DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Drug and Health Plan Choice
7500 Security Boulevard, Mail Stop C4-23-07
Baltimore, Maryland 21244-1850

March 9, 2010

VIA:
FEDERAL EXPRESS DELIVERY
EMAIL (Kary.Shankar@foxrxcare.com)
AND FACSIMILE (212-924-4290)

Mr. Kary Shankar
CEO, Senior Official for Contracting
Fox Insurance Company
40 West 25th Street – 6th Floor
New York, NY 10010
Phone: (877-369-9564)

Re: Notice of Immediate Termination of Prescription Drug Plan Contract Number S5557

Dear Mr. Shankar:

The Centers for Medicare & Medicaid Services ("CMS") hereby notifies you of its decision to immediately terminate (effective 11:59:59 P.M. EDT March 9, 2010) Fox Insurance Company's ("Fox") Prescription Drug Plan ("PDP") contract S5557 pursuant to 42 U.S.C. 1395w-112 (b)(3)(F), 42 C.F.R. §423.509 (b)(2), and Art. VIII.B. of the contract (number S5557) between CMS and Fox.

CMS has determined that Fox has failed to provide their enrollees with prescription drug benefits in accordance with CMS requirements as well as in a manner consistent with professionally recognized standards of health care. The significant magnitude of these deficiencies exposes Fox's enrollees to imminent and serious risk to their health, thus warranting the immediate termination of Fox's contract with CMS.

In layman's terms, CMS has found, among other things, that Fox has continually subjected its enrollees to impermissible hurdles in their attempts to obtain needed, and in some cases life sustaining, prescription medications. In many cases, Fox has required its enrollees to go through unnecessary and invasive medical procedures in order to obtain these drugs even on a delayed basis. Fox has been unable to satisfactorily address these

serious compliance deficiencies and to deliver services to its enrollees in a manner consistent with its obligations to CMS and to Medicare beneficiaries.

As described below, CMS' determination is pursuant to authorities found at 42 C.F.R. §423.509 (a)(1), §423.509 (a)(2), §423.509 (a)(5), and §423.509 (a)(6).

I. Prescription Drug Program Requirements—Access to and Provision of Benefits

A Medicare PDP enters into a contract with CMS, pursuant to which the PDP agrees to abide by a number of requirements based upon statute, regulations and program instructions. A PDP's central mission is to provide Medicare beneficiaries with required prescription medications within a framework of Medicare requirements that provide PDP enrollees with a number of beneficiary protections.

Each PDP maintains a drug formulary, or list of prescription medications, covered by the PDP. A number of Medicare requirements govern how PDPs create and manage their formularies. Each PDP is required to submit its formulary for review and approval by CMS on an annual basis (*See 42 C.F.R., §423.120(b)(2)(iv) and the Medicare Prescription Drug Benefit Manual, Pub.100-18, Chapter 6, §30.2*). A PDP 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 (*See 42 C.F.R., §423.120(b)(4)-(6) and Pub.100-18,Chapter 6, §30.3*). CMS' formulary review and approval process includes a review of the PDP's proposed use of drug utilization management processes to adjudicate Medicare prescription drug claims (Part D claims), including the use of prior authorization (PA) or step therapy (ST) requirements (*See 42 C.F.R. §423.272(b)(2) and Pub.100-18,Chapter 6, §30.2*).

Prior authorization is a utilization management technique used by PDPs (as well as commercial and other health insurers) that requires enrollees to obtain prior approval from the PDP for coverage of certain prescriptions prior to being prescribed the medication. PDP 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). PA 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 PDPs (as well as commercial and other health insurers) to ensure 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.

However, CMS has designated six drug classes in which Medicare beneficiaries must have ***uninterrupted access*** to all or substantially all of the drugs in that class. PDPs are not permitted to require PA or ST for members stabilized on drugs from the following "protected classes" (PA and ST are never allowed for antiretrovirals) (*See §1860D-*

4(b)(3)(G)(i) of the Social Security Act, 42 C.F.R. §423.120(b)(2)(v) and Pub.100-18, Chapter 6, §30.2.5):

- 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.

