FOLLOW-UP REVIEW REPORT

OF

BLUE CROSS OF CALIFORNIA

A FULL SERVICE HEALTH PLAN

DATE ISSUED TO PLAN: DECEMBER 21, 2012
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EXECUTIVE SUMMARY

On August 9, 2012, the California Department of Managed Health Care (the “Department”) notified Blue Cross of California (the “Plan”) that the follow up portion of the Routine Medical Survey had commenced, and requested the Plan to submit information regarding its uncorrected deficiencies as cited in the Final Report dated August 30, 2011. The survey team conducted the onsite portion of the survey from October 23, 2012 through October 25, 2011.

The Department assessed the following areas:

Quality Management
Utilization Management
Utilization Management/Prescription (RX) Drug

In the Preliminary Report for the Routine Medical Survey, the Department identified four deficiencies and instructed the Plan to implement corrective actions. By the date the Final Report was issued, the Plan four deficiencies remained uncorrected. The Plan was advised that the Department would conduct an onsite Follow Up Review to assess the status of those outstanding deficiencies and issue a report within 18 months of the date of the Final Report.

The Department conducted its Follow Up Review and found four outstanding deficiencies cited in the Final Report.

<table>
<thead>
<tr>
<th>#</th>
<th>DEFICIENCY STATEMENT</th>
<th>CURRENT STATUS</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>The Plan does not ensure that effective action is taken to improve care where deficiencies are identified. (Section 1370; Rule 1300.70(a)(1).)</td>
<td>Corrected</td>
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<tr>
<td>2</td>
<td>The Plan’s Quality Assurance Program does not effectively trend utilization management denials that are overturned by the Plan’s internal appeal processes to ensure timely review and modification to the Plan’s utilization management guidelines in order to avoid improper initial service denials. (Section 1367.01(j); Section 1370; Rule 1300.68(b)(1); Rule 1300.70(a)(3).)</td>
<td>Corrected</td>
</tr>
<tr>
<td>UTILIZATION MANAGEMENT</td>
<td></td>
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<tr>
<td>------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>3</strong></td>
<td>Corrected</td>
<td></td>
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<tr>
<td>The Plan does not consistently notify the provider and the enrollee of the anticipated decision date when the Plan is unable to approve, modify, or deny a request for authorization of a service within the required timeframe. (Section 1367.01(h)(5).)</td>
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<tr>
<td>UTILIZATION MANAGEMENT/PRESCRIPTION (RX) DRUGS</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4</strong></td>
<td>Corrected</td>
<td></td>
</tr>
<tr>
<td>The Plan’s prescription drug denial notices do not include a clear and concise explanation of the reasons for the Plan’s decision. (Section 1367.01(h)(4).)</td>
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SECTION I: SUMMARY OF OUTSTANDING DEFICIENCIES FROM FINAL REPORT AND FOLLOW-UP SURVEY FINDINGS

The following details the Department’s findings regarding the outstanding deficiencies. The Plan’s failure to correct deficiencies identified in the Final Report may be grounds for disciplinary action as provided by Health and Safety Code section 1380(i).

DEFICIENCIES

QUALITY ASSURANCE

Deficiency #1: The Plan does not ensure that effective action is taken to improve care where deficiencies are identified.

Statutory/Regulatory Reference: Section 1370; Rule 1300.70(a)(1)

Plan’s Initial Compliance Effort: Anthem Blue Cross acknowledged their grievance and appeal policy and procedure may not have provided the level of detail necessary to assess whether the Plan was ensuring that effective action is being taken when deficiencies are identified. Accordingly, the Plan revised its grievance and appeals policy to ensure that effective action is taken when deficiencies are identified. Specifically the Plan Policy provides:

1. Initial review for all quality of care cases is conducted by a Medical Director and, at his or her discretion, specialty providers.
2. The Plan Medical Director reviews the case, documents his or her findings and may recommend follow-up action.
3. The Plan Grievance and Appeal Department will follow through with the recommendations or actions. Grievance and Appeal will be responsible for closing the case and corresponding with the practitioner of review, as warranted.
4. The Plan Medical Director’s recommendations may include referral to the Peer Review Sub-Committee.
5. Additionally the Peer Review Sub-Committee may recommend corrective action to improve performance prior to a recommendation for denial. Practitioner-focused corrective or consequential actions will be taken in those cases where the Peer Review Sub-Committee findings result in confirmation of major quality of care deviations from established quality standards.

