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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: MR06
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding its responsibility for and oversight of persons employed or contracted to perform marketing and found they do not include a provision for conducting ongoing monitoring of all persons directly employed or contracted to perform marketing to ensure that they comply with all applicable laws and CMS policies, including CMS marketing guidelines. CMS reviewed Gateway's documentation regarding its monitoring of both internal and external marketing representatives' marketing activities, and found that the documentation did not confirm that marketing representatives are providing the written disclosure statement to all potential enrollees prior to enrollment or at the time of enrollment. CMS reviewed 10 samples of the executed contract and/or compensation structure used by Gateway's marketing representatives from a universe of 20 and found that all 10 cases were missing the following provisions from the executed contract/compensation structure: - a provision requiring that 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 - a provision stating that any coordinated marketing must be done in accordance with all applicable Part D laws, CMS policies, including CMS marketing guidelines, and all Federal health care laws (including civil monetary penalty laws).

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision for conducting ongoing monitoring of all persons directly employed or contracted to perform marketing to ensure that they comply with all applicable laws and CMS policies, including CMS marketing guidelines. Gateway 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. Gateway must provide documentation demonstrating that its monitoring of both internal and external marketing representatives' marketing activities includes monitoring that marketing representatives are providing the written disclosure statement to all potential enrollees prior to enrollment or at the time of enrollment. Gateway must revise its executed contract and/or compensation structure used by its internal and external marketing representatives to include the following provisions: 1) a provision requiring that 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 2) a provision stating that any coordinated marketing must be done in accordance with all applicable Part D laws, CMS policies, including CMS marketing guidelines, and all Federal health care laws (including civil monetary penalty laws).

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: MR09
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because over 30% of samples provided for WS-MR4_D, Provision of Notices Regarding Formulary Changes, were misclassified. The universe provided by Gateway is not representative of samples that CMS requested, and is therefore inadequate for determining compliance.

Corrective Action Required:

Gateway must provide CMS with an analysis and explanation of why the universe submitted for WS-MR4_D, Provision of Notices Regarding Formulary Changes, contained misclassified samples. Based on the analysis, Gateway must 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)

Date Report Generated: 9/30/2008

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

Findings: Not Met
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: PH03
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

Requirement:

Access to Long-Term Care Pharmacies - The Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria, to all long-term care (LTC) pharmacies in its Part D plan service area. The Part D sponsor must contract with a sufficient number of LTC pharmacies to provide all of its plans¿ institutionalized enrollees convenient access to their Part D benefits. Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they (1) provide plan enrollees access to covered Part D drugs dispensed at all pharmacies without regard to whether they are contracted network pharmacies, and (2) do not charge cost-sharing in excess of that required for qualified prescription drug coverage.

Reference:

42 CFR § 423.120(a)(5); MA-PD Solicitation; Long Term Care Guidance

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding access to long-term care pharmacies and found that they do not include a provision stating that Gateway must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to any long-term care pharmacy in its service area that requests the contract.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision stating that it must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to any long-term care pharmacy in its service area that requests the contract. Gateway 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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: FM03
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding formulary change notification and found they do not include procedures for providing 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:

Gateway must revise its policies and procedures to address the requirement to provide 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. Gateway 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
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: TP02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

Requirement:

Transition Process for Residents of Long-Term Care Facilities - The Part D sponsor must have and implement an appropriate transition process in accordance with CMS requirements for addressing the unique needs of long-term care (LTC) facility residents prescribed Part D drugs that are not on its formulary or that are on its formulary but require prior authorization or step therapy.