Additionally, a PDP 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 PDP'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, and the individual is unaware of what drugs are on the formulary or of the sponsor's exceptions process for providing access to drugs that are not on the formulary. This may be particularly true for full-benefit dual eligible (i.e., Medicare and Medicaid) beneficiaries 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 *(See 42 C.F.R. §423.120(b)(3) and Pub.100-18 Chapter 6, §30.4)*.

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 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 *(See 42 C.F.R. §423.120(b)(3) and Pub.100-18 Chapter 6, §30.4*).

II. Legal Basis for Immediate Termination

CMS is charged with overseeing a PDP's continuing compliance with applicable statutory, regulatory, and contractual requirements 42 C.F.R. § 423.503(d)(1). CMS may, at any time, terminate a contract with a plan sponsor for any of a number of reasons associated with a plan sponsor's deficient performance 42 C.F.R. § 423.509(a). Further, CMS may expedite the termination of a PDP sponsor's contract where CMS finds that a delay in termination, resulting from adherence to the termination procedures specified in 42 C.F.R. §423.509 (b)(2), (notice and reasonable opportunity to correct and right to a hearing), would pose an imminent and serious risk to the health of enrollees. *(See 42 U.S.C. 1395w-112 (b)(3)(F) 42 C.F.R. §423.509(a)(5) and Art. VIII.B. of the contract (number S5557) between CMS and Fox.)*

III. Determination to Immediately Terminate Pursuant to 42 C.F.R. § 423.509(a)(5)

Fox's non-compliance with processing claims for needed Part D medications, making coverage determinations and redeterminations, and failure to abide by prescription transition fill requirements, resulted in delayed and/or denied access to medically necessary drugs and therapies. Fox's delaying and/or denying access to these types of drugs (particularly protected class drugs, including: HIV, cancer, and anti-seizure medications), resulted in a failure to make medically necessary services available to beneficiaries to an extent such that there is an imminent and serious risk to the health and safety of enrollees. *(See Paragraph 8 of Attachment A, Declaration of Jeffrey A. Kelman M.D., and Paragraph 21 of Attachment B, Declaration of Cynthia G Tudor, Ph.D, dated March 9, 2010 and 42 C.F.R. §423.509(a)(5)).*

A. Events Leading Up to the Imposition of the Immediate Marketing and Enrollment Sanction on Fox

CMS first learned of Fox's noncompliance with CMS requirements regarding the imposition of prior authorization and step therapy requirements through numerous complaints made by physicians on behalf of patients who are Fox plan enrollees, as well as complaints directly from Fox enrollees. These complaints alleged that Fox had denied claims for protected class drugs and Part D drugs covered on Fox's formulary on the grounds that the enrollee had not complied with PA and ST criteria. However, in violation of CMS requirements, Fox never obtained CMS approval for the application of PA and ST criteria for these drugs. Based on the complaints received, CMS found that Fox had displayed these unapproved utilization management criteria for all of its enrollees on the Part D formulary posted on its public web site. This served as further confirmation for CMS that Fox has been using unapproved PA and ST criteria to adjudicate drug claims by its Part D plan members.

As a result, in numerous cases, Fox improperly denied its enrollees coverage of critical HIV, cancer, and seizure medications. Even short term delays in access to these types of medications not only pose a serious risk to the health and safety of the enrollees in question, they also pose a high risk of permanent damage as well.

CMS immediately contacted Fox regarding these serious issues and on February 11th and 12th during conference calls with CMS management, Fox confirmed that the company had imposed PA requirements that CMS had not reviewed or approved, despite the fact that Fox was aware of the applicable CMS requirements.

