

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard, Mail Stop C1-22-06
Baltimore, Maryland 21244-1850



Program Compliance and Oversight Group

November 19, 2010

VIA FEDERAL EXPRESS DELIVERY
EMAIL (rfahlman@arcadianhealth.com)
AND FACSIMILE: (510-817-1852)

Mr. Robert Fahlman
Chairman and CEO
Arcadian Management Services, Inc.
500 12th Street, Suite 350
Oakland, CA 94607
Phone: (510-817-1801)

Re: Notice of Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) For All Medicare Advantage-Prescription Drug Contracts

Dear Mr. Fahlman:

Pursuant to 42 C.F.R. § 422.756(d) and § 423.756(d), the Centers for Medicare & Medicaid Services (CMS) hereby provides notice to Arcadian Management Services, Inc. (Arcadian) of the imposition of intermediate sanctions for all of Arcadian's Medicare Advantage-Prescription Drug contract numbers: H0320, H2899, H3533, H4125, H4529, H5416, H5578, H5619, H5700, H5783, and H7179. These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries (42 C.F.R. § 422.750(a)(1); § 423.750(a)(1)) and the suspension of all marketing activities to Medicare beneficiaries. 42 C.F.R. § 422.750(a)(3); § 423.750(a)(3). This determination to impose intermediate sanctions will be effective 15 calendar days after the date of this notice, or on December 5, 2010, and will remain in effect until CMS is satisfied that the deficiencies upon which the determination is based have been corrected and are not likely to recur. 42 C.F.R. § 422.756(d)(3); § 423.756(d)(3).

As the parent organization for eleven (11) Medicare Advantage-Prescription Drug (MA-PD) contracts, Arcadian has been entrusted to provide Medicare beneficiaries with access to essential Medicare services. As such, Arcadian has the important responsibility to protect the interests not only of those beneficiaries who are enrolled in its Medicare Advantage plans, but also the interests of those Medicare beneficiaries to whom it markets its plans. CMS has determined that Arcadian has failed to meet this responsibility despite repeated notice and opportunity to cure and has placed the health and safety of Medicare beneficiaries at risk as a result.

Summary of Arcadian's Non-Compliance

CMS has imposed these intermediate sanctions as a result of Arcadian's longstanding pattern of prohibited marketing practices targeted to highly vulnerable populations in violation of federal law, CMS guidelines and Arcadian's contractual responsibilities to CMS. Arcadian's Medicare Advantage plans include, among other types of plans, seventeen (17) Special Needs Plans. Participants in Special Needs Plans are institutionalized individuals, dual eligible beneficiaries (subscribing to Medicaid and Medicare), and beneficiaries with severe or disabling chronic conditions. Typically these beneficiaries are low income individuals who in many cases cannot afford to buy their medication or to pay for health care providers who are not within their plan's formulary or network.

The numerous and repeated marketing violations, occurring over a lengthy period of time, together with the lack of an effective compliance program to prevent, detect and respond to compliance deficiencies, demonstrate that Arcadian has substantially failed to carry out the terms of its contracts with CMS and is operating its contract in a manner that is inconsistent with the effective and efficient administration of the Medicare program. 42 C.F.R. §§ 422.510(a)(1), 422.510(a)(2), 423.509(a)(1), 423.509(a)(2).

Background on CMS Marketing Oversight

CMS is responsible for overseeing communications between Medicare Advantage (MA) organizations and beneficiaries enrolled in their plans. Because MA organizations are Medicare contractors, communications to beneficiaries must comply with various statutory and regulatory requirements as well as CMS marketing guidelines. In September 2008, CMS issued final regulations designed to protect Medicare beneficiaries from deceptive or high-pressured marketing tactics by private insurance companies and their agents, brokers and plan representatives. Medicare Improvements for Patients and Providers Act (MIPPA) Sec. 103.

In an effort to ensure compliance with these marketing requirements and prohibitions, CMS initiated a comprehensive surveillance program that commenced in the Fall of 2008 for contract year 2009's Annual Election Period (AEP) and Open Enrollment Period (OEP). CMS' comprehensive surveillance program encompassed numerous surveillance activities including, among others, secret shopping of public marketing events and analysis of beneficiary complaint data. Each year CMS conducts marketing surveillance in the form of "secret shoppers" who attend public marketing events to make sure that the plan and its agents are accurately describing plan benefits, plan restrictions, and the premiums and cost sharing obligations of enrollees. "Shopping" public marketing events also affords CMS the opportunity to ensure that plans are not engaging in coercive or aggressive marketing tactics. In order to conduct this vital activity, CMS requires all plans to report all of their planned marketing events to CMS. 42 C.F.R. §§ 422.2274(d), 423.2274(d); Medicare Managed Care Manual, Pub. 100-16, Chapter 3, § 70.8.