The revised policy and procedure also provides that corrective action will be initiated as warranted and may include:

1. A written instructive communication to the practitioner of review.
2. A requirement for specific CME course(s).
3. A requirement for submission of an action plan to preclude similar incidents.
5. Referral to the Credentials Committee for possible contract termination.
6. If a participating practitioner does not respond to a corrective action request, the Plan Medical Director will initiate a phone call to obtain a response. If there is repeated non-
responsiveness, network contracting staff will be engaged as well as the Accountable Medical Organization Performance Oversight Council for additional action.

Department’s Finding Concerning Plan’s Initial Compliance Effort:

STATUS: NOT CORRECTED

Based upon the corrective actions undertaken, the Department has determined that this deficiency has not been corrected.

Although the Plan enhanced its grievance and appeals policy and procedures to delineate corrective actions and assign follow-up and tracking to the grievance and appeal staff, the emphasis on policy revisions is misplaced and the Plan’s corrective action plan does not address the specific issue raised in the deficiency.

The Survey findings revealed that the actions taken by the Plan’s Peer Review Sub-Committee are not commensurate with the severity of the quality of care issue identified in the case. The Plan’s corrective action plan is not adequate to address the Peer Review issue for the following reasons:

1. The Plan did not acknowledge or address the Plan’s substantial reliance on a policy to “track and trend” serious and confirmed quality of care problems.
2. Grievance and appeal policy revisions do not reflect the policy or processes performed in the Plan’s Peer Review Sub-committee; the subject of this deficiency.
3. The grievance policy changes do not reflect necessary adjustments to the peer review process that ensure the Peer Review Sub-Committee will impose corrective actions that are warranted by the facts, and follow through to ensure the proper resolution of the case.

Plan’s Subsequent Compliance Efforts: The Plan has continued to modify its Grievance and Appeals Policy in response to input from the Department. It has also reviewed and enhanced its Peer Review Sub-Committee activities to ensure that all potential quality issues are being thoroughly investigated, that appropriate corrective actions are being assigned as warranted by the facts, that cases are being referred to the Credentialing Committee as indicated, and that cases are being followed to the point of closure.

Department’s Findings Concerning Plan’s Subsequent Compliance Efforts: The Plan has incrementally modified its Grievance and Appeals Policy since the last Routine Medical Survey. The policy was reviewed during this Follow Up Review, and it is now consistent with the requirements of the regulation. Specifically, the revised policy addresses all of the elements required of the Plan in responding to serious and confirmed quality of care problems as compared to the Plan’s previous practice of limiting its response to “track and trend” actions. In addition, the policies and processes relative to the Peer Review Sub-Committee have been clearly defined in Sections VII and VIII of the revised Grievance and Appeals Policy. This committee is charged with conducting a thorough investigation of potential quality concerns and formulating corrective actions as required, with follow-up, to ensure proper resolution of cases.
Review of minutes, files, and staff interviews confirm that this committee is functioning in accordance with the revised policy.

Potential quality issues occur as a result of grievances, as referrals from other Plan operations, or from the findings of concurrent reviews. Issues are reviewed and investigated by clinical staff and assigned an initial level of severity. The levels are well documented and are assigned corresponding point values as part of the review. All issues with potential for adverse outcome are reviewed by a medical director, and in many cases, by an appropriate specialist. Any issue assigned a level 3 is automatically referred to the Peer Review Sub-Committee. As well, an annual report used to identify providers who have an aggregate score of 25 points (signaling substandard score) is also reviewed by a medical director; these providers may be referred to the Peer Review Sub-Committee for possible corrective action.

