

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850



**MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP**

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**July 15, 2014**

E-MAIL: [david.tilford@medica.com](mailto:david.tilford@medica.com)

Mr. David Tilford  
Chief Executive Officer  
Medica Holding Company  
401 Carlson Parkway  
Minnetonka, MN 55305  
Phone: (952) 992-3826

Re: 2012 Program Audit – Notice of Audit Closure for Medicare Advantage and/or Standalone Prescription Drug Plan Contracts: H2450, H2458, H3283, H7526

Dear Mr. Tilford:

On November 1, 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 and Grievances
3. Part C Organization Determinations and Appeals and Grievances
4. Parts C & D Compliance Program Effectiveness
5. Part C and Part D Outbound Enrollment Verification Calls (OEV)

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.

**This notice is to inform you that based on the evidence provided by your organization and the validations conducted, you have corrected all conditions. However, the following observations were noted:**

1. **Part D Formulary & Benefit Administration, Formulary Administration** - Sponsor now requires all staff to run a test claim after setting up a Prior Authorization (PA) record to ensure that it works as intended. However, additional system changes and reporting features could be implemented such

as requiring test claims when the PA record is closed and the implementation of a reporting process to identify staff that are not compliant with the test claim requirement.

- 2. Part D Formulary & Benefit Administration, Formulary Administration-** Sponsor demonstrated that it initially adjusted, and then subsequently turned off, the High Dollar High Dose (HDHD) edits that were primarily responsible for the failures identified in the initial audit. However, additional review of all High Dose (HD) edits could be performed to ensure that these HD limits are not imposing a quantity limit that is more restrictive than the CMS approved quantity limit or for a daily dose that does not exceed the FDA maximum daily dose for any labeled indication.
- 3. Part D Formulary & Benefit Administration, Formulary Administration-** Sponsor's corrective actions do not incorporate the package size of the product in its system logic, and as a result, it appears to allow some products that are not in their smallest marketed package size to be dispensed in excess of the plan design day supply limits. Sponsor should modify its system logic accordingly as well as strengthen its monitoring of rejected claims to ensure claims are not being rejected improperly.
- 4. Part D Formulary & Benefit Administration, Formulary Administration-** It appears that the pharmacies still have the ability to override a reject requiring a B versus D determination when this reject is returned to the pharmacy as a drug utilization review (DUR) reject. It is not clear that the pharmacist at the point of sale is utilizing the criteria from CMS regulations to make this override determination. Sponsor did demonstrate that it effectively monitors and researches the use of the override codes on these paid claims so it can address those claims that may have improperly been allowed to pay initially under Part D. Sponsor should implement processes to remove the capability for pharmacies to override the DUR edit that the claims processor uses to reject immunosuppressants that require a B versus D determination.
- 5. Part D Coverage Determinations, Appeals, and Grievances, Effectuation Timeliness-** Sponsors internal 2013 4th quarter audit results revealed that four lifetime approval letters were incorrectly issued with the standard approval template instead of the lifetime approval template. Sponsor stated it did not reissue the approval letters when the error was discovered. Sponsor should ensure the appropriate approval notification templates are issued to beneficiaries.
- 6. Part D Coverage Determinations, Appeals, and Grievances, Clinical Decision-Making -**Sponsor stated that when prescribers do not respond to requests for information, no further outreach is performed nor does Sponsor track and trend the non-responding prescribers. This may cause an unnecessary delay or denial of beneficiary access to medications. Sponsor should ensure prescriber outreach guidelines are established and followed. A process for identifying and addressing network providers who do not respond to outreach attempts should be followed.

**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.**

Mr. David Tilford

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CMS is closing your audit.

CMS considers your compliance program's effectiveness to be essential in preventing, detecting and responding to potential non-compliance and fraud, waste, and abuse. Therefore, CMS expects your organization to continue monitoring the effectiveness of the corrective actions you have implemented and to continue to measure and improve the effectiveness of your compliance program. In addition, your Account Manager will continue to monitor and oversee your operations and compliance program to ensure that your organization is in compliance with all CMS requirements.

If you have any questions concerning this notice, please contact Doreen Gagliano at 410-786-9733 or via email at [Doreen.Gagliano@cms.hhs.gov](mailto:Doreen.Gagliano@cms.hhs.gov).

Sincerely,

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