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


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

November 21, 2013

**VIA:**
**EMAIL (jconnel2@hfhs.org)**

Jim Connelly
Interim Chief Executive Officer
Health Alliance Plan
2850 W. Grand Blvd.
Detroit, MI 48202
Phone: 313-664-8355

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage - Prescription Drug Plan, and Prescription Drug Plan Contract Numbers: Health Alliance Plan of Michigan (H2312) and Alliance Health and Life Insurance Company (H2322 and S3440).

Dear Mr. Connelly:

Pursuant to 42 C.F.R. §§ 422.752(c)(1) and 423.752(c)(1), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Health Alliance Plan (HAP), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of $423,200 for violations found in each of the above-referenced contracts.

CMS has determined that HAP failed to provide its enrollees with benefits in accordance with CMS requirements. A Medicare Advantage and Prescription Drug Plan sponsor's central mission is to provide Medicare beneficiaries with medical services and prescription drug benefits within a framework of Medicare requirements that provide plan enrollees with a number of protections.

**History of Noncompliance**

CMS conducted a performance audit at HAP's Detroit, Michigan offices from July 16, 2012, through July 20, 2012. During the audit, CMS conducted reviews of HAP's operational areas to determine if HAP is following CMS rules, regulations, and guidelines. CMS found that HAP failed to comply with Medicare requirements related to formulary (i.e., prescription drug) transition supply. These deficiencies caused serious harm to its enrollees by disrupting

enrollees' access to prescription medications and health benefits. Subsequent review of HAP's formulary transition supply operations (in February of 2013) revealed that HAP continued to improperly deny its enrollees transition prescriptions to which they were entitled.

HAP disclosed to CMS in July of 2013, that inaccurate records were provided to CMS during the 2012 performance audit, where HAP employees created Medicare Part D Late Enrollment Penalty (LEP) beneficiary notices and included the notices in audit files provided to CMS to suggest compliance with CMS requirements, but the notices were not actually sent to beneficiaries. In response to HAP's self-disclosure, CMS conducted an additional audit at HAP's Detroit, Michigan office between August 26 and August 29, 2013, and identified numerous other instances of noncompliance in critical Parts C and D operational areas, including enrollment, premium billing/late enrollment penalty (LEP) and compliance program. These operational failures caused serious harm to or had a significant likelihood of causing serious harm to enrollees, including failing to advise enrollees of their LEP appeal rights, billing enrollees inaccurate premium amounts, and failing to notify beneficiaries that their enrollment requests were denied.

**Formulary and Benefit Administration Requirements**

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan sponsors and to Medicare Advantage sponsors that offer prescription drug benefits. Sponsors of these plans (Part D Sponsors) are required to enter into a contract with CMS by which the sponsor agrees to comply with a number of requirements based upon statute, regulations, and program instructions.

*Formulary*
*42 C.F.R. §§ 423.120(b)(2)(iv) and 423.120(b)(4)-(6); Internet Only Manual (IOM) Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.3.*

Each Part D sponsor maintains a drug formulary or list of prescription medications covered by the sponsor. A number of Medicare requirements govern how Part D sponsors create and manage their formularies. Each Part D sponsor is required to submit its formulary for review and approval by CMS on an annual basis. A Part D sponsor can change its formulary mid-year, but in order to do so must first obtain prior CMS approval, and then notify its enrollees of any changes, including any changes in cost-sharing amounts for formulary drugs. The CMS formulary review and approval process includes a review of the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare prescription drug claims (Part D claims), including the use of prior authorization or step therapy requirements.

*Utilization Management Techniques*
*42 C.F.R. § 423.272(b)(2); IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.*

Prior authorization is a utilization management technique used by Part D sponsors (as well as commercial and other health insurers) that requires enrollees to obtain approval from the sponsor for coverage of certain prescriptions prior to being prescribed the medication. Part D enrollees

can find out if prior authorization is required for a prescription by asking their physician or checking their plan's formulary (which is available online). Prior authorization guidelines are determined on a drug-by-drug basis and may be based on Food and Drug Administration (FDA) and manufacturer guidelines, medical literature, safety, appropriate use, and benefit design.

Quantity limits are a utilization management technique used by Part D sponsors. A sponsor may place a quantity limit on a drug for a number of reasons. A quantity limit may be placed on a medication as a safety edit based on FDA maximum daily dose limits. Quantity limits may also be placed on a drug for dosage optimization, which help to contain costs.

*Protected Class Drugs*
*§ 1860D-4(b)(3)(G) of the Social Security Act; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2.5*

Part D sponsors are ***not*** allowed to require prior authorization or step therapy for enrollees stabilized on drugs that have been designated as "protected class drugs." Protected class drugs are drugs that are typically critical to the health and safety of the population for whom the drugs are prescribed. There are six classes of drugs to which Medicare enrollees must have ***uninterrupted access*** to all of the drugs in that class. The six protected classes are:

- Anti-depressants (e.g., fluoxetine, venlafaxine, sertraline) used for treating depression;
- Antipsychotics (e.g., Risperdal, Zyprexa, Seroquel) used for treating psychiatric disorders;
- Anticonvulsants (e.g., divalproex, Lyrica, carbamazepine) used for preventing or reducing seizures;
- Antiretrovirals used for the treatment of HIV and AIDS;
- Antineoplastics used for the treatment of cancers; and
- Immunosuppressants used to prevent the rejection of transplants.