Additionally, CMS learned that Fox was not complying with CMS requirements regarding coverage determination timeframes which require PDPs, pursuant to 42 CFR §423.572(a), to make a determination on an expedited request no later than 24 hours after receiving the request. In at least one instance Fox's noncompliance with these

requirements led to an enrollee enduring a significant delay in receiving needed HIV therapy, when Fox did not make a determination for over 120 hours. *(See Attachment C: HIV Drug documentation).* Additionally, pursuant to 42 CFR § 423.572(d), Fox was required to forward the enrollee's request to the independent review entity (IRE) under contract with CMS within 24 hours after expiration of the adjudication timeframe and failed to do so.

CMS also learned, from beneficiary complaints, and from its own review of Fox coverage determination files, that Fox failed to provide transition coverage of drugs that beneficiaries had been on in 2009 and denied those claims in 2010 requesting prior authorization, which violates CMS' transition policy (*See 42 CFR § 423.120(b)(3) and Pub. 100-18, Chapter 6, Section 30.4.5).* Numerous claims were inappropriately required to go through a PA process, including drugs used to treat serious conditions like hepatitis, pulmonary hypertension and diabetes.

On February 26, 2010, CMS notified Fox of the immediate imposition of sanctions suspending marketing and enrollment sanctions on its contract S5557 based on Fox's "persistent and substantial failure to comply with important Part D requirements that are critical to protecting the health of its Medicare Prescription Drug Plan (PDP) enrollees." The letter notified Fox that "CMS believes these issues to be of such a serious nature that if left uncorrected, CMS will consider taking action to immediately terminate your contract." *(See Attachment D: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Marketing & Enrollment)).*

B. March 2010 Onsite Audits

Because of the serious nature of the deficiencies that necessitated the imposition of marketing and enrollment sanctions, CMS conducted onsite audits at Fox corporate headquarters in New York, New York and ProCare Rx (Fox's subcontracted Pharmacy Benefits Manager) in Duluth, Georgia on March 2-4, 2010. At the conclusion of these audits, CMS further validated the serious nature and extent of these deficiencies and determined that a delay in termination would pose an imminent and serious risk to the health of enrollees. *(See Kelman Declaration , Paragraphs 8 and 9 and Tudor Declaration, Paragraph 21).*

CMS found that Fox continued to: 1) impose PA requirements and improperly require ST in violation of 42 C.F.R. § 423.272(b)(2) in cases in which doing so could put enrollee health at risk by impeding timely access to needed and protected class drugs; 2) failed to adhere to required coverage determination timeframes pursuant to 42 C.F.R. §§ 423.568(a), 423.572(a), and 423.572(d) intended to ensure prompt enrollee access to needed drugs; and 3) failed to ensure that beneficiaries taking a drug that is not on Fox's formulary receive continued coverage of the drug under Part D transition requirements. *(See Paragraphs 9-15 of the Tudor Declaration).*

Furthermore, during the onsite audits CMS identified additional serious compliance deficiencies including: 1) the application of high costs edits, that were programmed in Fox's claims processing system to appear as prior authorization requirements, in violation of 42 C.F.R. § 423.272(b)(2); 2) failing to ensure an independent level of review during the coverage redetermination process in violation of 42 C.F.R. § 423.590(f); 3) failing to utilize the statutorily required DRUGDEX compendium in violation of § 1860 D-2(e)(1)(B) and § 1927(g)(1)(B)(i) of the Social Security Act, resulting in the erroneous denial of drugs to enrollees; and 4) failing to develop and implement a compliance plan sufficient to meet the requirements of 42 C.F.R. § 423.504(b)(4)(vi)(A) through (G).

Unapproved PA and ST Requirements

Fox implemented unapproved prior authorization (PA) requirements which were misrepresented as "high cost edits" (i.e., flagging drugs in their systems simply because they are expensive or exceed a certain cost threshold). When used appropriately, high cost edits are implemented by health plans to prevent inadvertent claims overbilling. For example, injectable drug products are often billed by the package quantity of one (unit) instead of by the number of syringes (10) contained within the unit. If the pharmacy bills for 10 units instead of one the price for this prescription would be 10 times higher. These high cost edits are intended to be utilized as a simple alert to the pharmacist and resolved at the point of sale after pharmacist confirmation. Routinely, pharmacists resolve these edits at the pharmacy counter and the beneficiary leaves with their medication with no significant delay. However, Fox inappropriately utilized this edit and the message sent to the pharmacist indicted that PA requirements had not been met ("PRIOR AUTH REQUIRED:;COST EXCEEDS MAXIMUM") for formulary drugs that did not require PA. No additional information was provided to the pharmacist since the enrollees, doctors and pharmacists assumed that the PA requirements were not satisfied even though Fox did not, have CMS approved PA requirements for those drugs.

