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

PROGRAM COMPLIANCE AND OVERSIGHT GROUP

June 19, 2012

VIA:
FEDERAL EXPRESS DELIVERY
EMAIL (tom_s_paul@uhc.com)
AND FACSIMILE (1-952-931-5634)

Mr. Tom Paul
Chief Executive Officer, UnitedHealthcare Medicare & Retirement
UnitedHealth Group, Inc.
9701 Data Park Drive
Minnetonka, MN 55343
Phone: 1-952-931-5557

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage Organization and Prescription Drug Plan Contracts;
Contract Numbers: H0151, H0251, H0303, H0316, H0319, H0321, H0401, H0408, H0543, H0609, H0620, H0624, H0710, H0752, H0755, H1080, H1108, H1111, H1286, H1303, H1509, H1717, H1944, H2001, H2111, H2182, H2226, H2228, H2406, H2654, H2802, H2803, H2905, H2931, H3107, H3113, H3164, H3209, H3307, H3379, H3387, H3456, H3659, H3749, H3805, H3812, H3887, H3912, H3920, H3921, H4102, H4406, H4456, H4514, H4522, H4527, H4590, H4604, H4837, H4971, H5005, H5008, H5253, H5407, H5417, H5424, H5435, H5440, H5507, H5516, H5532, H5652, H5749, H5998, H6952, H7187, H7949, H8748, H9011, R3175, R5287, R5342, R5674, R7444, S5805, S5820, S5921

Dear Mr. Paul:

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 UnitedHealth Group, Inc. (hereafter "United") that CMS has made a determination to impose a civil money penalty (CMP) in the amount of $2,175,000 for all Medicare Advantage Organization and Prescription Drug Plan Contracts.

Summary of Noncompliance

Pursuant to 42 CFR § 422.504(e) and § 423.505(e), CMS conducted an audit of United in October 2011. United was informed of the audit in a letter dated August 22, 2011, and CMS conducted the audit at United's Minnetonka, Minnesota offices from October 17-21, 2011.

The audit tested United's adherence to CMS requirements by reviewing United's prescription drug claims, data systems, and operations for consistency with the 2011 CMS-approved formulary. After conducting an extensive review of United's rejected claims data, the CMS auditors concluded that United failed to provide prescription drugs consistent with its CMS-approved formularies and benefit coverage transition policies, which resulted in a significant number of beneficiaries not receiving prescribed drugs (including protected class drugs) in accordance with their benefit plan, in violation of Medicare Part D program requirements at 42 C.F.R. §§ 423.120(b)(2)(iv), 423.120(b)(3), 423.505(b)(17) (2011) and 423.272. In subsequent monitoring, CMS identified additional significant violations of Part D requirements. These violations have directly adversely affected (or have the substantial likelihood of adversely affecting) United's enrollees across all 87 contracts.

Relevant Prescription Drug Program Requirements Regarding Access to and Provision of Benefits

Medicare Part D Prescription Drug Program requirements apply both to stand-alone Prescription Drug Plan sponsors and to Part C Medicare Advantage sponsors that offer prescription drug benefits. Sponsors of these plans 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. 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.

Each Part D sponsor maintains a drug formulary, or list of prescription medications, covered by the Part D 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 (42 C.F.R. § 423.120(b)(2)(iv); Medicare Prescription Drug Benefit Manual, Pub.100-18, ch. 6 § 30.2). A Part D sponsor can change its formulary mid-year, but must obtain prior CMS approval and must notify its enrollees of any changes, including any changes in cost-sharing amounts for formulary drugs (42 C.F.R. §§ 423.120(b)(4)-(6); Medicare Prescription Drug Benefit Manual, Pub.100-18, ch. 6 § 30.3). CMS' formulary review and approval process includes a review of the Part D sponsor's proposed use of drug utilization management processes to adjudicate Medicare prescription drug claims, including the use of prior authorization (PA), step therapy (ST), and quantity limits (42 C.F.R. § 423.272(b)(2); Medicare Prescription Drug Benefit Manual, Pub.100-18,ch. 6 § 30.2).

Prior authorization is a utilization management technique used by Part D sponsors that requires enrollees to obtain prior approval from the Part D sponsor for coverage of certain prescriptions prior to being prescribed the medication. Enrollees can find out if prior authorization is required

for a prescription by 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 FDA and manufacturer guidelines, medical literature, safety, appropriate use and benefit design.

Step therapy is a utilization management technique used by Part D sponsors to ensure that when an enrollee begins drug therapy for a medical condition, the first drug chosen is the most cost-effective and safest drug, and other more costly or risky drugs are only prescribed if they prove to be clinically necessary. The goal of ST is to control costs and minimize clinical risks.

