DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard, Mail Stop C1-22-06
Baltimore, Maryland 21244-1850

Medicare Part C and D Oversight and Enforcement Group

February 28, 2014

E-MAIL: **ILamirault@alamedaalliance.org**

Ingrid Lamirault
Chief Executive Officer
Alameda Alliance for Health
1240 South Loop Road
Alameda, CA 94502

Re: 2012 Program Audit – Notice of Audit Closure for Medicare Advantage and/or Standalone Prescription Drug Plan Contracts: H7292

Dear Ms. Lamirault:

On February 25, 2013, the Centers for Medicare & Medicaid Services (CMS) issued the final audit report to your organization for the above-referenced Medicare Advantage and/or Prescription Drug Plan contracts. The audit evaluated your organization's compliance with CMS requirements in the following areas:

1. Part D Formulary and Benefit Administration
2. Part D Coverage Determinations and Appeals
3. Part D Grievances
4. Part C Organization Determinations and Appeals
5. Part C Grievances and Dismissals
6. Part C Access to Care
7. Parts C & D Agent/Broker Oversight
8. Parts C & D Compliance Program Effectiveness
9. Enrollment and Disenrollment
10. Late Enrollment Penalty (LEP)

Your organization was afforded 90 calendar days from the report date to provide data and documents to CMS to demonstrate and attest that all of the deficiencies in the audit report were sufficiently corrected and not likely to recur. CMS reviewed your evidence of correction submission and also conducted a review to validate the implementation of required corrective actions and immediate corrective actions.

This notice is to inform you that based on the evidence provided by your organization and the validations conducted; you have corrected all conditions except:

<u>The following conditions still remain from the audit report:</u>

1. **Part D Coverage Determinations and Appeals – Appropriateness of Clinical Decision Making, Condition iii.** - The Alameda Alliance denial letter included inaccurate information in 5 cases reviewed during the audit. This condition was not validated as corrected because Alameda Alliance's internal controls were not effective in ensuring that denial letters provided to beneficiaries and prescribers contained an adequate rationale or correct information specific to each individual case and clearly documented next steps to obtain coverage or formulary alternatives. This condition was noted in 4 of 5 cases reviewed during the validation (CDM-01, CDM-02, CDM-03, and CDM-04).

2. **Part D Grievances, Additional Findings, Call Log, Condition ii.** - The beneficiary complaint should have been identified and processed as a coverage determination in 6 cases reviewed during the audit. This condition was not validated as corrected because Alameda Alliance does not have an effective process in place to identify beneficiary complaints that are coverage determination requests. Alameda Alliance stated that a new process was implemented in May 2013 as a result of the initial CMS audit and that the exceptions identified during the validation were likely a result of the learning curve applicable to the new process. This condition was noted in 2 out of 6 cases reviewed during the validation (CL-01 and CL-03).

3. **Compliance Program Effectiveness, Element VI. Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks, Condition i.** - Alameda Alliance failed to establish and implement an effective system for identification of compliance risks. This condition was not validated as corrected because the same issue was observed in 2 of 5 cases reviewed during the validation (CPE VI Sample, Record #4 and Record #5). While Alameda Alliance developed an annual risk assessment to identify potential compliance risks, the documentation provided for 2 audit/monitoring samples indicated that the criteria used to audit the effectiveness of these efforts is still incomplete. In addition, the workplan contained only five audits, three of which pertained to Medicare compliance. In addition, two of the three Medicare compliance audits were conducted as pre-delegation audits to assess new vendors to ensure they were ready to take over delegated functions. The Compliance audit workplan did not include any internal operational departments or include a process for responding to audit results and validation of corrective action plans (CAPs), as is required in section 50.6.3. Additionally, based on the documentation submitted, it appears that operational areas are self-auditing, which is not in compliance with section 50.6.5. Therefore, CMS recommends that Alameda Alliance review the monitoring and auditing tools provided in the January 25, 2013 HPMS Memo titled, "2013 Program Audit Process and Protocols".

