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

January 12, 2017

Michael Gallagher
President and CEO
AvMed, Inc.
4300 NW 89 Blvd.
Gainesville, FL 32606

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Contract Number: H1016

Dear Mr. Gallagher:

Pursuant to 42 C.F.R. §§ 422.752(c)(1), 422.760(b), 423.752(c)(1), and 423.760(b), the Centers for Medicare & Medicaid Services (CMS) is providing notice to AvMed, Inc. (AvMed) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$764,375** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number H1016.

An MA-PD organization's primary responsibility is to provide Medicare enrollees with medical services and prescription drug benefits in accordance with Medicare requirements. CMS has determined that AvMed failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of AvMed's Medicare operations from July 25, 2016 through August 5, 2016. In a program audit report issued on December 5, 2016, CMS auditors reported that AvMed failed to comply with Medicare requirements related to Part C and Part D organization/coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 422, Subpart M, and Part 423, Subpart M. AvMed's failures in these areas were systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees. The enrollees experienced, or likely experienced, delayed or denied access to covered benefits, increased out-of-pocket costs, and/or inadequate grievance or appeal rights.

Part C and Part D Organization/Coverage Determination, Appeal, and Grievance Requirements
(42 C.F.R. Part 422, Subpart M; 42 C.F.R. Part 423, Subpart M; Chapter 18 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18); Chapter 13 of the Medicare Managed Care Manual (IOM Pub. 100-16))

A Medicare enrollee has the right to contact his or her plan sponsor to express general dissatisfaction with the sponsor's operations, activities, or behavior. These types of complains must be processed as grievances. An enrollee can also make a specific complaint about the denial of coverage for Part C medical services or Part D drugs to which the enrollee believes he or she is entitled. Sponsors are required to classify these types of complaints as organization determinations (Part C medical services) or coverage determinations (Part D drugs). It is critical for a sponsor to properly classify each complaint as a grievance, organization/coverage determination, or both. Improper classification may result in enrollees not receiving the required level of review, and/or experiencing delayed access to medically necessary or life-sustaining treatments.

The first level of review is the organization determination or coverage determination, which is conducted by the plan sponsor. The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination or coverage determination.

If the organization or coverage determination is adverse (i.e., not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of the appeal – called a reconsideration (Part C) or redetermination (Part D) – is handled by the plan sponsor and must be conducted by a person who was not involved in the organization determination or coverage determination decision. The second level of appeal is made to an independent review entity (IRE) that contracts with CMS. If the sponsor does not issue the reconsideration decision timely, the decision is considered to be unfavorable to the enrollee and must be automatically sent to the IRE.

Violations Related to Part C and Part D Organization/Coverage Determinations, Appeals and Grievances

CMS determined that AvMed violated the following Part C and Part D organization/coverage determination, appeal, and grievance requirements:

1. Failure to appropriately auto-forward coverage determinations and/or redeterminations (standard and/or expedited) to the Independent Review Entity (IRE) for review and disposition. As a result, the enrollees did not receive an independent review of their coverage requests and may have experienced inappropriate denials of or delays in access to medications. This deficiency violates 42 C.F.R. §§ 423.568(h), 423.572(d), 423.578(c)(2), 423.590(c) and (e), and Chapter 18, Sections 40.4, 50.6, 70.7.1, and 70.8.2 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

2. Failure to notify beneficiaries and providers, if the providers requested the service, of its decisions within 14 calendar days of receipt of standard organization determination requests. As a result, the enrollees may have experienced delayed access to approved services. Enrollees either did not receive their pre-service organization determination decisions timely, or they never received them at all. This

deficiency violates 42 C.F.R. § 422.568(b), and Chapter 13, Section 40.1, Paragraph 1 of the Medicare Managed Care Manual (IOM Pub. 100-16).

3. Failure to provide enrollees with written notice of their right to file a complaint with the Quality Improvement Organization (QIO) in the sponsor's quality of care grievance resolution letters. As a result, enrollees were unaware of their right to have the QIO investigate their quality of care concerns. . This deficiency violates 42 C.F.R. § 422.564(e)(3)(iii) and Chapter 13, Section 20.2, Paragraph 5 of the Medicare Managed Care Manual (IOM Pub. 100-16).

4. Failure to effectuate payment reconsiderations for enrollees within 60 days after sponsor received the request for reimbursement. As a result, enrollees were not reimbursed within the required timeframes, which may have resulted in financial hardship for the enrollees. This deficiency violates 42 C.F.R. § 422.618(a)(2), and Chapter 13, Section 70.7.3, Paragraph 1 of the Medicare Managed Care Manual (IOM Pub. 100-16).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 422.752(c)(1), § 422.760(b), § 423.752(c)(1), and § 423.760(b), CMS has determined that AvMed's violations of Parts C and D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. AvMed failed substantially:

- To carry out the terms of its contract with CMS (42 C.F.R. § 422.510(a)(1) and 42 C.F.R. § 423.509(a)(1));
- To comply with the requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 422.510(a)(4)(ii) and § 423.509(a)(4)(ii)).

Right to Request a Hearing

AvMed 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. AvMed must send a written request for a hearing to the Departmental Appeals Board office listed below by March 13, 2017. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which AvMed disagrees. AvMed 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:

Kevin Stansbury
Acting Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: kevin.stansbury@cms.hhs.gov

If AvMed 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 March 14, 2017. AvMed may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS. To notify CMS of your intent to make payment and for instructions on how to make payment, please call or email the enforcement contact provided in the email notification.

Impact of CMP

Please note, this action will factor into AvMed's Star Rating and Past Performance calculations. For Star Ratings, there will be a deduction of up to 40 points from the Beneficiary Access and Performance Problems measure. For Past Performance, your organization will receive one negative past performance point.

Further failures by AvMed to provide its enrollees with Medicare benefits in accordance with CMS requirements may result in CMS imposing additional remedies available under law, including contract termination, intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

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

Sincerely,

/s/

Vikki Ahern
Director
Medicare Parts C and D Oversight and Enforcement Group

cc: Kevin Stansbury, CMS/CM/MOEG/DCE
Mortez Williams, CMS/ CMHPO/Region IV
Michael Taylor, CMS/ CMHPO/Region IV
Hugo Huapaya, CMS/ CMHPO/Region IV