Reference:

42 CFR § 423.120(b)(3); MA-PD Solicitation; Information for Part D Sponsors on Requirements for a Transition Process; Transition Process Requirements for Part D Sponsors

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding the transition process for residents of long-term care facilities and found they were missing a provision for abiding by extensions to the transition period in accordance with CMS policy.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision for abiding by extensions to the transition period in accordance with CMS policy. Gateway 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)

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

Findings: Not Met
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD01
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding notices in network pharmacies that provide instructions for obtaining a coverage determination or requesting an exception and found they do not include the following provisions: - a provision for arranging with its network pharmacies to post or distribute the "Medicare Prescription Drug Coverage and Your Rights" notice 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, and - 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. Gateway's submitted documentation does indicate that it conducts ongoing monitoring of network pharmacies, however, the submitted documentation does not adequately demonstrate that Gateway is ensuring its network pharmacies are posting or distributing notices regarding procedures for obtaining a coverage determination or requesting an exception.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision for arranging with its network pharmacies to post or distribute the "Medicare Prescription Drug Coverage and Your Rights" notice 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. Gateway must also revise its policies and procedures 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. Gateway 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. Gateway must demonstrate that it is ensuring its network pharmacies are posting or distributing the "Medicare Prescription Drug Coverage and Your Rights" notice.

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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); MA-PD Solicitation; Reporting Requirements Section VII: Appeals Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals; Information for Part D Sponsors on Requirements for a Transition Process

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures for receiving, tracking, addressing, and maintaining records of coverage determinations and found they do not include the following: - provisions for making timely coverage determinations (standard and expedited) that address basic coverage, supplemental benefits, and cost sharing, - a provision stating that individuals who can request a standard or expedited coverage determination are (1) the enrollee, (2) the enrollee's appointed representative, on behalf of the enrollee, and (3) the prescribing physician, on behalf of the enrollee, - a definition a coverage determination in accordance with § 423.566(b)(1-5), and - a provision for quarterly reporting of all data requested in Part D Reporting Requirements: Appeals

Corrective Action Required:

Gateway must revise its policies and procedures to include provisions for making timely coverage determinations (standard and expedited) that address basic coverage, supplemental benefits, and cost sharing, and quarterly reporting of all data requested in Part D Reporting Requirements: Appeals. Policies and procedures need to also include a statement that individuals who can request a standard or expedited coverage determination are the enrollee, the enrollee's appointed representative, on behalf of the enrollee, and the prescribing physician. In addition, policies and procedures need to include a definition of a coverage determination in accordance with § 423.566(b)(1-5). Gateway 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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD03
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
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Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification of coverage determinations concerning drug benefit and found they do not include a provision stating that Gateway 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. Gateway's policies and procedures state that the member and physician are notified of the determination within 72 hours after Gateway receives supporting documentation from the physician concerning the request. CMS also found that Gateway's policies and procedures lack a provision stating that failure to notify the enrollee within the 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.

Corrective Action Required:

Gateway must revise its policies and procedures to include the following: - a provision stating that Gateway 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, and - a provision stating that failure to notify the enrollee within the timeframe constitutes an adverse coverage determination that requires 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. Gateway 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
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

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Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
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Element Release Date: 5/23/2008
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3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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); MA-PD Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

Gateway does not meet this requirement because CMS requested Gateway's policies and procedures regarding enrollee notification of coverage determinations concerning payment and Gateway was unable to provide these policies and procedures. CMS reviewed 10 sample cases of standard coverage determinations concerning payment from a universe of ten and found that four cases demonstrated that the enrollee was not notified of the coverage determination decision timely.

Corrective Action Required:

Gateway must develop policies and procedures for coverage determinations concerning payment that include the following provisions: (1) Gateway 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, (2) Gateway 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, (3) Gateway 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 (4) failure to notify the enrollee within the timeframe constitutes an adverse coverage determination that requires 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. Gateway 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. Gateway must provide documentation to CMS demonstrating that it provides timely notification to enrollees of its coverage determinations concerning payment.

