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

PROGRAM COMPLIANCE AND OVERSIGHT GROUP

December 14, 2012

VIA:
EMAIL (walvin@hap.org)
AND FACSIMILE (313-664-8479)

William Alvin
Chief Executive Officer
Health Alliance Plan
2850 W. Grand Blvd.
Detroit, MI 48202
Phone: 313-664-8360

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage, Medicare Advantage - Prescription Drug Plan, and stand-alone Prescription Drug Plan Contract Numbers: Health Alliance Plan of Michigan (H2312), Alliance Health and Life Insurance Company (H2322 and S3440), and Midwest Health Plan, Inc. (H5685)

Dear Mr. Alvin:

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 amount of $75,000 for the following Medicare Advantage (MA), Medicare Advantage-Prescription Drug Plan (MA-PD), and stand-alone Prescription Drug Plan (PDP) Contracts: Health Alliance Plan of Michigan (H2312), Alliance Health and Life Insurance Company (H2322 and S3440), and Midwest Health Plan, Inc. (H5685).

CMS has determined that HAP failed to provide its enrollees with services and benefits in accordance with CMS requirements. An MA-PD/PDP sponsor's central mission is to provide Medicare enrollees with medical services and prescription drug benefits within a framework of Medicare requirements that provide enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an 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 regulations and guidelines. CMS reviewed HAP's prescription drug claims, data systems, and operations and discovered that HAP inappropriately rejected claims for its enrollees, failed to provide its enrollees with prescription drug coverage as required by its CMS-approved formularies, and failed to comply with CMS requirements governing the processing of Part C grievances, organization determinations, and Part C appeals. § 1860D-4(b)(3)(G) of the Social Security Act; 42 C.F.R. Part 422, Subpart M (and related beneficiary protection provisions in Subparts C and F and contract provisions in Subpart K) and 42 C.F.R. Part 423, Subparts C and K. Violations in these areas can result in enrollees experiencing delays or denials in receiving covered medical services or prescription drugs, and increased out-of-pocket costs. These violations directly adversely affected (or had the substantial likelihood of adversely affecting) HAP's enrollees.

Part C Grievance, Organization Determination, and Appeal Relevant Requirements

Medicare enrollees have the right to contact their plan sponsor to express general dissatisfaction with the operations, activities, or behavior of the plan sponsor or to make a specific complaint about the denial of coverage for services to which the enrollee believes he or she is entitled. Sponsors are required to classify complaints about coverage for services as a request for an organization determination. 42 C.F.R. §§ 422.564 (b), 422.566(b).

The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination. 42 C.F.R. § 422.566(c). The first level of review is the organization determination, which is conducted by the plan sponsor, and the point at which beneficiaries or their physicians submit justification for the service or benefit. 42 C.F.R. § 422.566. Coverage decisions must be made in accordance with Medicare coverage guidelines, Medicare covered benefits, and each sponsor's CMS-approved coverage policies. 42 C.F.R. § 422.101(a-b). If the organization determination is adverse (not in favor of the enrollee), the enrollee has the right to file an appeal. 42 C.F.R. § 422.578. There are different decision making timeframes for the review of organization determinations and appeals. 42 C.F.R. § 422.568, 422.572, and 422.590.

Deficiencies Related to Organization Determinations and Appeals

CMS identified serious violations of Part C requirements in HAP's organization determinations operations. HAP's violations include:

- Failure to pay for Medicare covered services. This is in violation of 42 C.F.R. § 422.101(a). For example, HAP auto-denies unclassified procedures without requesting documentation to make appropriate organization determinations.

Prescription Drug Program 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.

Step therapy is another utilization management technique used by Part D sponsors (as well as commercial and other health insurers) to ensure that when enrollees begin drug therapy for a medical condition, the first drug chosen is cost-effective and safe, and other more costly or risky drugs are only prescribed if they prove to be clinically necessary. The goal of step therapy is to control costs and minimize clinical risks.

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 non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber 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

CMS identified serious violations of Part D requirements in HAP's formulary and benefit administration operations. HAP's violations include:

- Improperly rejected claims as non-formulary and required an inappropriate prior authorization during beneficiary transition, resulting in the inappropriate denial or delay of Part D drugs (including protected class medications) to beneficiaries. This is in violation of 42 C.F.R. §§ 423.104(a), 423.120(b)(3), 423.505(b)(17), and § 1860D-4(b)(3)(G) of the Social Security Act;

- Improperly applied utilization management edits during the 90 day transition period for long term care beneficiaries, resulting in the inappropriate denial or delay of Part D drugs

(including protected class medications) to beneficiaries. This is in violation of 42 C.F.R. §§ 423.104(a), 423.120(b)(3), 423.505(b)(17), and § 1860D-4(b)(3)(G) of the Social Security Act.

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 Part D requirements are significant enough to warrant the imposition of a CMP. In violating multiple Part D requirements, HAP failed substantially to carry out the terms of its MA, 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).

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. Parts 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 February 13, 2013. 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:

Patricia Axt
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
MAIL STOP: C1-22-06
Baltimore, MD 21244
Email: Trish.Axt@cms.hhs.gov
FAX: 410-786-6301

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 February 14, 2013. 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
Acting Director
Program Compliance and Oversight Group

cc: Ms. Elizabeth Lopez-Cepero, CMS/ CMHPO/Region V
Ms. Lisa Riley, CMS/ CMHPO/Region V
Ms. Pamela Nicholson, CMS/CMHPO/Region V