Fox's action resulted in thousands of rejected claims and thus beneficiaries leaving pharmacies without their medications. The CMS audit teams determined that Fox continued to issue these denials, even after the sanctions were imposed, based on their review of claims data that demonstrated these edits were still in place at the time of the onsite audits on March 2-4, 2010. *(See Kelman Declaration, Paragraph 8, and Tudor Declaration, Paragraph 9).*

Fox's actions required unnecessary and improper tests and procedures of beneficiaries that resulted in significant delay in beneficiaries' receipt of necessary drugs. In some cases, these requirements included invasive procedures. Specific examples include requiring a Bioelectric Impedance Analysis (BIA) prior to allowing payment for Serostim, requiring cardiac catheterization prior to allowing payment for Tracleer, requiring ejection fraction tests prior to allowing payment for Tykerb, and requiring PET scans prior to allowing payment for Gleevac. These beneficiaries should not have been required to undergo these procedures prior to obtaining these drugs. *(See Tudor Declaration, Paragraph 11).*

Inappropriate Fox denials for high cost drugs would, in many cases, force enrollees to make decisions of whether to pay for their drugs out of pocket or forego the life-sustaining medication. Given the low income status of 90% of Fox's enrollees, the option of paying out of pocket would prove too cost prohibitive. For example, the enrollee who was inappropriately denied Gleevec would be required to pay about $4,200 per month for this drug alone. The same is true for the enrollees who were inappropriately denied Tracleer (about $5,000 per month), Serostim (about $6,600 per month), and Tykerb (about $3,600 per month).

Failure to Follow CMS Coverage Determinations Requirements

Fox admitted during the onsite audits that the company does not use the compendia, DrugDex, which is required by statute, in making their decisions as to whether they should cover a beneficiary claim for a prescription drug. Fox instead has utilized and continues to utilize other non-Medicare approved compendia in its decision making (including drugs.com). An enrollee is entitled to receive covered Part D drugs prescribed for medically accepted indications. Pursuant to Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 10.6, it is the Part D sponsor's responsibility for ensuring covered Part D drugs are prescribed for medically accepted indications. Pursuant to § 1860 D-2(e)(1)(B) of the Social Security Act, which incorporates §1927(k)(6) of the Act by reference, a "medically accepted indication" includes any use for a covered outpatient drug that is supported by one or more citations included or approved for inclusion in any of the compendia described in § 1927(g)(1)(B)(i). The compendia listed in §1927 (g)(1)(B)(i) of the Act are the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications) and the DRUGDEX Information System. *(See Kelman Declaration, Paragraph 8, and Tudor Declaration, Paragraph 16).*

Fox's failure to use DrugDex resulted in inappropriate denials of drugs to beneficiaries. For example, CMS discovered that Fox had 455 PA denials for the drug Lyrica between January 1, 2010 and February 15, 2010. For Lyrica (an anti-convulsant) the FDA label cites four medically approved indications while DrugDex cites 12. Since Fox was relying on a compendia that only listed the FDA indications, Fox would have (and did) inappropriately deny claims for Lyrica for the remaining 8 approved medical indications cited in DrugDex that were not cited in the FDA label. In addition, many appeals case files cited as the reason for denying a claim for a drug that the indication was not an FDA indicated use and the reviewer made no reference to any review of that claim based on the CMS required compendia. *(See Kelman Declaration, Paragraph 8, and Tudor Declaration, Paragraph 16).*

In addition, Fox allows the same physician who makes an adverse coverage determination to also perform the redetermination. This practice is in clear violation of CMS regulations. Pursuant to 42 C.F.R. § 423.590(f) a redetermination must be reviewed by a physician independent from the initial coverage determination. However,

while onsite, CMS reviewed a sample of redetermination files and interviewed the Medical Director (the individual responsible for this process) and learned that in the majority of cases, the same physician who had made the initial coverage determination decision to deny the drug also made the redetermination decision.