CMS also uses a centralized complaints repository called the Complaints Tracking Module (CTM). CMS Regional Office staff or 1-800-MEDICARE customer service representatives enter complaints into the CTM. A specific designation used in the CTM is "marketing

misrepresentations.” This designation was developed to capture complaints related to marketing violations or abuses that impacted beneficiaries’ health care or prescription drug benefit decision-making processes.

CMS is also concerned about agent/broker behavior in one-to-one settings (i.e., in an individual meeting at their home, retirement home or assisted living facility) with Medicare beneficiaries and has set up mechanisms to allow beneficiaries to register complaints. Beneficiaries with complaints about their health care plan are urged to call their plan directly so that the plan is given the opportunity to resolve any issues. To report issues that remain unresolved by their plan, Medicare suggests that beneficiaries call 1-800-MEDICARE. Complaints made to 1-800-MEDICARE are tracked through the CTM. CTM allows CMS to isolate all marketing-related grievances made by individual beneficiaries. As part of an effective compliance plan, plans should investigate agents and take appropriate corrective actions based on beneficiary complaints. Such corrective action could include imposing disciplinary measures like suspension or termination of the agent where appropriate.

Record of Noncompliance with CMS Marketing Rules

Arcadian has been under CMS scrutiny since 2008 because of its marketing practices. Through analysis of information in the CTM, CMS identified Arcadian as an outlier with respect to the number of complaints received from Medicare beneficiaries who were marketed to by Arcadian in a one-to-one setting.

In October 2009, the CMS issued the first of numerous written warning letters to Arcadian regarding its concerns about complaints it had received of marketing abuses and misrepresentations. CMS warned Arcadian that its compliance with marketing requirements would be evaluated based upon whether it succeeded in reducing the number of its marketing misrepresentation complaints. In response, at CMS’ request, Arcadian provided CMS with a business plan in December 2009 that included policies and procedures purportedly designed to ensure agent/broker compliance with CMS marketing requirements. CMS repeatedly warned Arcadian that it would continue to analyze its performance and that Arcadian might be subject to stronger compliance and enforcement action if CMS were to continue to uncover marketing violations.

Nevertheless, Arcadian continued to appear month after month as an outlier with respect to sales and marketing complaints, including complaints that Arcadian marketing agents had misrepresented plan benefits, such as providing inaccurate assurances to beneficiaries that their physicians were in the plan network and/or that their medications were in Arcadian’s formulary; complaints that Arcadian agents had enrolled Medicare beneficiaries in an Arcadian plan without the beneficiary’s knowledge or consent, and complaints about direct solicitation and other prohibited marketing practices by agents and brokers selling Arcadian products. Specifically, from January 2010 through August 2010 Arcadian’s percentage of misrepresentation complaints has ranged from 2 to 3.5 times the national average. As recently as October 2010, misrepresentation complaints against Arcadian were more than twice the national average.

In addition, Arcadian was the second lowest performer of all Medicare Advantage plans whose marketing events were attended as part of CMS' marketing surveillance program for public sales events during open enrollment for the 2010 plan year. In this regard, Arcadian received a Notice of Non-Compliance and three Warning letters over the period from late 2009 and through April 2010 based on marketing violations observed at public events for contract year 2010. The violations included, among others,

- Requiring beneficiaries to provide contact information in violation of 42 C.F.R. § 422.2268(o); 423.2268(o);
- Not discussing coverage gap in violation of 42 C.F.R. §§ 422.2268(e); 423.2268(e)
- Employing scare tactics in violation of 42 C.F.R. §§ 422.2268(o); 423.2268(o); and
- Providing inaccurate information regarding the drug coverage in violation of 42 C.F.R. §§ 422.2268(e); 423.2268(e)..

With respect to complaints reported to CMS by or on behalf of beneficiaries, among the violations cited by complainants and verified by CMS are the following:

- Agents/brokers enrolled beneficiaries in plans without their prior knowledge or consent in violation of 42 C.F.R. §§ 422.2272(b), 422.2268(e); 422.2268(o), 423.2272(b), 423.2268(e), and 423.2268(o).
- Agents/brokers misled or confused beneficiaries or misrepresented information regarding the plan, including type, network restrictions, scope of coverage, contents of plan formulary, identification of providers in network, and loss of traditional Medicare as a result of plan enrollment in violation of 42 C.F.R. § 422.2268(e) and § 423.2268(e).
- Agents/brokers misrepresented the plan as endorsed by Medicare or as part of the government's Healthcare Reform or the Affordable Care Act in violation of 42 C.F.R. § 422.2268(e) and § 423.2268(e).
- Agents/brokers marketed through door-to-door solicitation, cold calls and other unsolicited means of direct contact in violation of 42 C.F.R. § 422.2268(d) and § 423.2268(d).
- Agents/brokers marketed beyond the scope of appointment in violation of 42 C.F.R. § 422.2268(g) and § 423.2268(g).
- Agents/brokers engaged in aggressive sales tactics and abusive behavior in violation of 42 C.F.R. § 422.2268(e) and § 423.2268(e).

