

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



PROGRAM COMPLIANCE AND OVERSIGHT GROUP

October 9, 2012

VIA:
EMAIL (atran@care1st.com)
AND FACSIMILE (323-889-6270)

Anna Tran
Chief Executive Officer
Care1st Health Plan
601 Potrero Grande Drive
Monterey Park, CA 91755
Phone: 323-889-6638

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Plan Contract Numbers: Care1st Health Plan (H5928) and Care1st Health Plan of Arizona (H5430)

Dear Ms. Tran:

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 Care1st Health Plan (Care1st) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$50,000 for the following Medicare Advantage-Prescription Drug Plan (MA-PD) Contracts: Care1st Health Plan of Arizona H5430 and Care1st Health Plan H5928.

CMS has determined that Care1st failed to provide its enrollees with services and benefits in accordance with CMS requirements. A Part D sponsor's central mission is to provide Medicare enrollees with prescription medications within a framework of Medicare requirements that provide enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an audit at Care1st's Monterey Park offices from June 11, 2012 through June 15, 2012. During the audit, CMS conducted reviews of Care1st's operational areas to determine if Care1st is following CMS rules, regulations and guidelines. CMS reviewed Care1st's prescription drug claims, data systems, and operations and discovered that Care1st inappropriately rejected claims for its enrollees. These inappropriate claim rejections resulted in enrollees experiencing a delay in obtaining their prescription drugs, or not receiving their drugs at all. After conducting an extensive review of Care1st's rejected claims data, the CMS auditors concluded that Care1st failed to provide its enrollees with prescription drug coverage as required by its CMS-approved formularies. Care1st's failures violate the Medicare Part D program requirements contained at § 1860D-4(b)(3)(G) of the Social Security Act and 42 C.F.R. §§ 423.120(b)(2)(iv), 423.120(b)(3), 423.505(b)(17) and 423.272. Each violation has directly adversely affected (or has the substantial likelihood of adversely affecting) Care1st's enrollees across the two (2) contracts to which the penalty applies by delaying or denying enrollee access to vital medications.

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 prior 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)(i) of the Social Security Act; 42 C.F.R. § 423.120(b)(2)(v); 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 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.

Deficiencies Related to Formulary and Benefit Administration

CMS identified multiple, serious violations of Part D requirements in Care1st's formulary and benefit administration operations. Care1st's violations include:

- Failure to properly administer its CMS approved prescription drug benefit in violation of 42 C.F.R. §§ 423.104(a) and 423.120(b)(2)(iv);

- Failure to provide timely and appropriate point-of-service claims adjudication in violation of 42 C.F.R. § 423.505(b)(17), and, failure to provide coverage for protected class drugs in violation of § 1860D-4(b)(3)(G) of the Social Security Act. More specifically, Care1st implemented a high cost dollar edit of which was not resolvable at the point-of-service, which caused an inappropriate rejection of claims for **all** Part D drugs whose cost exceeded \$500; and
- Failure to properly administer its CMS approved formulary by applying unapproved step therapy, prior authorization, and quantity limits (including those for protected class drugs) in violation of 42 C.F.R. §§ 423.104(a) and 423.120(b)(2); *see also* IOM Pub.100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2. and Chapter 7, Section 60.6.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 422.752(c) and 423.752(c), CMS has determined that Care1st's violations of Part D requirements are significant enough to warrant the imposition of a civil money penalty. In violating multiple Part D requirements, Care1st failed substantially to carry out the terms of its MA-PD and PDP contracts with CMS and failed to carry out its contracts 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

Care1st may request a hearing to appeal CMS' determination in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. Care1st 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 December 10, 2012. 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 Care1st disagrees. Care1st 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

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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 Care1st 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 December 11, 2012. Care1st may choose to have the penalty deducted from your monthly payment, transfer the funds electronically, or mail a check to CMS.

Please note that any further failures by Care1st to comply with these or any other CMS requirements may subject your organization to other applicable remedies available under law, including 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 Care1st 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: Mr. Jonathan Blum, CMS/CM
Mr. Timothy Love, CMS/CM
Ms. Ann Duarte, CMS/CMHPO/Region IX
Mr. Max Wong, CMS/CMHPO/Region IX
Mr. Kenneth Gardner, CMS/CMHPO/Region IX