<u>The following observations:</u>

1. **Formulary & Benefit Administration, Formulary Administration** – Alameda Alliance's reject messaging screens within the prescription claims adjudication system are not adequate to

ensure that pharmacists at the point of sale are aware of the approved quantity/days supply limit. This could lead to delay in beneficiary access to medications and possibly result in a beneficiary receiving no medications at all or receiving a sub-therapeutic dose. It is recommended that Alameda Alliance consider providing improved reject messaging stating quantity and days supply limits that would allow pharmacists to consult with the prescribing physician regarding the formulary dosing rather than resulting in the pharmacists altering the prescription to meet the quantity limit.

2. **Part D Coverage Determinations and Appeals – Appropriateness of Clinical Decision Making -** Alameda Alliance did not translate the denial reason in its Spanish-language denial letter. Alameda Alliance stated that the denial reason is a free text field which must be added to their Spanish-language template. The individual who completed the letter failed to translate the denial reason from English to Spanish. CMS recommends that Alameda Alliance strengthen its internal controls to ensure all letters are completed accurately and translated appropriately, as needed.

3. **Part C Organization Determinations and Appeals, Appropriateness of Clinical Decision-Making –** Alameda Alliance prematurely requested extensions to the adjudication timeframe for organization determination requests. While an extension is allowed to occur if the beneficiary requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the beneficiary, Alameda Alliance notified beneficiaries of the extension between 2 and 8 days of the receipt of the requests. CMS recommends that Alameda Alliance exercise diligence in processing requests and taking extensions at an appropriate interval after receipt of requests for organization determinations, if the beneficiary requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the beneficiary.

4. **Part C Organization Determinations and Appeals, Appropriateness of Clinical Decision-Making -** Alameda Alliance conducted outreach to their contracted providers in an attempt to secure data and information needed to make a clinically appropriate decision, however, some providers did not respond to Alameda Alliance's request for additional documentation. CMS recommends that Alameda Alliance take appropriate measures to ensure that contracted providers respond to additional documentation requests.

5. **Part C Organization Determinations and Appeals, Appropriateness of Clinical Decision-Making -** It was observed during the validation that Alameda Alliance prematurely issued denials after extending the timeframe for making the organization determination. Specifically, Alameda Alliance denied organization determination requests within 8 days of taking an extension to the adjudication timeframe for organization determination requests and before receipt of the clinical information needed to make an appropriate clinical decision. Alameda Alliance must take appropriate measures to ensure that established accepted standards of medical practice are employed in the assessment of an individual's medical condition through indications from the treating provider or from the individual's medical record prior to denying organization determination requests.

6. **Part C Organization Determinations and Appeals, Appropriateness of Clinical Decision-Making -** It was observed during the validation that Alameda Alliance failed to properly oversee their delegated entity. Specifically, the delegated entity used an outdated version of the Notice of Denial of Medical Coverage (NDMC). Alameda Alliance must ensure that delegated entities use the current version of the NDMC.

7. **Compliance Program Effectiveness, Element VI, Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks -** Alameda Alliance confirmed to CMS that an audit of its compliance program is performed every 2 years. However, CMS guidance states that Sponsors should audit its compliance program annually. CMS recommends that Alameda Alliance perform an annual audit of its compliance program.

Your validation provided CMS with a reasonable assurance you are in compliance with program requirements tested during the audit. However, CMS will require heightened monitoring of the conditions and/or observations noted above to ensure Sponsor continues to implement effective correction. Your Account Manager will contact you to address these issues.

CMS is closing your audit.

If you have any questions concerning this notice, please contact Mr. Darryl Brookins at 410-786-7542 or via email at Darryl.Brookins@cms.hhs.gov.

Sincerely,

/s/

Tawanda Holmes
Director, Division of Audit Operations
Medicare Part C and D Oversight and Enforcement Group

cc:
Michelle Turano, CMS/CM/MOEG
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