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD05
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
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Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification of adverse coverage determinations and found they do not include a provision for providing written notification to the enrollee and/or other applicable party of an adverse coverage determination. Gateway is required to send written notice to the enrollee's appointed representative instead of the enrollee if the enrollee has identified an appointed representative. CMS reviewed 10 requests for standard coverage determinations concerning payments samples from a universe of 10 and found that 6 cases were deficient because the written notice provided to the enrollee was not CMS-approved.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision for providing written notice of an adverse coverage determination to the to the enrollee's appointed representative instead of the enrollee if the enrollee has identified an appointed representative. Gateway 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. Gateway must provide documentation to CMS demonstrating that it uses a CMS-approved notice template for informing enrollees and/or applicable parties of adverse coverage determinations.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD06
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding decisions to accept or deny requests for expedited coverage determinations and found they do not include a telephone number for receipt of oral requests by the designated office and/or department that receives both oral and written requests. In addition, CMS found that Gateway's policies and procedures do not include a provision: - discussing the means for making expedited decisions within the appropriate timeframe for requests received outside of normal business hours, or - stating that all oral requests must be documented in writing and that documentation of the request must be maintained in a case file.

Corrective Action Required:

Gateway must revise its policies and procedures to include a telephone number of the designated office and/or department that receives both oral and written requests. Gateway must also revise its policies and procedures to include: - a provision for making expedited decisions within the appropriate timeframe for requests received outside of normal business hours, and - a provision stating that all oral requests must be documented in writing and that documentation of the request must be maintained in a case file. Gateway 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)

Date Report Generated: 9/30/2008

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

Findings: Not Met
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD07
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification following a decision to deny a request for expedited coverage determination and found they do not include a provision for automatically transferring the request to the standard coverage determination process, giving the enrollee and his or her prescribing physician, if involved, prompt oral notice of the denial, and subsequently delivering (i.e., mailing) written notice to the enrollee within 3 calendar days.

Corrective Action Required:

Gateway must revise its policies and procedures regarding enrollee notification following a decision to deny a request for expedited coverage determination to include a provision for automatically transferring the request to the standard coverage determination process, giving the enrollee and his or her prescribing physician, if involved, prompt oral notice of the denial, and subsequently delivering (i.e., mailing) written notice to the enrollee within 3 calendar days. Gateway 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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD08
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification following a decision to deny a request for an expedited coverage determination and found they do not include the following: - a provision stating that both oral and written notice must provide an explanation that Gateway must process the request using the 72 hour timeframe for standard determinations, - a provision stating that both oral and written notice must inform the enrollee of the right to file an expedited grievance, - a provision stating that both oral and written notice must inform the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support, or - a provision stating that both oral and written notice must provide instructions about Gateway's grievance process and its timeframes

Corrective Action Required:

Gateway must update its policies and procedures to include the following provisions: 1) a provision stating that both oral and written notice must provide an explanation that the Part D sponsor must process the request using the 72 hour timeframe for standard determinations, 2) a provision stating that both oral and written notice must inform the enrollee of the right to file an expedited grievance, 3) a provision stating that both oral and written notice must inform the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support, and 4) a provision stating that both oral and written notice must provide instructions about the Part D sponsor¿s grievance process and its timeframes. Gateway 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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD09
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification following a decision on expedited coverage determination and found they do not include the following provisions: - a provision stating that 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. Gateway's policies and procedures do not include a deadline for providing written notification to the enrollee, and do not clearly apply to other types of coverage determinations beyond exceptions. - a provision stating that failure to notify the enrollee within the 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, or - a provision stating that the Part D sponsor must inform the enrollee within 24 hours when the case is forwarded to the IRE.