The Peer Review Sub-Committee minutes were reviewed by the Department, and in each case, investigation and discussion were documented, appropriate corrective action was developed, and follow-up was conducted to the point of case closure, up to (and including) network termination when indicated.

The Department reviewed two file sets during the Follow-up Review:

1) Twenty-nine cases across the two file sets assigned a level 0, 1 or 7 (indicating no quality issue, a minimal quality concern, or a communication issue, respectively) were reviewed. All levels were found to be appropriately assigned.

2) Twenty-seven cases across the two file sets assigned level 2 (indicating mild to moderate severity quality concern) or 3 (indicating highest severity quality concern) were reviewed. All cases were confirmed as quality issues of greater severity.

- Five of the 27 cases were assigned level 3 based on significant adverse outcomes. In each of the five cases, the Peer Review Sub-Committee’s investigation and discussion were documented, appropriate corrective action plans were developed, and follow-up was conducted to the point of case closure, up to (and including) network termination when indicated.
- Twenty-two of the 27 cases were assigned level 2. (One of the 22 cases was originally assigned level 3 but reduced to level 1 after additional investigation.) Each of the remaining 21 level 2 cases included evidence of investigation and corrective action with appropriate follow-up where indicated. However, once the Plan assigned the level, regardless of whether or not a provider had agreed to the occurrence of a quality of care issue, the Plan did not notify the provider of its final determination.

Following staff interviews, the Plan agreed that notification of the final determination in level 2 cases is required. Consequently, prior to completion of the Follow Up Review, the Plan made an additional change to the policy and crafted a provider notification letter. The Department reviewed these documents and concluded that the changes would satisfy this concern.

It is recommended that the Department follow up on implementation of this change during the next Routine Medical Survey.
The following level 2 cases are representative of those reviewed by the Department:

File ID 0510860834 (#7)
There was a delay in getting a call back to the enrollee, who was experiencing side effects from a medication for hyperthyroidism. No adverse outcome was noted. The provider responded to the Plan’s request for information, initiated corrective action within the office, and communicated with the enrollee. The Plan reviewer assigned level 2 to the case and accepted the treating provider’s response. There is no evidence that the Plan’s final determination was communicated to the provider.

File ID 0510886624 (#14)
The enrollee who had a lap band implanted for several years complained of vomiting and other discomforts and requested removal of the band. The patient’s assigned medical group denied the request for band removal. The specialty reviewer confirmed a quality issue as there was no evidence that the provider group had completed any recent studies or investigations to determine whether or not the patient had evidence of obstruction, which would necessitate removal of the band. Multiple documents confirm that all providers were aware of the patient’s condition and the issues. Following specialist review, the Plan reviewer assigned a level 2 to the surgeon for failure to rule out presence of obstruction. The removal was subsequently approved. There is no evidence that the Plan’s final determination was communicated to the provider.

File ID 0510906725 (#21)
The enrollee complained of delay in care for newly diagnosed diabetes mellitus. Based on a review of medical records from the enrollee’s provider group, it was determined that the enrollee had been followed by a physician assistant (PA) who was no longer with the medical group. The medical group’s response included corrective action that would avoid any delay in the future. The Plan reviewer assigned level 2 to the PA. The case was not sent to the Peer Review Sub-Committee as required by the Grievance and Appeals Policy. There was no indication that the Plan’s final determination was communicated to the provider.

**Table 1**
Quality Management File Review Issues

<table>
<thead>
<tr>
<th>FILE TYPE</th>
<th>NUMBER OF FILES</th>
<th>ELEMENT STATEMENT</th>
<th>COMPLIANT</th>
<th>DEFICIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0, 1, &amp; 7 Potential Quality Issues</td>
<td>29</td>
<td>Level Assignment Appropriate?</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>Level 2 &amp; 3 Potential Quality Issues</td>
<td>27</td>
<td>Appropriate Corrective Action and Follow Up</td>
<td>27</td>
<td>0</td>
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</table>

**STATUS: CORRECTED**
Based upon the corrective actions undertaken by the Plan, the Department has determined that this deficiency has been fully corrected.