*Transition of Coverage*
*42 C.F.R. § 423.120(b)(3) and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.4.*

Additionally, a Part D sponsor must provide for an appropriate transition process for enrollees prescribed any Part D drugs that are not on its formulary in certain designated situations. A Part D Sponsor's transition process must address situations in which an individual brings a prescription for a drug that is not on the formulary to a participating pharmacy. This may be particularly true for full-benefit dual eligible (i.e., Medicare and Medicaid) enrollees who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. Part D sponsors must have systems capabilities that allow them to provide a one-time, temporary supply of a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or quantity limits under a sponsor's utilization management rules). In the long-term care setting, the temporary supply of non-formulary Part D drugs must be for at least 91 days, and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed. The transition

process is designed to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

**Deficiencies Related to Formulary and Benefit Administration – Transition of Coverage**

During the formulary transition validation review, CMS confirmed ongoing, serious violations of transition of coverage requirements. HAP's violations include:

- Failure to provide long term care beneficiaries with multiple transition fills of non-formulary medication. This is in violation of 42 CFR § 423.104(a), 42 CFR § 423.120(b)(3)(i)(D), and § 1860D-4(b)(3)(G) of the Social Security Act.

- Failure to provide continuing beneficiaries a transition supply of medication due to inappropriately applying a quantity limit during transition. This is in violation of 42 CFR § 423.104(a), 42 CFR § 423.120(b)(3)(i)(D), and § 1860D-4(b)(3)(G) of the Social Security Act.

- Failure to properly identify beneficiaries as new and failure to provide a transition fill. This is in violation of 42 CFR § 423.104(a), 42 CFR § 423.120(b)(3)(i)(A-C), and § 1860D-4(b)(3)(G) of the Social Security Act.

- Failure to provide new beneficiaries a transition supply of medication due to inappropriately applying a prior authorization during transition. This is in violation of 42 CFR § 423.104(a), 42 CFR § 423.120(b)(3)(i)(A-C), and § 1860D-4(b)(3)(G) of the Social Security Act.

**Relevant Enrollment Requirements**

An MA/PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines. *See* 42 C.F.R. §§ 422.60(e), 423.32(c). When an enrollment request is incomplete, the sponsor must document its efforts to obtain the information required to complete the enrollment request. *See* Medicare Managed Care Manual, Chapter 2 §40.2.2, Medicare Prescription Drug Benefit Manual, Chapter 3 §40.2.2. The sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS. *See* 42 C.F.R. §§ 422.60(e)(3), 423.32(d).

**Deficiencies Related to Enrollment**

HAP failed to process enrollment requests in accordance with CMS enrollment guidelines. This is a violation of 42 C.F.R. §§ 422.60(e), 423.32 (c) and (d). This failure resulted in the following deficiencies:

- Failure to issue a request for information letter to beneficiaries to follow up on incomplete enrollment requests. This does not comply with the Medicare Managed Care Manual, Chapter 2 §40.2.2, and the Medicare Prescription Drug Benefit Manual, Chapter 3 §40.2.2.

- Failure to provide beneficiaries with prompt notice of denial of enrollment request. This is in violation of 42 C.F.R. §§ 422.60(e), 423.32(d).

- Failure to issue enrollment confirmation letters to beneficiaries. This is in violation of 42 C.F.R. §§ 422.60(e)(3), 423.32(d).

**Relevant Premium Billing/Late Enrollment Penalty (LEP) Requirements**

Part D sponsors must charge enrollees a consolidated monthly Part D premium. 42 C.F.R. § 423.293(a). A Part D enrollee who did not enroll when s/he was first eligible and had a break in creditable prescription drug coverage for a continuous period of at least 63 days or longer, is subject to a late enrollment penalty (LEP), which penalty is added to and increases the base beneficiary premium for that enrollee. 42 C.F.R. §§ 423.46(a) and 423.286(d)(3).

Part D plan sponsors are responsible for determining, at the time of enrollment, whether a beneficiary was previously enrolled in a Medicare prescription drug plan or had other creditable coverage prior to applying to enroll in their plan, and whether there were any lapses in coverage of 63 days or more. 42 C.F.R. § 423.46(b). Part D plan sponsors inform CMS of these lapses in creditable coverage so that CMS can compute the LEP and inform the sponsor of the LEP amount. 42 C.F.R. § 423.46(b). Creditable coverage period determinations are reported to CMS in the form of full uncovered months, also referred to as a number of uncovered months (NUNCMO). The NUNCMO reflects the number of full calendar months that a beneficiary did not have Medicare prescription drug coverage or other creditable prescription drug coverage. 42 C.F.R. § 423.46(b), Medicare Prescription Drug Benefit Manual, Chapter 4 § 30. The sponsor then bills the beneficiary for the LEP amount calculated by and provided by CMS, as part of the premium. 42 C.F.R. § 423.286(d)(3).