Corrective Action Required:

Gateway must revise its policies and procedures to include the following: (1) a provision stating that 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, (2) a provision stating that failure to notify the enrollee within the 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, (3) a provision stating that the Part D sponsor must inform the enrollee within 24 hours when the case is forwarded to the IRE. Gateway 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
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CD10
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification following a decision on an expedited coverage determination and found they do not include a provision stating that if the decision is adverse, then Gateway must use a notice consistent with the CMS-issued standard notice, Notice of Denial of Medicare Prescription Drug Coverage. Also, Gateway's policies and procedures do not include a provision stating that if oral notice is provided for adverse decision, the notice must satisfy the following requirements: - States the specific reason for the denial and take 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.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision stating that if the decision is adverse, then it must use a notice consistent with the CMS-issued standard notice, Notice of Denial of Medicare Prescription Drug Coverage. Gateway must also update its policies and procedures to include a provision stating that if oral notice is provided for adverse decision, the notice must satisfy the following requirements: - States the specific reason for the denial and take 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. Gateway 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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CE02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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); MA-PD 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 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals; Information for Part D Sponsors on Requirements for a Transition Process

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding processing requests for exceptions for non-formulary drugs and found they do not include provisions stating that: - An enrollee's appointed representative shall be permitted to file a request for a non-formulary exception (the enrollee or the enrollee's prescribing physician is also able to file a non-formulary exception request, which Gateway already states in its policies and procedures), - If Gateway makes a request for additional supporting medical documentation, then it must clearly identify the type of information that must be submitted, - If Gateway is waiting on a physician's statement in support of a formulary exception request, Gateway must wait a minimum of 96 hours after receiving a standard request or a minimum of 48 hours after receiving an expedited request before issuing its determination on the formulary exception, or - Gateway must grant a formulary exception when it determines that 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, and the drug would be covered but for the fact that it is an off-formulary drug. Also, CMS reviewed the file "CP-200-MC.doc," which states, "For a non-formulary drug to be granted an exception, evidence to support medical necessity must be submitted to Gateway Health Plan Medicare Assured, which show either: - Documentation of therapy failure with Plan Formulary alternatives, including drug name, strength, dates used and reason for failure or - Medical rationale for reasonable expectation of adverse reactions to the patient with a formulary medication." These policies and procedures lack a provision stating that the prescribing physician's statement could also indicate that the requested drug is medically required and other on-formulary drugs and dosage limits will not be effective because 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.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision stating that: - An enrollee's appointed representative shall be permitted to file a request for a non-formulary exception (the enrollee or the enrollee's prescribing physician is also able to file a non-formulary exception request, which Gateway already states in its policies and procedures), - The prescribing physician's statement must indicate that the requested drug is medically required and other on-formulary drugs and dosage limits will not be effective because 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, - If Gateway makes a request for additional supporting medical documentation, then it must clearly identify the type of information that must be submitted, - If Gateway is waiting on a physician's statement in support of a formulary exception request, Gateway must wait a minimum of 96 hours after receiving a standard request or a minimum of 48 hours after receiving an expedited request before issuing its determination on the formulary exception, and - Gateway must grant a formulary exception when it determines that 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, and the drug would be covered but for the fact that it is an off-formulary drug. Gateway 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
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: CE03
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures for determining cost-sharing for approved exceptions and found they do not include a provision stating that enrollees are not required to request an approval following the initial prescription for the remainder of the plan year.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision stating that enrollees are not required to request an approval following the initial prescription for the remainder of the plan year. Gateway 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
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: GV01
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding the categorization of complaints as inquiries, grievances, or coverage determinations and found they did not include provisions for properly categorizing complaints as inquiries, grievances, or coverage determinations/appeals. The policies and procedures Gateway submitted for this element assume that the complaint has already been categorized as a grievance. CMS requested Gateway's notice template for informing enrollees about inquiries involving excluded drugs and Gateway was unable to provide a notice that is consistent with the CMS-issued model notice, Notice of Inquiry Regarding an Excluded Drug. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines. CMS reviewed 7 samples of standard grievances from a universe of 7 and found 3 cases where Gateway improperly categorized the complaint as a grievance. CMS reviewed 10 samples of standard coverage determinations concerning payment from a universe of 10 and found 3 cases where the complaint was not properly categorized as a coverage determination.

