notifying enrollees about requesting a reconsideration. These notices must be consistent with the CMS-issued model notices, `Notice of Redetermination' and `Notice for Request for Reconsideration'. If BCBSM does not have notice templates that have been approved by CMS, then it must submit them for CMS approval through the normal marketing review submission process, and provide evidence that it has done this for the purpose of this audit. BCBSM must conduct training of appropriate staff on the use of these templates and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Audit Guide Version: PDP Sponsor Part D Audit Guide Version 1
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Estimated Visit Start Date: 2/26/2007
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CAP Accepted Date: 7/12/2007

Requirement:

Expedited Coverage Redetermination Reversals - If, on an expedited redetermination of a request for benefit, the Part D sponsor reverses, in whole or in part, its coverage determination, it must authorize or provide the benefit under dispute as expeditiously as the enrollee¿s health requires, but no later than 72 hours after the date the Part D sponsor receives the request for redetermination.

Reference:

42 CFR § 423.638(a); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf and CD02_GA09 - Part D Appeals Policy.pdf) and found that they do not include a provision for authorizing or providing the benefits in dispute within the 72-hour required timeframe if, on an expedited redetermination of a request for benefit, BCBSM reverses, in whole or in part, its coverage determination. Additionally, BCBSM made this statement in a memo: `We did not have a written procedure for this at the time. We are documenting this procedure and tracking it with a corrective action plan.' CMS requested documentation that demonstrates that BCBSM has systems for authorizing or providing a benefit under dispute within 72 hours of receiving the request for redetermination if the expedited redetermination results in a reversal. BCBSM was unable to provide such documentation.

Corrective Action Required:

BCBSM must revise its policies and procedures to include a provision for authorizing or providing the benefits in dispute within the 72-hour required timeframe if, on an expedited redetermination of a request for benefit, BCBSM reverses, in whole or in part, its coverage determination. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must develop, implement, and provide documentation to CMS that it has a system for authorizing or providing a benefit under dispute within 72 hours of receiving the request for redetermination if the expedited redetermination results in a reversal. BCBSM must conduct training of appropriate staff on the existence and use of these systems and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained.

CMS Part D Audit Report

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Audit Type: Routine
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Estimated Visit Start Date: 2/26/2007
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Requirement:

Review of Adverse Coverage Determinations - The Part D sponsor must ensure that a person or persons who were not involved in making the coverage determination conducts the redetermination. When the issue is a denial based on lack of medical necessity, the Part D sponsor must ensure the redetermination is made by a physician with the expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

Reference:

42 CFR § 423.590(f)(1-2); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed BCBSM's policies and procedures (RE02_RE03_RE04_RE07_RE09_RE10_PR05 - Expedited Redetermination.pdf and CD02_GA09 - Part D Appeals Policy.pdf) and found that they do not include a provision to require that a person or persons who were not involved in making the initial coverage determination conduct the redetermination. The documentation BCBSM provided (Redeterminations-First and Second Level Appeals) does not demonstrate compliance with the requirement that the redetermination is conducted by a person or persons not involved in making the initial coverage determination. Thirty percent or more of sample cases provided for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, and WS-RE2_D, Requests for Standard Redeterminations Concerning Payment, were misclassified. These universes are not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must revise its policies and procedures to include a provision that requires a person or persons who were not involved in making the initial coverage determination to conduct the redetermination. BCBSM must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS that details the nature of this training, including: the materials used in the training, the individuals conducting the training, and the individuals being trained. BCBSM must provide CMS with an analysis and explanation of why the universes submitted for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, and WS-RE2_D, Requests for Standard Redeterminations Concerning Payment, contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

CMS Part D Audit Report

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Requirement:

Timely Transfer to IRE Upon Reconsideration Request - In cases where an enrollee has filed a reconsideration request and the IRE has requested the enrollee's file, the Part D sponsor must transfer the case file to the IRE within 24 hours (expedited requests) or 48 hours (standard requests) from the time it receives the IRE¿s request for the case file.

Reference:

Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because thirty percent or more of sample cases provided for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, and WS-RE2_D, Requests for Standard Redeterminations Concerning Payment, were misclassified. These universes are not representative of cases that CMS requested, and are therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must provide CMS with an analysis and explanation of why the universes submitted for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits, and WS-RE2_D, Requests for Standard Redeterminations Concerning Payment, contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

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Part D Sponsor Response Received Date:
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CAP Accepted Date: 7/12/2007

Requirement:

Effectuation of Third Party Reversals ¿ Benefits (Standard) - If, on appeal of a request for benefit, the Part D sponsor 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee¿s health requires but no later than 72 hours after the date it receives notice reversing the determination. The Part D sponsor must also inform the IRE that the organization has effectuated the decision.

Reference:

42 CFR § 423.636(b)(1); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

BCBSM does not meet this requirement because CMS reviewed internal data on BCBSM's compliance with reconsideration decisions and found that in one of one case it did not provide a notice to the IRE that it effectuated a reversal decision. Over 30% of sample cases provided for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefit, were misclassified. The universe provided by BCBSM is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must demonstrate to CMS that it effectuates a decision that has been reversed by the IRE for cases concerning drug benefit within the timeframes required by CMS and notifies the IRE of the effectuation of any reconsideration decision that fully or partially reverses BCBSM's redetermination decision. BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-RE1_D, Requests for Standard Redeterminations Concerning Drug Benefits contained misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.

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Audit Type: Routine
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Requirement:

Effectuation of Third Party Reversals ¿ Payment (Standard) - If, on appeal of a request for payment, the Part D sponsor 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D sponsor must authorize the payment within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D sponsor must also inform the IRE that the organization has effectuated the decision.

Reference:

42 CFR § 423.636(b)(2) - Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

CMS was not able to determine that BCBSM meets this requirement because thirty percent or more of sample cases provided for WS-RE2_D, Requests for Standard Redeterminations Concerning Payment, were misclassified. The universe provided by BCBSM is not representative of cases that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

BCBSM must provide CMS with an analysis and explanation of why the universe submitted for WS-RE2_D, Requests for Standard Redeterminations Concerning Payment, contains misclassified cases. Based on the analysis, BCBSM is to provide to CMS, the root cause as well as a detailed corrective action plan to ensure that this element will be met consistently.