Failure to Follow CMS' Transition Requirements

Fox admitted to CMS during the onsite audits that Fox has had no drug transition process for current enrollees who were impacted by the change in Fox's drug formulary from 2009 to 2010. In other words, Fox failed to provide a one-time prescription fill of an enrollee's existing medication until they could transfer the enrollee from drugs that were covered on their formulary in 2009 to ones that were covered on their 2010 formulary, as required by CMS regulations. Fox claimed that it was the company's intent to transition these members to drugs that were covered on their new formulary before the first of the year. However, instead of granting affected enrollees "transition fills" of their previously covered drug as required by CMS guidance, Fox required the enrollee to go through unauthorized prior authorization requirements in order to obtain their existing prescription that should have been provided. In assessing the impact of this violation, CMS found that there were approximately 50 drugs for which PA was improperly added in 2010. CMS found that there were at least 5,600 beneficiaries who had claims for these drugs during the last quarter of 2009. Each of these beneficiaries was not afforded the transition benefit during 2010 and instead was subjected to a PA requirement which had the effect of delaying and/or denying their access to needed drugs. *(See Kelman Declaration, Paragraph 8, and Tudor Declaration, Paragraph 12).*

During the onsite audits it was determined that Fox failed to allow coverage of protected class drugs and instead required PA or ST in violation of CMS rules. While CMS does not know the total number of beneficiaries who were inappropriately subjected to these requirements, CMS has determined that at least 333 members stabilized (i.e., their medical condition or disease was stabilized) on protected class drugs had PA or ST inappropriately applied in 2010, thus delaying their access to these medications and creating a real risk that their health status might deteriorate, possibly significantly. In addition, CMS discovered that all of the coverage determinations (requested as a result of the denial) for these beneficiaries were subsequently and inappropriately denied which resulted in further delay to those beneficiaries receiving their needed medications. *(See Kelman Declaration, Paragraph 8, and Tudor Declaration, Paragraph 10).*

This is an example (one of many) of how a beneficiary was affected by these serious deficiencies (violations of PA and ST requirements, coverage determination requirements and transition requirements) on the part of Fox and the delays it caused enrollees in obtaining needed medications. Gleevec, a drug used to treat Gastrointestinal Stromal Tumors, is on the CMS approved 2009 and 2010 formularies for Fox with no prior authorization or step therapy required. However, claims for this drug were denied inappropriately at point of sale (due to the high cost edit) on several dates (October 14, 2009; December 13, 2009; December 15, 2009; and December 16, 2009). These

rejections triggered a clinical review of the case utilizing criteria that were not approved by CMS. The adverse coverage determination letter dated October 16, 2009 states that the information supplied was insufficient, and that a PET/CT report is to be sent. In response, copies of the PET/CT scan were faxed to Fox on December 17, 2009. Fox again denied the drug on December 18, 2009 based on clinical information. The physician requested an expedited appeal on December 31, 2009 and again on January 13, 2010. The case was not auto-forwarded to the independent review entity (IRE) as required by federal regulations for cases that have exceeded the review time lines. The adverse coverage determination was upheld by Fox in a denial letter that was faxed to the physician on February 12, 2010. The IRE overturned Fox's decision on February 14, 2010 on the basis that 1) it was prescribed for a medically-accepted indication supported by DRUGDEX, making it coverable under Part D, and 2) the drug was on formulary without coverage restrictions. *(See Attachment E: GLEEVAC Drug Documentation)*.