Effect of Non-Compliance on Plan Beneficiaries

From September 1, 2009, through August 30, 2010, 352 Medicare beneficiaries registered formal complaints regarding Arcadian agent/broker misconduct with CMS. Complaints came from

enrollees in all Arcadian contracts. CMS investigated the complaints by telephoning a subset of 78 complainants. These 78 complainants were selected to represent the range of violations that had been reported, such as misrepresenting that the treating physician was in the network or that the drug was in the Arcadian formulary, cold calling, aggressive or abusive sales tactics, etc. Also, particularly egregious allegations were selected for validation. Of those called, CMS was able to establish contact with 60 of the 78 complaining beneficiaries. CMS found that 47 of the 60 complaints (78%) of marketing misrepresentation and other prohibited marketing tactics were supportable.

CMS' investigation revealed multiple instances of Arcadian agent/broker misconduct that have adversely impacted Arcadian's enrollees, improperly influenced their choice of Medicare Advantage plans and, in numerous cases, threatened their health and safety. Arcadian agents made incomplete and incorrect statements to beneficiaries regarding the plan network. For example, an Arcadian enrollee from the State of Washington, who is legally blind and who lives alone, reported that an Arcadian agent called and obtained her permission to visit on a certain date, but that the agent did not arrive until 8:30 p.m. The beneficiary states that he "dozed off" during the presentation. The Arcadian agent had pre-entered on the enrollment form the name of a doctor who was not the beneficiary's physician of choice. Although her doctor was not a member of the plan network, the agent told the beneficiary that after she enrolled, she could switch to her preferred physician. When she learned that her doctor did not accept the plan insurance, the beneficiary called 1-800-MEDICARE and complained. In response, the Arcadian agent called and scolded her for making a complaint.

CMS' investigation also determined that there were numerous instances where Arcadian enrollees suffered delays in access to treatment or medication as a result of Arcadian's agent/broker misconduct. For example, an Arcadian enrollee and cancer patient lodged a complaint that the Arcadian agent who came to her house told her that her cancer doctor was in the plan's network. The enrollee later learned that this was incorrect. As a result, she went without chemotherapy treatment for weeks until she could return to her doctor (after leaving Arcadian and returning to traditional Medicare). By that time, a CT scan revealed that her cancer had progressed.

Similarly, an Arcadian agent met with a disabled girl's father, and enrolled the daughter after providing inaccurate assurances that her medications would be covered. The girl suffered a delay in obtaining her anti-seizure medication that caused her to undergo an 18-day hospitalization during which she developed skin ulcers.

Record of Noncompliance with Compliance Plan Requirements

In July 2010, CMS conducted an audit of various Arcadian core performance areas, including the effectiveness of its compliance program. CMS determined that Arcadian failed to comply with five of the seven required elements of an effective compliance program. This is in direct violation of CMS regulatory and contractual requirements. 42 C.F.R. § 422.503(b)(4)(vi); § 423.504(b)(4)(vi). The deficiencies in Arcadian's compliance program have contributed to its

systemic failure to operate its MA and MA-PD contracts effectively. All of the following deficiencies were confirmed:

- Arcadian's Board of Directors and senior management did not formally approve or endorse the Standards of Business Conduct;
- Arcadian did not implement all of the required policies and procedures to articulate the organization's commitment to comply with all applicable Federal and State Standards;
- Arcadian did not adequately staff its Compliance Department and provide sufficient financial resources to the Compliance Department for the size of the organization;
- Arcadian did not provide any evidence that senior management had involvement in developing and reviewing its Standards of Business Conduct;
- Arcadian's internal monitoring and auditing procedures were not adequate to ensure compliance with Part C and D requirements;
- Arcadian did not have an effective mechanism in place for monitoring and auditing first tier, downstream and related entities (including its sales agents and brokers);
- Arcadian did not conduct risk assessments related to fraud, waste and abuse; and
- Arcadian did not perform specific or additional monitoring and oversight activities to prevent, detect and respond to fraud, waste and abuse.

CMS has a responsibility to protect its beneficiaries and to ensure that the organizations with which we contract take their obligations as Medicare business partners seriously. CMS has no confidence that, without a demonstrably effective compliance program, Arcadian will be able to effectively prevent, detect and redress compliance deficiencies, including those involving its oversight of the conduct of its agents and brokers.