Corrective Action Required:

Gateway must provide CMS with a CMS-approved or accepted notice for informing 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 Gateway does not have a notice template that has been approved or accepted 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. Gateway 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. Gateway must revise its policies and procedures to ensure they include provisions for promptly and correctly categorizing incoming complaints as inquiries, grievances or coverage determinations/appeals. Gateway 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. Gateway must provide documentation to CMS that illustrates Gateway is correctly categorizing complaints as grievances, coverage determinations/appeals or inquiries. In addition, Gateway must provide documentation showing that it notifies enrollees whether their complaint is subject to grievance or coverage determination processes, per CMS requirements.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: GV02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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); MA-PD Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals; Reporting Requirements for Section V: Grievances

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding tracking, addressing, and maintaining records of grievances and found they do not include a provision for tracking as well as maintaining, at a minimum, the date of receipt, disposition of the grievance, and the date that the enrollee was notified of the disposition. CMS reviewed Gateway's documentation regarding its systems for logging or capturing enrollees' grievances and found that it does not indicate that Gateway tracks the mode of receipt of the grievance (e.g., telephone) or the person or entity that filed the grievance. Discussions with Gateway staff confirmed that submitted documentation did not contain these data elements.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision 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. Gateway 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. Gateway must provide documentation of its systems that demonstrate Gateway tracks and stores the mode of receipt of the grievance and the person or entity filing the grievance.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: GV03
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

Requirement:

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

Reference:

MA-PD Solicitation

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding grievance process training and found they did not include provisions for training relevant staff on grievance policies and procedures. CMS reviewed Gateway's training documentation and found that it did not demonstrate that Gateway conducts staff training on its grievance policies and procedures.

Corrective Action Required:

Gateway must develop policies and procedures regarding grievance process training that contain a provision for training relevant staff and contractors (if applicable) on grievance policies and procedures. Gateway 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. Gateway must provide documentation demonstrating that it has and implements training on grievance policies and procedures for staff and contractors (if applicable).

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: GV04
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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); MA-PD Solicitation; Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification of grievance disposition and found they lack the following provisions: - a provision stating that all concerned parties must be notified of grievance disposition as expeditiously as the enrollee's case requires, based on the enrollee's health status, but not later than 30 days after the Sponsor receives the oral or written grievance. Gateway's policies and procedures state that it will not issue a final disposition until it receives a signed grievance acknowledgment form from the enrollee or the enrollee's appointed representative. Gateway's policy is not compliant with CMS¿ requirement that a Part D sponsor accept oral grievances. - a provision stating that the 30-day timeframe may be extended by 14 days or less if the enrollee requests the extension or if Gateway justifies a need for additional information and documents how the delay is in the interest of the enrollee, and - a provision stating that the enrollee must immediately be notified in writing when Gateway extends the deadline. In addition, CMS found that Gateway's policy of resolving second -level grievances within 45 days of receipt is noncompliant with the requirements expressed in Chapter 18 of the Prescription Drug Benefit Manual, which states that all grievances must be resolved within 30 days of receipt. CMS reviewed seven sample cases from a universe of seven and found that five cases failed to demonstrate that Gateway adjudicated the grievances correctly. Specifically: - 4 sample cases didn't demonstrate that Gateway provided written notice to the enrollee when it decided to extend the deadline for resolving the grievance, - 3 cases didn't demonstrate that Gateway resolved the grievance timely, - 1 case failed to demonstrate that Gateway resolved the issue fully In addition, CMS requested Gateway's notice template for informing enrollees of grievance deadline extension and Gateway was unable to provide a notice is consistent with the CMS-issued model Notice of Plan's Decision to Extend the Deadline for Making a Decision Regarding a Grievance. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines.