Failure to Follow CMS Compliance Plan Requirements

Additionally, during the onsite audits Fox's Compliance Officer (Mr. Sandip Mukherjee)[1] admitted that Fox has no compliance plan or structure in effect and no internal auditing or monitoring of Fox's business operations is conducted, including no processes to oversee their first tier, downstream or related entities compliance with CMS program requirements. This is in direct violation of CMS regulatory and contract requirements and has contributed to Fox's overwhelming systemic failure to operate its PDP contract effectively and in compliance with CMS requirements and its contract with CMS. All of the following deficiencies were confirmed during CMS' onsite audits and are in direct violation of CMS requirements regarding compliance programs:

- Fox has not developed any written compliance policies or procedures and Standards of Conduct articulating the organization's commitment to comply with all applicable Federal and State standards.
- Fox does not have an independent Compliance Officer. The person designated as the Compliance Officer is also the General Counsel and reports to three senior managers. He has no position description detailing his duties, responsibilities or authorities as a Compliance Officer.
- Fox does not have a Compliance Committee or a Board Compliance Oversight Committee.
- Fox has no compliance education and training program for its employees and/or their first tier, downstream or related entities.
- Fox has not established lines of communication for employees, first tier, downstream or related entities to report suspected compliance violations.

[1] Toward the end of the site visit, Fox introduced Mr. Kerry McDonald, whom we were told had been hired that day by Fox as the new Chief Compliance Officer. The description herein represents the state of Fox's compliance department as of the first day of the audit, which is the day that we conducted our compliance-oriented interviews and document reviews.

- Fox has not established any disciplinary guidelines for its employees, first tier, downstream or related entities. Fox does not have a non-retaliation policy for those who report instances of non-compliance.
- Fox has not established any monitoring or auditing activity to test and confirm compliance with the Part D benefit regulations.
- Fox has not established any policies or procedures to promptly respond to detected offenses nor have they established appropriate disciplinary or corrective action for noncompliance.
- The Compliance Officer stated that the Fraud, Waste and Abuse Plan provided to CMS was created strictly to satisfy business requirements mandated by various state licensing agencies. The plan has never been presented to or approved by the Board of Directors and has never been implemented by Fox. *(See Tudor Declaration, Paragraphs 18 and 19).*

The results of the onsite audits confirmed that Fox is not complying with CMS requirements in the administration of its formulary, which has resulted in denying and delaying access to prescription medications, including life sustaining medications, for its enrollees. The onsite audits also demonstrated to CMS that Fox, in many cases by its own admission, lacks required internal controls, an adequate process for oversight and monitoring or its subcontractors and related entities, and lacks knowledge of even basis CMS requirements regarding its operation as PDP.

CMS has a responsibility to not only protect its beneficiaries, but to protect the Medicare Trust Fund, and to ensure that the organizations we contract with take their obligations as Medicare business partners seriously. CMS has no confidence that Fox has the necessary administrative capabilities and infrastructure to redress the severe deficiencies that CMS has uncovered. Given the potential dire consequences to Fox's enrollees, CMS does not believe that it would be in the public interest to give Fox time to attempt to ameliorate these deficiencies.

IV. Additional Legal Bases Supporting Termination of Fox's Contract with CMS

Fox substantially failed to carry out the terms of its Prescription Drug Plan contracts with CMS (42 C.F.R. §423.509(a) (1)) and 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. §423.509(a) (2)).

- Fox continually failed to provide access to Part D benefits as described in its 2010 approved bid by imposing impermissible PA and ST criteria (including the inappropriate execution of high cost edits), failed to properly adjudicate coverage determination and redeterminations on a timely basis, and failed to properly provide for refills of current medications as required under Part D transition requirements.

- Fox failed to adhere to the conditions necessary to contract with CMS as a Part D plan sponsor as specified under 42 C.F.R. § 423.504(b)(4)(vi) by failing to maintain a compliance plan.

Fox failed to comply with the requirements in subpart M of Part 423 related to appeals and grievances (42 C.F.R. §423.509(a)(6)).