Basis of Intermediate Sanction

CMS has determined that Arcadian's failure to comply with CMS statutes, regulations, and guidance, as set forth above and incorporated herein by reference, provides sufficient evidence and proves sufficient basis for the imposition of intermediate sanctions. 42 C.F.R. §§ 422.752(b); §423.752(b). Specifically, CMS finds that:

- ***Arcadian has failed substantially to carry out the terms of its contracts with CMS. 42 C.F.R. § 422.510(a)(1); § 423.509(a)(1)***
- ***Arcadian is carrying out its contracts with CMS in a manner that is inconsistent with the effective and efficient implementation of the program. 42 C.F.R. § 422.510(a)(2); § 423.509(a)(2).***
- ***Arcadian substantially failed to comply with the marketing requirements in subpart V of Parts 422; 423. 42 C.F.R. §§ 422.510(a)(12); 423.509(a)(9).***

In addition, Arcadian's conduct, as described above, is within the scope of marketing violations singled out by Congress for sanctions in the amendments to § 1857(g) of the Social Security Act, as set forth at § 6408 of the Affordable Care Act.

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. § 422.756(a)(2) and § 423.756(a)(2), Arcadian has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by November 30, 2010. Please note that for purposes of responding to this notice or requesting a hearing, CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail, in this case, November 20, 2010. If you choose to submit a rebuttal, please send it to the attention of Brenda J. Tranchida at the address listed below.

Right to Request a Hearing

Arcadian may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§ 422.660 through 696 and 423.650 through 668. Pursuant to 42 C.F.R. § 422.756(b) and § 423.756(b), your written request for a hearing must be received by CMS within 15 calendar days of your receipt of this notice, or by December 6, 2010¹. Please note, however, that a request for a hearing will not delay the date specified by CMS when the sanction becomes effective. Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

Arcadian must submit a request for hearing to the following CMS official:

Brenda J. Tranchida
Director
Program Compliance and Oversight Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
MAIL STOP: C1-22-06
Baltimore, MD 21244
Email: brenda.tranchida@cms.hhs.gov
FAX: 410-786-6301

You must also send a courtesy copy of your request by e-mail to the CMS Hearing Officer on the date you mail your request. CMS will consider the date the Office of Hearings receives your e-mail or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of your request. Your request for a hearing must include the name, fax number and e-mail address of the contact within your organization (or the attorney who has a letter of authorization to represent your organization) with whom you wish us to communicate regarding the hearing request. The courtesy copy of the request for a hearing must be sent to the CMS Hearing Office at the following address:

¹ If the 15th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request.

Mr. Robert Fahlman
November 19, 2010
Page 8 of 9

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare and Medicaid Services
2520 Lord Baltimore Drive
Suite L
Mail Stop LB-01-22
Baltimore, MD 20244-2670
Phone: (410) 786-3169
E-Mail: Benjamin.Cohen@cms.hhs.gov

Please note that we are closely monitoring your organization and Arcadian may also be subject to other applicable remedies available under law, including the imposition of additional sanctions, penalties, or other contract and/or enforcement actions as described in 42 C.F.R. Part 422, Subparts K and O and Part 423, Subparts K and O.

If you have any questions about this determination, please contact Trish Axt at (410) 786-0095 or by email at trish.axt@cms.hhs.gov.

Sincerely,

/s/

Brenda J. Tranchida
Director
Program Compliance and Oversight Group

cc: Mr. Jonathan Blum, CMS/CM
Mr. Timothy Hill, CMS/CM
Ms. Danielle Moon, CMS/CM/MCAG
Ms. Helaine Fingold, CMS/CM/MCAG
Ms. Cynthia Tudor, CMS/CM/MDBG
Ms. Jennifer Shapiro, CMS/CM, MDBG
Ms. Judith Geisler, CMS/CM/MDBG
Ms. Cheri Rice, CMS/CM/MPPG
Mr. Randy Brauer, CMS/CM/MPPG
Mr. Michael Crochunis, CMS/CM/MEAG
Ms. Mary Wallace, CMS/OEABS
Mr. Jon Booth, CMS/OEABS
Mr. Peter Ashkenaz, CMS/OEABS
Mr. Greg Jones, CMS/OL
Mr. John Spiegel, CMS/CPI
Mr. James Kerr, CMS/OA/CMHPO

Mr. Robert Fahlman

November 19, 2010

Page 9 of 9

Mr. Paul Collura, CMS/CMHPO
Ms. Julie Kennedy, CMS/CMHPO/Region VI
Ms. Pam Conroy, CMS/CMHPO/Region VI
Ms. Carol Bennett, DHHS/OGC
Ms. Jill Abrams, DHHS/OGC
Ms. Janet Nolan, DHHS/OGC
Ms. Nancy Brown, DHHS/OIG/OCIG
Mr. Benjamin Cohen, CMS/OA
Ms. Tawanda Holmes, CMS/CM/PCOG