Corrective Action Required:

Gateway must revise its policies and procedures to include the following: 1) a provision stating that all concerned parties must be notified of grievance disposition as expeditiously as the enrollee's case requires, based on the enrollee's health status, 2) a provision stating that the 30-day timeframe may be extended by 14 days or less if the enrollee requests the extension or if the Part D sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee, and 3) a provision stating that the enrollee must immediately be notified in writing when the Part D sponsor extends the deadline for resolving the grievance. In addition, Gateway must revise its policies and procedures to state that all grievances are resolved within 30 days after receipt. Gateway 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. Gateway must provide documentation to CMS that demonstrates it adjudicates enrollee grievances fully and within the timeframes required by CMS. Gateway must provide CMS with a CMS-approved or accepted notice for informing enrollees of grievance deadline extension (i.e., a notice consistent with the CMS-issued model notice, Notice of Plan's Decision to Extend the Deadline for Making a Decision Regarding a Grievance). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: GV05
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS requested Gateway's notice template for notification of grievance disposition and Gateway provided a notice that is not consistent with the CMS-issued model notice, Notice of Plan's Decision Regarding a Grievance. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines.

Corrective Action Required:

Gateway must provide CMS with a CMS-approved or accepted notice for notification of grievance disposition (i.e., a notice consistent with the CMS-issued model notice, Notice of Plan's Decision Regarding a Grievance). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: GV06
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS requested Gateway's notice template for notification of grievance disposition and found that it is not consistent with the CMS-issued model notice, Notice of Plan's Decision Regarding a Grievance. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines.

Corrective Action Required:

Gateway must provide CMS with a CMS-approved or accepted notice for notification of grievance disposition (i.e., a notice consistent with the CMS-issued model notice, Notice of Plan's Decision Regarding a Grievance). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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.

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RE02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures for accepting and addressing requests for expedited redeterminations and found that, while they do contain the telephone number for prescribing physicians to make expedited redetermination requests, they do not include the telephone number for receiving oral requests from enrollees or their appointed representatives or a provision for maintaining documentation of expedited redetermination requests in a case file.

Corrective Action Required:

Gateway must revise its policies and procedures to include the telephone number for receiving oral requests from enrollees or their appointed representatives and a provision for maintaining documentation of expedited redetermination requests in a case file. Gateway 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
Audit ID: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RE04
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

Requirement:

Actions Following Decision to Deny Request for Expedited Redetermination - If the Part D sponsor denies a request for an expedited redetermination, it must automatically transfer the request to the standard redetermination timeframe, provide prompt oral notice to the enrollee, according to CMS requirements, and provide equivalent written notice within 3 calendar days of the oral notice.

Reference:

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

Deficiencies:

Gateway does not meet this requirement because CMS requested Gateway's notice template for notifying an enrollee that a request for an expedited redetermination is denied and Gateway was unable to provide a notice consistent with the CMS-issued model notice, Notice of Right to an Expedited Grievance, for this element. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines.

Corrective Action Required:

Gateway must provide CMS with a CMS-approved or accepted notice for notifying an enrollee that a request for an expedited redetermination is denied (i.e., a notice consistent with the CMS-issued model notice, Notice of Right to an Expedited Grievance). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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.

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RE05
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding timely notification and effectuation of standard redeterminations concerning covered drug benefit and found they do not include a provision stating that failure to notify the enrollee within the timeframe constitutes an adverse redetermination. CMS reviewed Gateway's notices for providing notification on an adverse redetermination and for requesting a reconsideration and Gateway was unable to provide notices consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration. Also, the notices Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines. CMS reviewed a sample of 10 requests for standard redeterminations concerning drug benefit from a universe of 42 and found that 10 cases are non-compliant. 8 cases were non-compliant because Gateway did not demonstrate that it provides enrollees with the notice, Request for Reconsideration, for denied redeterminations concerning drug benefit. 2 cases were non-compliant because Gateway did not provide timely notification to the enrollee of its decision.