- Fox failed to adhere to requirements regarding timely coverage determinations on expedited PA requests and subsequently failed to forward the requests to CMS' independent review entity (IRE) within 24 hours of the expiration of the adjudication timeframe in accordance with CMS regulatory requirements.
- Fox failed to adhere to requirements regarding the use of an independent reviewer for redeterminations of coverage decisions. This failure to ensure independence between the first and second level appeal process is in direct violation of CMS regulatory requirements.
- Fox failed to use the statutorily required compendia in making its coverage decisions. Failure to use DrugDex, as required by statute, resulted in inappropriate denials of drugs.

V. Notice to Enrollees

Concurrent with this letter, CMS is notifying the enrollees of Fox's PDP contract S5557 of this contract determination. To ensure continuity of care, CMS has arranged for the immediate transition of Fox's enrollees to a Prescription Drug Plan offering a comparable benefit package. Fox must cooperate in effectuating this transition, and will be notified under separate cover about information, data, and record (including medical records) transition issues.

VI. Right to Request a Hearing

This contract determination is effective at 11:59:59 P.M. EDT on March 9, 2010. Pursuant to 42 C.F.R. §423.509(c)(2) Part D plan sponsor does not have the opportunity to submit a corrective action plan prior to termination. Although the effective date of this contract determination will not be stayed, the contract determination may be appealed by an authorized official of Fox timely requesting a hearing pursuant to the procedures outlined in 42 C.F.R. Part 423 Subpart N. Pursuant to 42 C.F.R. §423.651, your written request for a hearing must be received by CMS within 15 calendar days from the date CMS notified you of this determination, or no later than March 25, 2010. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or overnight mail (i.e., March 10, 2010). Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

Fox may 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

A courtesy copy of your request should also be sent 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 request for a hearing must be sent to the CMS Hearing Office at the following address:

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

If you have any questions about this determination, please contact Jennifer Smith at (410) 786-1404 or by email at jennifer.smith2@cms.hhs.gov.

Sincerely,

Brenda Tranchida
Director
Program Compliance and Oversight Group

Attachments

Attachment A – Declaration of Jeffrey Kelman, M.D., M.M.Sc. dated March 9, 2010
Attachment B – Declaration of Cynthia G. Tudor, Ph.D. dated March 9, 2010
Attachment C – HIV/AIDS Drug Documentation
Attachment D – Notice of Immediate Imposition of Marketing & Enrollment Sanction Letter from CMS to Fox, dated February 26, 2010
Attachment E – GLEEVEC Drug Documentation

cc: Mr. Jonathan Blum, CMS/CPC
Mr. Timothy Hill, CMS/CPC
Dr. Jeff Kelman, CMS/CPC
Ms. Cynthia Tudor, CMS/CPC/MDBG
Ms. Jennifer Shapiro, CMS/CPC/MDBG
Ms. Judith Geisler, CMS/CPC/MDBG
Ms. Danielle Moon, CMS/CPC/MCAG
Ms. Heidi Arndt, CMS/CPC/MCAG
Mr. Thomas Hutchinson, CMS/CPC/MPPG
Mr. Randy Brauer, CMS/CPC/MPPG
Mr. Anthony Culotta, CMS/CPC/MEAG
Ms. Mary A. Laureno, CMS/OBIS
Mr. Peter Ashkenaz, CMS/OEA
Ms. Laurie McWright, CMS/OL
Mr. Greg Jones, CMS/OL
Ms. Kimberly Brandt, CMS/OFM/PI
Mr. James Kerr, CMS/OA/CMHPO
Ms. Janis Remer, CMS/CMHPO/Region II
Mr. Reginald Slaten, CMS/CMHPO/Region II
Ms. Carol Bennett, DHHS/OGC
Ms. Leslie Stafford, DHHS/OGC
Mr. Donald Kosin, DHHS/OGC
Ms. Jill Abrams, DHHS/OGC
Ms. Nancy Brown, DHHS/OIG/OCIG
Mr. Paul Collura, CMS/CMHPO
Mr. Benjamin Cohen, CMS/OA
Ms. Jennifer Smith, CMS/CPC/PCOG