The Department finds that the Plan has embraced the need to correct this deficiency since the last Routine Medical Survey. The Grievance and Appeals Policy and procedures are now consistent with the regulation. Evidence exists that the Plan aggressively pursues potential quality issues with thorough investigation, corrective action as indicated, and follow-up when needed. The issue of final provider notification following assignment of level 2, as noted above, was discussed with the Plan. As a result, the Plan has taken appropriate action, i.e., further revision to the Grievance and Appeal Policy and development of a provider notification letter.

**Deficiency #2: The Plan’s Quality Assurance Program does not effectively trend utilization management denials that are overturned by the Plan’s internal appeal processes to ensure timely review and modification to the Plan’s utilization management guidelines in order to avoid improper initial service denials.**

**Statutory/Regulatory Reference:** Section 1367.01(j); Section 1370; Rule 1300.68(b)(1); Rule 1300.70(a)(3)

**Plan’s Initial Compliance Effort:** In 2011 Anthem Blue Cross implemented a monthly 360 Reporting process, which allows the Plan to conduct a manual drill down analysis in order to evaluate top appeals and overturns by member and provider clinical and administrative appeal categories to determine why the appeals are being received, and determine effective actions that can be taken to reduce appeals in particular categories. As an example, the Plan provided its 360 Report for May 2011 which identified balance billing appeals as a leading cause for overturned administrative appeals. In response, the Plan assembled a balance billing advisory group developed corrective actions to reduce balance billing appeals.

The Plan also addressed its 360 Reporting with respect to overturned appeals to show the overturn rate at the drug level, and developed actions to facilitate improvements in the authorization process to reduce appeals, which were initially overturned for lack of medical information, and construct and disseminate information to the Pharmacy Council to improve drug policy.

The Plan stated in its corrective action response that it will also begin reporting denials by service code with corresponding appeal rates to the West Region Quality Committee and Medical Management Committee to facilitate tracking and trending. Additionally, the Plan stated it has a systems enhancement project underway for a new grievance and appeals tracking system.

**Department’s Finding Concerning Plan’s Initial Compliance Effort:**

**STATUS: NOT CORRECTED**

Based upon the corrective actions undertaken, the Department has determined that this deficiency has not been corrected.
The Plan’s proposed corrective actions included the implementation of a monthly 360 Report and this Report will provide information to allow the Plan the ability to analyze and evaluate clinical and administrative appeals and overturns. However, the Plan did not provide a template of the Report, a copy of a mock Report or describe the data collection or the reporting process in sufficient detail to demonstrate how it will resolve the issues identified in the Survey.

Regarding the issue specifically identified by the Department; high overturn rates for clinical denials regarding bariatric surgery and Lyrica, the Plan’s corrective action plan did not acknowledge the Department’s findings or describe a process to determine the reasons for the high overturn rates for these treatments. The 360 Report will be fitted with service codes that will facilitate the ability to track and trend clinical overturn rates sometime in the future. The Plan’s corrective action plan did not include information of when service codes will be configured or the date the trending of clinical appeals will be possible. The Plan provided a general reference to its efforts to improve its grievance and appeals tracking system and it is not known how or whether these changes are intended to address the issues raised in the survey.

The Plan's corrective action plan did not address the oversight and accountability within the organization responsible to understand and resolve a concerning trend in clinical overturn rates, such as the high overturn rates on bariatric surgery or Lyrica or others that may be identified through 360 Reports in the future. In the Plan’s example that identified a high overturn rate for balance billing, corrective actions were assigned to an “advisory group.”

**Plan’s Subsequent Compliance Efforts:** The Plan has continued to improve reports for its denial files. Presently, reports are generated monthly for all overturns on appeal and also for all overturns following independent medical review.

