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

April 21, 2014

E-MAIL: chris.palmieri@vnsny.org

Mr. Chris Palmieri
Chief Executive Officer
Visiting Nurse Service Choice
1250 Broadway, 11th Floor
New York, NY 10001

Re: 2012 Program Audit – Notice of Audit Closure for Medicare Advantage and/or Standalone Prescription Drug Plan Contracts: H5549 and H5303

Dear Mr. Palmieri:

On January 28, 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. Compliance Program Effectiveness
8. Agent/Broker Oversight
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:

The following conditions still remain from the audit report:

1. **Part D Formulary and Benefit Administration, Formulary Administration, Condition i.** – VNSNY failed to properly administer its CMS approved formulary by imposing unapproved quantity limits on formulary medications. This condition was not validated as corrected because the same condition was identified in 2 of 5 samples reviewed during the validation (FA-1 and FA-2).
2. **Part D Formulary and Benefit Administration, Additional Findings, Condition i.** – VNSNY lacks of point of sale system controls to prevent over utilization. This condition was not validated as corrected because the same condition was identified in 5 of 5 samples reviewed during the validation (FA-11, FA-12, FA-13, FA-14, and FA-15).
3. **Part C Organization Determinations and Appeals, Effectuation Timeliness, Condition i.** – When VNSNY received a request for a service, it did not notify the enrollee of its determination expeditiously, i.e., no later than 14 calendar days after the date the plan received the request. This condition was not validated as corrected because the same condition was identified in 5 of 5 samples reviewed during the validation (ET-1, ET-2, ET-3, ET-4, and ET-5).
4. **Part C Organization Determinations and Appeals, Appropriateness of Clinical Decision-Making, Condition iii.** – VNSNY did not assume financial responsibility for emergency and urgently needed services. This condition was not validated as corrected because the same condition was identified in 4 of 10 samples reviewed during the validation (CDM-5, CDM-6, CDM-7, and CDM-10).
5. **Part C Grievances and Dismissals, Dismissals, Condition ii.** – VNSNY did not use the 14 day extension for appeals when they had not received the Authorization of Representation (AOR) form by the conclusion of the 30 day timeframe. CMS was unable to validate correction of this condition through sample review as the validation universe provided did not contain any pre-service requests dismissed for failure to provide a requested AOR nor was an AOR noted to have been requested in any sample selected for other conditions validated.

The following new conditions were identified during the validation:

1. **Part C Organization Determinations and Appeals, Clinical Decision Making -** VNSNY failed to provide a written denial letter for a standard or expedited organization determination request. VNSNY stated that its process regarding payment denials did not include notice of denial of payment to the beneficiary in instances where there is no member liability. When the beneficiary does not receive notice of the denial, he/she may not be aware that there is no beneficiary liability and does not receive appeal rights. Additionally, there is a risk that the beneficiary could be pursued by the provider for payment (CDM-1, CDM-2, CDM-3, CDM-4, CDM-5, CDM-6, CDM-7, CDM-8, CDM-9, and CDM-10).
2. **Part C Organization Determinations and Appeals, Clinical Decision Making -** When VNSNY denied a request for payment from a non-contracted provider, the remittance advice/notice did not contain all required information related to the appeals process. VNSNY's appeal rights insert did not include a copy of the Waiver of Liability (WoL) form, nor did it contain an internet link to obtain the form. Failure to provide complete notifications regarding the denial of a request for payment may potentially cause financial harm to the beneficiary (CDM-5, CDM-6, CDM-7, CDM-8, and CDM-10).

3. **Part C Grievances and Dismissals, Dismissals -** VNSNY submitted a dismissal case to the IRE prior to the conclusion of the appeal time frame. VNSNY misunderstood the dismissal requirement. VNSNY believed that since the 60th day of the appeal timeframe fell on a Saturday, if the case had been held until Monday to be sent to the IRE, it would have been untimely. The beneficiaries' requests may have been denied prematurely, potentially resulting in a lapse in coverage, a delay in access to care/medication, and/or financial hardship (DIS-2 and DIS-3).