There are six drug classes with respect to which plans must include all of the drugs in that class on their formularies. These are drugs that are typically critical to the health and safety of the population for whom they are prescribed. Therefore, Part D sponsors are not permitted to require PA or ST for members stabilized on drugs from the "protected classes." The protected classes are immunosuppressants (for prophylaxis of organ transplant rejection), antidepressants, antipsychotics, anticonvulsants, antiretrovirals and antineoplastics. See § 1860D-4(b)(3)(G) of the Social Security Act.

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. Part D sponsors must have systems capabilities that allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require PA or ST 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 transition to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity (42 C.F.R. § 423.120(b)(3); Medicare Prescription Drug Benefit Manual, Pub.100-18 ch. 6 § 30.4).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 423.752(c), CMS has determined that United's violations of Part D requirements are significant enough to warrant the imposition of a civil money penalty. In violating multiple Part D requirements, United failed substantially to carry out the terms of its Medicare Advantage (MA) and Prescription Drug Plan (PDP) contracts with CMS and failed to carry out its contracts with CMS in a manner that is consistent with the effective and efficient implementation of the program (42 C.F.R. § 423.509(a)(1) and (2)).

United failed the formulary and benefit administration portion of the October 2011 audit because CMS identified multiple, serious violations of Part D requirements in United's administration of its formulary. United's violations discovered during the audit and through subsequent monitoring include:

- Improperly rejected prescriptions at the point of service as non-formulary when in fact, the drugs are on United's formulary, in violation of 42 C.F.R. § 423.104(a), and

§ 423.120(b)(2); see also Medicare Prescription Drug Benefit Manual, Pub. 100-18, ch. 6 § 30.2.

- Failure to provide timely and appropriate point-of-service claims adjudication in violation of 42 C.F.R. § 423.505(b)(17).

- Failure to follow CMS requirements regarding transition supplies of prescription drugs, including failing to provide for the appropriate transition of new enrollees and existing beneficiaries prescribed Part D drugs that are not on United's formulary in violation of 42 C.F.R. § 423.120(b)(3).

- Failure to provide coverage for protected class drugs in violation of § 1860D-4(b)(3)(G) of the Social Security Act.

- Improperly applied step therapy and prior authorization criteria in point-of-service edits, and quantity limits (including those for protected class drugs) that were not approved by CMS, in violation of 42 C.F.R. § 423.104(a) and § 423.120(b)(2); see also Medicare Prescription Drug Benefit Manual, Pub. 100-18, ch. 6 § 30.2.; ch. 7 § 60.6.

Additionally, CMS found that United had limited oversight of its contracted prescription benefit managers (PBMs), failure to adequately monitor for inappropriately rejected claims, inconsistent assessment of member impacts, inconsistent disclosure of self identified Part D claims processing issues to CMS, and failure to implement quality assurance measures to ensure system edits are appropriate, in violation of 42 C.F.R. §423.504(b)(4)(vi)(f) and regulations cited above.

Right to Request a Hearing

Your organization may request a hearing to appeal CMS' determination in accordance with the procedures outlined in Subpart T of 42 C.F.R. § 422 and 42 C.F.R. § 423. In accordance with the requirements of 42 C.F.R. § 422.1006, § 423.1006, § 422.1020, and § 423.1020, you must send a written request for a hearing to the Departmental Appeals Board office listed below, with a copy to CMS at the address listed below, within 60 calendar days from receipt of this notice of our initial determination, or by August 20, 2012. The request for hearing must identify the specific issues, the findings of fact and conclusions of law with which you disagree, and specify the basis for each contention that the finding or conclusion of law is incorrect. Your request should be sent to:

Oliver Potts
Chief, 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 your 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 you do 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 August 21, 2012. You 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 United 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 you have any questions about this notice, please call or email the enforcement contact provided in your 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. Cynthia Tudor, CMS/CM/MDBG
Ms. Jennifer Shapiro, CMS/CM/MDBG
Ms. Arrah Tabe-Bedward, CMS/CM/MEAG
Ms. Michelle Turano, CMS/CM/PCOG
Ms. Patricia Axt, CMS/CM/PCOG/DCE
Ms. Danielle Moon, CMS/CM/MCAG
Mr. Brian Cook, CMS/OC

Mr. Tony Salters, CMS/OC
Mr. Greg Jones, CMS/OL
Mr. James T. Kerr, CMS/CMHPO
Mr. Paul Collura, CMS/CMHPO
Ms. Ayanna Busby-Jackson CMS/CMHPO/Region IX
Mr. David Sayen CMS/CMHPO/Region IX
Ms. Deborah Chasan-Sloan, DHHS/OGC
Ms. Jill Abrams, DHHS/OGC
Mr. Gerald T. Walters, CMS/OFM
Mr. Oliver Potts, DHHS/DAB
Ms. Nancy Brown, DHHS/OIG/OCIG