An independent California Medical Policy Committee (CMPC) has been established and implemented since the last Routine Medical Survey.

All overturns are researched and reviewed by a nurse. If overturns for a particular procedure exceed industry standard (presently 36% for independent medical review), or if there are five or more overturns for a denial of a specific procedure, they are referred to the Medical Director and subsequently to the CMPC for potential revision of medical policy.

**Department’s Findings Concerning Plan’s Subsequent Compliance Efforts:** Reports for overturns on appeal, and for overturns by independent medical review were reviewed in detail during the Follow Up Survey. These reports identify specific procedures that have been denied and the denials subsequently overturned. If the rate or number reaches a set threshold, as noted above, the guidelines for approving the treatment are reviewed by a Medical Director and the CMPC.

The Plan has demonstrated that treatment guidelines have been appropriately revised. As a result, denials and overturns for certain procedures have declined as trended from quarter to quarter. Examples include Breast MRI and Bariatric Sleeve Gastrectomy. In regard to Bariatric Sleeve Gastrectomy, overturns have essentially been eliminated. The
guideline for use of Botox for migraines has been revised with a subsequent significant decrease in denials and overturns. The guidelines used for approval or denial of requests for the drug Lyrica was thoroughly reviewed and although the evidence did not lead to a significant change in the guidelines, the Plan has recognized limited off-label use of the drug and has focused on obtaining additional information following requests for the drug. The Plan has also improved communication with providers on the issue. These measures have resulted in a decrease in denials and overturns for Lyrica.

In addition to review of overturns, the CMPC also reviews and provides input and feedback to the Plan's National Policy Committee. This input has resulted in changes to the national policy: A guideline change in the use of the drug Benlysta in patients diagnosed with Lupus; input from centers of excellence (e.g., UCLA Medical Center) and the American Gastroenterology Association resulting in a guideline change for the use of radiofrequency ablation for Barrett’s esophagitis.

The CMPC also considers recommendations from local specialists for policy change. This input has resulted in a local, and subsequently a national, policy change for the treatment of certain conditions (e.g., Barrett’s esophagitis). Other recommendations have been reviewed for balloon sinuplasty and cardiac MRI.

When there has been a change in policy, providers are notified by a mass e-mail notification. Also, a Web-based conference is held three times per quarter for all providers through which these changes are communicated. The Plan uses annual provider audits to reinforce its policy changes.

The Plan continues to develop an automated grievance and appeals tracking system (referred to by Plan staff as MAGI) to replace and improve upon the current manual processes. The Department will assess the Plan’s implementation of its automated grievance and appeals tracking system during the next Routine Survey. This system will be fully operational in California in the third quarter of 2013.

STATUS: CORRECTED

Based upon the corrective actions undertaken, the Department has determined that this deficiency has been fully corrected.

The Department finds that the Plan has demonstrated significant process changes to address this deficiency. Overturns for specific procedures and processes are now routinely monitored. Thresholds for consideration of policy change have been defined. All overturns are evaluated and those that meet pre-established thresholds are referred to a Medical Director and the newly formed and independent California Medical Policy Committee. These new processes are effective with evidence that specific guidelines have been revised and overturn rates have improved, thereby avoiding improper initial service denials and subsequent delays in care.

UTILIZATION MANAGEMENT

Deficiency #3: The Plan does not consistently notify the provider and the enrollee of the anticipated decision date when the Plan is unable to
approve, modify, or deny a request for authorization of a service within the required timeframe.

Statutory/Regulatory Reference: Section 1367.01(h)(5)

Plan’s Initial Compliance Effort: The Plan acknowledged in its corrective action response to the Department that the Plan failed to send delay notifications to the enrollee and provider in three of the seven cases identified by the Department as deficient, but stated that in six of the seven cases identified by the Department were “post-service reviews” not resulting in delay of the requested service to the enrollee. In response to the Department’s findings the Plan implemented the following corrective action steps:

1. The Plan convened an educational meeting with American Imaging Management leadership and compliance staff on June 16, 2011 regarding appropriate and timely handling of notifications. American Imaging Management sent an attestation back to Anthem Blue Cross confirming their understanding and commitment to timely handling of notifications. Also, American Imaging Management committed to instituting an internal audit process to avoid confusion in future. The Plan’s delegation oversight audits of American Imaging Management will also continue to monitor for compliance.