Observations:

1. **Part D Formulary and Benefit Administration, Formulary Administration -** VNSNY inappropriately entered prior authorizations (PA) under Part B at a generic product identifier (GPI) level 14. Entering an authorization at a GPI level 14 requires beneficiaries to unnecessarily repeat the authorization process when changing strengths of medications that had already been determined to pay under Part B. This practice may cause delays in access to formulary medications. CMS recommends VNSNY enter Part B authorizations at a less restrictive GPI level. During the validation, VNSNY indicated that effective August 23, 2013; their new policy was to enter Part B PAs at a GPI level 12 and effective for 10 years effective August 23, 2013. VNSNY updated all Part B PA records entered prior to August 23, 2013 to reflect the new policy, which was demonstrated through the review of sample cases. VNSNY estimated that 9 drugs and 28 beneficiaries (63 prior authorization records) had Part B prior authorization records updated to reflect the new policy.
2. **Part C Organization Determinations and Appeals, Clinical Decision Making -** VNSNY did not make the payment decision within 60 days after the receipt of the organization determination request. The beneficiary may be confused regarding the status of the organization determination, and/or appeal rights, and could potentially experience a lapse in coverage, a delay in access to care, and/or financial hardship. VNSNY should ensure that payment decisions regarding organization determinations are made timely.
3. **Part C Organization Determinations and Appeals, Clinical Decision Making -** VNSNY failed to perform sufficient outreach to the prescriber or beneficiary to obtain additional information necessary to make an appropriate clinical decision. VNSNY's failure to gather all necessary information prior to reaching a coverage decision may lead to an inappropriate denial, causing the beneficiary a delay and/or denial of access to care, and/or financial hardship. VNSNY should perform sufficient outreach to the prescriber or beneficiary to obtain additional information necessary to make an appropriate clinical decision.
4. **Part C Organization Determinations and Appeals, Clinical Decision Making -** VNSNY failed to ensure that a denial letter was complete and accurate, including an adequate rationale specific to the denial. Failure to include adequate and understandable information regarding the denial may impair the beneficiary's ability to mount an adequate appeal and could result in delay in/denial of care and/or financial hardship. VNSNY should ensure that denial letters are complete and accurate, including an adequate rationale specific to the denial.
5. **Part C Organization Determinations and Appeals, Clinical Decision Making –** VNSNY did not prepare a written explanation and send the case file to the IRE in a timely manner upon affirming, in whole or in part, its adverse decision on a standard payment reconsideration. Failure to timely auto-forward reconsideration requests to the IRE could potentially cause a delay in access to care and/or financial hardship for the beneficiary. VNSNY should prepare a written

explanation and send the case file to the IRE in a timely manner upon affirming, in whole or in part, its adverse decision on a standard payment reconsideration.

6. **Part C Organization Determinations and Appeals, Clinical Decision Making -** VNSNY did not ensure that the initiation of a reconsideration was by an authorized representative of the beneficiary. Failure to verify the legitimacy of an AOR could result in the inappropriate release of federally protected personal health information, a HIPAA violation. VNSNY should ensure that reconsiderations are initiated by the beneficiary or their authorized representative and an AOR form is on file where required by CMS.
7. **Compliance Program Effectiveness, Effective System for Routine Monitoring, Auditing and Identification of Compliance Risk -** VNSNY was observed to have established a system for tracking the receipt and disposition of HPMS memos. However, the tracking system could be strengthened by ensuring more consistent follow-up occurs for all HPMS memos that are still outstanding. Also, VNSNY should consider establishing an expected completion date when one isn't specified within the HPMS memo so that everyone within the organization will understand what is expected and what is considered late.
8. **Compliance Program Effectiveness, Effective Training and Education -** VNSNY's Compliance Program policies and procedures (P&Ps) related to compliance and FWA training did not include a requirement that newly appointed governing body members receive general compliance and FWA training within 90 days of appointment. CMS recommends that VNSNY update P&Ps to require general compliance and FWA training for newly appointed governing body members within 90 days of appointment, consistent with CMS requirements.

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.

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 Ms. Carmen Ayala-Bladt at 212-616-2312 or via email at Carmen.Ayala-Bladt@cms.hhs.gov.

Sincerely,

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

cc:
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