Part D sponsors must provide enrollees a written notice about the LEP (both initial implementation of LEP and any adjustments to the LEP) within 10 calendar days of receiving notice of the LEP amount from CMS, including information about how to request a review ("appeal rights") of the penalty. 42 C.F.R. § 423.46(c), Medicare Prescription Drug Benefit Manual, Chapter 4 § 50.1.

At the start of each calendar year, the LEP amount will change based on the change to the national base beneficiary premium. Part D plan sponsors must adjust their bills accordingly to reflect the new base premium amount, and notify affected enrollees of this new amount via premium bill or separate notice. 42 CFR § 423.286(d)(3), Medicare Prescription Drug Benefit Manual, Chapter 4 § 40.3.

**Deficiencies Related to Premium Billing/LEP Determinations**

CMS identified serious violations of Premium Billing/LEP Determinations, including the following:

- Failure to send notification to beneficiaries of LEP and appeal rights. This is in violation of 42 C.F.R. § 423.46(c), and is inconsistent with the Medicare Prescription Drug Benefit Manual, Chapter 4 § 50.1.

- Failure to process LIS/LEP files, including failure to update LEP premium amounts for the 2012 and 2013 calendar years, and charging beneficiaries LEP amounts not dictated by CMS, after receiving retroactive Number of Uncovered Months (NUNCMO) updates from CMS, thus billing inaccurate premiums to beneficiaries. This is a violation of 42 CFR § 423.286(d)(3).

**Relevant Disclosure of Information Requirements**

Parts C and D sponsors are required to permit CMS to evaluate, among other areas, the enrollment and disenrollment records through inspection, audit or other means. Sponsors are required to submit to CMS any information deemed necessary by CMS for the administration or evaluation of the Medicare program. 42 CFR §§422.504(e-f) and 423.505(e-f).

**Providing Inaccurate Information to CMS**

HAP violated Parts C and D requirements by providing inaccurate records to CMS and its designee:

- HAP confirmed to CMS in September of 2013 (as part of the follow-up to the July 2013 self-disclosure referenced above), that a HAP LEP Manager directed HAP employees in February 2012 to generate LEP appeal letters (the letters were not actually sent to the beneficiaries) and include the letters in member files provided to the independent review entity in order to appear compliant with the LEP beneficiary appeal letter requirement.

- HAP also confirmed to CMS in September 2013 that some of the LEP letters produced in February 2012 were subsequently provided to CMS in July 2012 during the CMS performance audit, and that HAP employees generated additional LEP appeal letters in advance of the 2012 performance audit, for other member files subject to the audit, to suggest compliance with the LEP appeal letter requirement.

**Basis for Civil Money Penalty**

Pursuant to 42 C.F.R. §§ 422.752(c) and 423.752(c), CMS has determined that HAP's violations of Parts C and D requirements are significant enough to warrant the imposition of a CMP. In violating Parts C and D requirements, HAP failed substantially to carry out the terms of its MA-PD and PDP contracts with CMS and failed to carry out its contract with CMS in a manner consistent with the effective and efficient implementation of the program. 42 C.F.R §§ 422.510

(a)(1) and (2) and 423.509(a)(1) and (2). HAP's violations directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees. 42 C.F.R §§ 422.760 (b)(2) and 423.760(b)(2).

**Right to Request a Hearing**

HAP may request a hearing to appeal CMS's determination in accordance with the procedures outlined in 42 C.F.R. §§ 422 and 423, Subpart T. HAP must send a written request for a hearing to the Departmental Appeals Board office listed below within 60 calendar days from receipt of this notice or by January 21, 2014. 42 C.F.R. §§ 422.1006, 423.1006, 422.1020 and 423.1020. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which HAP disagrees. HAP must also specify the basis for each contention that the finding or conclusion of law is incorrect. The request should be sent to:

Civil Remedies Division
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6132
330 Independence Ave., S.W.
Cohen Building Room G-644
Washington, D.C. 20201

A copy of the hearing request should also be sent to CMS at the following address:

Michael Dibella
Acting Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
MAIL STOP: C1-22-06
Baltimore, MD 21244
Email: Michael.Dibella@cms.hhs.gov
FAX: 410-786-4480

If HAP does not request an appeal in the manner and timeframe described above, the initial determination by CMS to impose a CMP will become final and due on January 22, 2014. HAP may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS.

Please note that further failures by HAP may result in additional applicable remedies available under law, up to and including contract termination, the imposition of intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

If HAP has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

Gerard J. Mulcahy
Director
Medicare Part C and D Oversight and Enforcement Group

cc: Ms. Elizabeth Lopez-Cepero, CMS/ CMHPO/Region V
Ms. Dolores Perteet, CMS/ CMHPO/Region V
Mr. Kenvin Ivory-Kennedy, CMS/ CMHPO/Region V