2. The Plan agreed to implement a process to ensure consistent use of claim system codes to generate the pended (claims) post-service notification letter to both member and provider. A workgroup has been underway to address this area and several operational options are being tested to meet this requirement.

3. Also, the Plan agreed to initiate system program enhancements to ensure that the post-service pended claims notification letter includes all required Department elements. The workgroup is operationalizing this piece with several options being tested to meet this requirement.

Department’s Finding Concerning Plan’s Initial Compliance Effort:

STATUS: NOT CORRECTED

Based upon the corrective actions undertaken, the Department has determined that this deficiency has not been fully corrected.

Although the Department recognizes the Plan’s compliance efforts to ensure the Plan consistently notifies the provider and enrollee of the anticipated decision date, the Department noted that the Plan’s directions to American Imaging Management and systems upgrades have not been fully implemented and therefore, the correction of this deficiency has not been demonstrated by the Plan, nor verified by the Department.

Plan’s Subsequent Compliance Efforts: In collaboration with American Imaging Management (AIM), the Plan conducted a root cause analysis of delayed or failed provider/enrollee notification. A process change was implemented via AIM’s Non-Application Change Management Committee (NACM) on September 23, 2011. Staff training on this specific issue was completed, including turnaround timeframes, on September 26, 2011. A formal training document was also developed, which includes
the entire workflow process. Comprehensive training for all staff was completed by
November 15, 2011.

As part of the corrective action plan, AIM completed a targeted weekly audit of all
California cases involving notifications to providers and enrollees of anticipated decision
dates when the Plan is unable to approve, modify, or deny requests for authorization of
services. The audits covered the period from the date of the implemented process
change through October 12, 2011. A total of 269 cases were reviewed; of these 24 were
initiated by a servicing provider. The results of the review demonstrated that 100% were
closed within the proper turnaround time.

The Plan also initiated a new process requiring its Claims Department to send a letter to
the provider and enrollee, requesting clinical information, when a claim is received
without the required authorization. Upon receipt of the requested information, claim staff
forward the information to the Utilization Management Department for review and
authorization as appropriate. If no information is received within the required timeframe,
the Claims Department mails a letter of denial to the provider and enrollee based on
lack of information.

The Department reviewed 30 utilization management denial files. Of those 30 files, the
Department found 28 files evidencing that the Plan communicated its decision to
providers within 24 hours. Of the 30 files, 20 files were for prior authorization and
concurrent review. Of these 20 files, the Department determined that 19 files
demonstrate that the Plan was compliant with the requirement of notifying provider(s)
within 24 hours of a decision that involves a prior authorization request or a concurrent
review of service(s).

| TABLE 2 |
| Utilization Management Standard Denial File |

<table>
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<tr>
<th>FILE TYPE</th>
<th>NUMBER OF FILES</th>
<th>ELEMENT STATEMENT</th>
<th>COMPLIANT</th>
<th>DEFICIENT</th>
<th>NOT APPLICABLE FILES</th>
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<tr>
<td>Utilization Management Standard Denial File</td>
<td>30</td>
<td>General Timeliness of Decision and Notification to Provider and Member</td>
<td>30 (100%)</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Utilization Management Standard Denial File</td>
<td>30</td>
<td>Decision communicated to Provider within 24 hours</td>
<td>28 (93%)</td>
<td>2</td>
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Utilization Management Standard Denial File

<table>
<thead>
<tr>
<th></th>
<th>Fax/Phone Provider within 24 hours for Prior Auth and Concurrent Review Cases</th>
<th>19 (95%)</th>
<th>1</th>
<th>10</th>
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**Department’s Findings Concerning Plan’s Subsequent Compliance Efforts:** During interviews with AIM staff, it is apparent that AIM has a full understanding of the Department’s requirement to process requests received from all providers within the required timeframes. Previously, AIM faxed requests to ordering providers for additional information and waited for their responses, resulting in delays in decision making. The new process requires Plan staff to make telephone calls to the providers (both ordering and servicing) to obtain the necessary information. This ensures that all necessary information is obtained before the deadline, and a decision is made within the required timeframe.