Corrective Action Required:

Gateway must update its policies and procedures to include a provision stating that failure to notify the enrollee within the timeframe constitutes an adverse redetermination. Gateway must conduct training of its 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. Gateway must provide CMS with documentation demonstrating that Gateway provides enrollees with the notice, Request for Reconsideration, for denied redeterminations concerning drug benefit and makes decisions on standard redeterminations in a timely manner. Gateway must provide CMS with CMS-approved or accepted notices for providing notification on an adverse redetermination and for requesting a reconsideration (i.e., a notice consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration, respectively). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RE06
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding timely notification and effectuation of standard redeterminations concerning payment and found they do not include the following: - a provision stating that it 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, - a provision stating that failure to notify the enrollee within the timeframe constitutes an adverse redetermination, or - a provision stating that the Part D sponsor must inform the enrollee, within 24 hours, when the case is forwarded to the IRE. CMS reviewed Gateway's notices for providing notification on an adverse redetermination and requesting a reconsideration and Gateway was unable to provide notices consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines.

Corrective Action Required:

Gateway must update its policies and procedures to include the following: - a provision stating that failure to notify the enrollee within the timeframe constitutes an adverse redetermination, and - a provision stating that the Part D sponsor must inform the enrollee, within 24 hours, when the case is forwarded to the IRE. Gateway must conduct training of its 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. Gateway does not need to update its policies and procedures to include a provision stating that it 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. CMS reviewed the file, "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc." Because it was revised outside the audit period, CMS did not review it to determine compliance with this element. However, CMS did determine that "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc" contains provisions that demonstrate that Gateway has corrected the deficiency in its policies and procedures that CMS is citing for this element. Gateway must provide CMS with CMS-approved or accepted notices for providing notification on an adverse redetermination and for requesting a reconsideration (i.e., a notice consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration, respectively). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RE07
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures regarding enrollee notification following decision on expedited redetermination and requesting medical information required for making a decision on an expedited redetermination and found they do not include provisions stating that: - Gateway must notify the enrollee (and the prescribing physician involved, as appropriate) of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after it received the request for an expedited redetermination, - Notification of a favorable decision may be made orally or in writing, or - Gateway must inform the enrollee, within 24 hours, when the case is forwarded to the IRE CMS reviewed Gateway's notices for providing notification on an adverse expedited redetermination and for requesting a reconsideration and Gateway was unable to provide notices consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration. Also, the notice Gateway provided did not display the contract number in the lower left- or lower right-hand corner in accordance with CMS Marketing guidelines. CMS reviewed a sample of 3 requests for expedited redeterminations from a universe of 3 and found that 2 cases are non-compliant because Gateway did not provide notices consistent with the CMS -issued model notices, Notice of Redetermination and Request for Reconsideration, for adverse expedited redeterminations.

Corrective Action Required:

Gateway must revise its policies and procedures to include provisions stating that: - Gateway must notify the enrollee (and the prescribing physician involved, as appropriate) of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after it received the request for an expedited redetermination, - Notification of a favorable decision may be made orally or in writing, and - Gateway must inform the enrollee, within 24 hours, when the case is forwarded to the IRE Gateway must conduct training of its 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. Gateway must provide CMS with CMS-approved or accepted notices for providing notification on an adverse redetermination and for requesting a reconsideration (i.e., a notice consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration, respectively). If Gateway does not have a notice template that has been approved or accepted 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. Gateway 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. Gateway must provide CMS with documentation demonstrating that Gateway provide notices consistent with the CMS-issued model notices, Notice of Redetermination and Request for Reconsideration, for adverse expedited redeterminations.

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RE10
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed 2 standard requests for reconsiderations from a universe of 42 and found that Gateway did not forward one case to the IRE timely upon request.