In interviews, Plan utilization management staff demonstrated a new process that has been operationalized to generate post-service notification letters to enrollees and providers from the Claims Department as soon as a claim is received and no authorization is in the system. As soon as the requested information is received, it is forwarded to The Utilization Management Department to generate an authorization decision. If no information is received within the required timeframe, a denial letter is generated stating that there was no information received. This letter includes all required appeal information and is sent to both the provider and the enrollee.

**STATUS: CORRECTED**

Based upon the corrective actions undertaken, the Department has determined that this deficiency has been corrected.

**UTILIZATION MANAGEMENT/PRESCRIPTION (RX) DRUGS**

**Deficiency #4: The Plan’s prescription drug denial notices do not include a clear and concise explanation of the reasons for the Plan’s decision.**

**Statutory/Regulatory Reference:** Section 1367.01(h)(4)

**Plan’s Initial Compliance Effort:** Anthem Blue Cross stated in their corrective action response that the Plan’s denial notices specific to Lyrica were corrected as of 7/1/2010, as a result of two independent Quality Improvement Programs. First, a Denial Rationale Workgroup was established in 2009 to create a standard style guide to draft clear and concise denial rationale and to be used by Plan Medical Directors for writing rationales. The Denial Rationale Workgroup continues to meet and style guide has been revised in 2010 and 2011.
Secondly, the revised pharmacy rationales were phased in at the time the Plan transitioned to its new Pharmacy Benefit Manager. The Plan established a committee to write compliant denial rationales for all medications referred for review to the Plan’s Medical Directors by the Plan’s Pharmacy Benefit Manager.

The Plan conducted an analysis on June 10, 2011 of Lyrica Denials from 7/1/2010 - 12/31/2010 to review internal appeals and to assess the denial language for member understanding. All Lyrica Denial Letters included one of the following four rationales which were written in accord with the criteria of the style guide:

1. …because of the information provided your request cannot be approved. Records do not show you have a covered condition. The covered conditions are seizures, diabetic peripheral neuropathy, post herpetic neuralgia, or fibromyalgia. Records do not show you have tried the preferred drugs in the past 6 months. The preferred drugs for a diagnosis of diabetic peripheral neuropathy are Cymbalta, carbamazepine, tricyclic antidepressants, gabapentin, or trazodone. The preferred drugs for a diagnosis of post herpetic neuralgia are carbamazepine, gabapentin, lidocaine patch, or tricyclic antidepressants. This decision was based on your plan's prior authorization criteria for Lyrica.

2. …because of the information provided your request cannot be approved. Records do not show you have widespread pain and skeletal pain in the center of your body for at least 3 months. This decision was based on your plan's prior authorization criteria for Lyrica.

3. …because of the information provided your request cannot be approved. Records do not show you have pain in at least 11 of 18 typical areas. This decision was based on your plan's prior authorization criteria for Lyrica.

4. …because of the information provided your request cannot be approved. Records do not show you have tried the preferred drugs in the past six months. The preferred drugs are cyclobenzaprine, Cymbalta, tricyclic antidepressants, fluoxetine, or Savella. This decision was based on your plan's prior authorization criteria for Lyrica.

**Department’s Finding Concerning Plan's Initial Compliance Effort**

**STATUS: NOT CORRECTED**

Based upon the corrective actions undertaken, the Department has determined that this deficiency has not been fully corrected.

Although the Plan had assembled a “Denial Rationale Workgroup” which created a standardized style guide to be used to draft clear and concise language for its denial letters, the examples provided in the Plan’s corrective action are not clear and concise.

In the first example provided by the Plan it is unclear whether the request for Lyrica is being denied because the enrollee does not have a "covered condition" or whether the enrollee has not tried the preferred drugs in the past six months for the diagnoses listed in the denial letter. Additionally, the Plan states “this decision was based on your plan’s
prior authorization criteria for Lyrica” but fails to actually define what is the Plan’s prior authorization criteria for Lyrica.

**Plan’s Subsequent Compliance Efforts:** The Plan’s medical leadership conducted a training program in October 2011 for all Medical Directors on functional writing skills. The training instructed participants how to write the rationales for their decisions in “clear and concise” language. The program used information from the Health Industry Collaboration Effort (ICE) and from Flesch-Kincaid readability standards (4th to 6th grade reading level) to develop the curriculum. The basic principles of the training are as follows:

1. Keep the rationale simple, stating only the reason pertaining to that particular denial.
2. State that if new information is received, other criteria may apply.
3. In cases of step therapy, state the criteria that preferred drugs must be tried before requested drugs can be approved.

The Plan has audited the “rationale language” on a monthly basis and provided feedback to specific Medical Directors when their language was still found to be inadequate. Since the training was conducted, there has been significant improvement. Currently, the Plan is auditing 10% of the rationale language statements to ensure compliance.

**Department’s Findings Concerning Plan’s Subsequent Compliance Efforts:** During interviews with Plan staff, it is apparent that they are aware of the “clear and concise” language requirement. The Plan used materials from ICE on “clear and concise” language and on other resources (Flesch-Kincaid readability standard) to train the medical directors. Since the training, audits are performed on a regular basis to provide feedback to the Medical Directors on this issue. According to Plan staff, there are still some letters that should be improved, but there has been significant improvement. The correction is evidenced by the following examples:

- Our clinical reviewer concluded the following because the information provided does not show you have a covered condition; your request cannot be approved. Medical studies we have seen only show that Nuvigil is effective to treat narcolepsy, obstructive sleep apnea-hypopnea syndrome, or shift work sleep disorder (SWSD). Your records show that you have sleepiness from mood. This decision was based on your plan’s prior authorization criteria for Nuvigil.
- Our clinical reviewer concluded the following because of the information provided; we cannot approve your request. Documentation has not been provided showing you have tried both epinastive (generic Elestat) and azelastine hydrochloride (generic Optivar). Documentation includes, but is not limited to, chart notes or prescription claims records or receipts. We based this decision on your plan’s prior authorization criteria for non-preferred ophthalmic allergy drugs.

In an audit of the pharmacy denial files, 91% were found to have “clear and concise” language.
An incidental finding is that only 87% of total 53 files showed the name of the reviewer in the letter. Plan staff are aware of this deficiency and a “permanent fix” is being planned by the end of 2012 where the medical director’s name is automatically inserted into the letter. At this time, the name has to be manually entered.

<table>
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<tr>
<th>FILE TYPE</th>
<th>NUMBER OF FILES</th>
<th>ELEMENT STATEMENT</th>
<th>COMPLIANT</th>
<th>DEFICIENT</th>
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<td>Pharmacy Denial Files</td>
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<td>Timeliness of decision,</td>
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<td></td>
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<td>Appropriate staff handling,</td>
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<td>Appeal information</td>
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<tr>
<td>Pharmacy Denial Files</td>
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<td>Denial Reason in Clear and Concise</td>
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<td>Pharmacy Denial Files</td>
<td>53 (Tier 1 and 2)</td>
<td>Name of reviewing physician on the</td>
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**STATUS: CORRECTED**

Based upon the corrective actions undertaken, the Department has determined that this deficiency has been fully corrected.
SECTION II: SURVEY CONCLUSION

The Department has completed its Routine Medical Survey of the Plan.