Corrective Action Required:

Gateway must provide documentation to CMS demonstrating that it consistently forwards cases to the IRE timely.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RV01
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures for effectuating third party reversals on an appeal of a request for a benefit and found they do not include provisions stating that: - The benefit under dispute must be authorized or provided within 72 hours from the date Gateway receives notice reversing the decision, or - A notice must be sent informing the IRE of the effectuation. CMS reviewed internal data on Gateway's compliance with reconsideration decisions concerning drug benefit and found that in one of three cases it did not effectuate the IRE's decision in a timely manner.

Corrective Action Required:

No corrective action is required on Gateway's policies and procedures. CMS reviewed the file, "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc." Because it was revised outside the audit period, CMS did not review it to determine compliance with this element. However, CMS did determine that "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc" contains provisions that demonstrate that Gateway has corrected the deficiency in its policies and procedures that CMS is citing for this element. Gateway 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.

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
Contract Number: H5932
Audit ID: 2261
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RV02
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

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:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures for effectuating third party reversals on an appeal of a request for payment and found they do not include provisions stating that: - Payment must be authorized within 72 hours from the date Gateway receives notice reversing the decision, - Payment must be made no later than 30 days from the date Gateway receives notice reversing the decision, or - A notice must be sent informing the IRE of the effectuation.

Corrective Action Required:

Gateway must revise its policies and procedures to include a provision requiring a notice to be sent informing the IRE of the effectuation. Gateway must conduct training of its 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. No corrective action is required on Gateway's policies and procedures that lack provisions for authorizing payment within 72 hours from the date Gateway receives notice reversing the decision and making payment no later than 30 days from the date Gateway receives notice reversing the decision. CMS reviewed the file, "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc." Because it was revised outside the audit period, CMS did not review it to determine compliance with this element. However, CMS did determine that "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc" contains provisions that demonstrate that Gateway has corrected the aforementioned deficiencies in its policies and procedures that CMS is citing for this element.

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: 2261
Contract Number: H5932
Part D Sponsor Name: GATEWAY HEALTH PLAN, INC.

Audit Guide Version: MA-PD Sponsor Part D Audit Guide Version 1
Auditing Element: RV03
Audit Type: Routine
Audit Location: Desk Review
Date Report Issued: 12/11/2007
Date Report Due: 1/25/2008
Element Accepted Date: 2/21/2008
Element Release Date: 5/23/2008
Element Projected Completion Date: 5/1/2008

3 Year Reporting Cycle: 1/1/2006 - 12/31/2008
Estimated Visit Start Date: 10/22/2007
Estimated Visit Start Date: 10/26/2007
Actual Visit Start Date: 10/22/2007
Actual Visit End Date: 10/26/2007
Part D Sponsor Response Received Date: 1/25/2008
Part D Sponsor Response Due Date: 1/25/2008
CAP Release Date: 5/23/2008
CAP Accepted Date: 2/21/2008

Requirement:

Effectuation of Third Party Reversals ¿ Benefits (Expedited) - If the expedited determination or expedited redetermination for benefits by the Part D sponsor 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 24 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 § 423.638(b); Prescription Drug Benefit Manual; Chapter 18 ¿ Part D Enrollee Grievances, Coverage Determinations, and Appeals

Deficiencies:

Gateway does not meet this requirement because CMS reviewed Gateway's policies and procedures for effectuating third party reversals on an appeal of an expedited request for a benefit and found they do not include provisions stating that: - The benefit under dispute must be authorized or provided as expeditiously as the enrollee's health requires but no later than 24 hours after the date it receives notice reversing the decision, and - A notice must be sent informing the IRE of the effectuation.

Corrective Action Required:

No corrective action is required on Gateway's policies and procedures. CMS reviewed the file, "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc." Because it was revised outside the audit period, CMS did not review it to determine compliance with this element. However, CMS did determine that "(Medicare) Policy on Reconsideration for Drugs,revised 08.07.doc" contains provisions that demonstrate that Gateway has corrected the deficiency in its policies and procedures that CMS is citing for this element.