

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



---

February 26, 2010

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

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

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) For: Prescription Drug Plan Contract Number S5557

Dear Mr. Shankar:

Pursuant to 42 C.F.R. §423.756, the Centers for Medicare & Medicaid Service (CMS) is hereby providing notice to Fox Insurance Company (Fox) of the imposition of intermediate sanctions for contract number: S5557. These intermediate sanctions will consist of suspension of enrollment of Medicare beneficiaries (42 C.F.R. §423.750(a)(1)) and suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. §423.750(a)(3)).

CMS is imposing these intermediate sanctions immediately because it has determined that Fox's conduct poses a serious threat to the health and safety of Medicare beneficiaries. Based on this determination, the intermediate sanctions will be effective immediately, February 26, 2010, pursuant to 42 C.F.R. § 423.756(d)(2), and will remain in effect until CMS is satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur.

## **Summary of Fox Insurance Company Noncompliance**

Fox Insurance Company has demonstrated a 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. This substantial noncompliance has resulted in significant impediments to Fox's enrollees' ability to promptly access needed Part D drugs, and potentially puts Fox's current and future enrollees' health at risk. Among other findings of non-compliance, Fox has (1) imposed prior authorization (PA) requirements and improperly required step therapy (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. Fox is contractually bound to provide Part D benefits as described in the bids approved each year by CMS.

CMS became aware of Fox's non-compliance with requirements for imposing prior authorization and step therapy requirements through complaints made by physicians on behalf of patients who are Fox plan enrollees, and complaints directly from Fox enrollees. These complaints involved the denial of 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 these criteria were not approved by CMS. As a result, coverage was improperly denied for critical HIV, cancer, and seizure medications. On February 11<sup>th</sup> and 12<sup>th</sup> during conference calls with CMS management, Fox admitted that it had imposed PA requirements that had neither been reviewed nor approved by CMS while understanding that CMS approval was a requirement. 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 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 serves as further confirmation that Fox has been using unapproved PA and ST criteria to adjudicate drug claims by its Part D plan members.

Additionally, CMS has concrete evidence that Fox's non-compliance with required coverage determination timeframes led, in at least one instance, to a significant delay in HIV therapy that could put the patient's health at serious risk. On February 4, 2010, CMS was copied on a letter from a provider to Fox. According to the letter, on January 13, 2010, at 2:14 PM, the provider requested via fax that Fox make an expedited determination on a prior authorization for an HIV medication (Atripla). After no determination was received, subsequent requests were made less than 24 hours after the initial request, almost 45 hours after the initial request, and 120 hours after the initial request. Approval was received via fax from Fox on January 18, 2010 at 3:46 PM, 121 hours and 32 minutes after the initial request was made by the provider. Pursuant to 42 CFR §423.572(a), Fox was required to make its determination on the expedited request

no later than 24 hours after receiving the request. 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 has also learned through beneficiary complaints, and a review of the record of Fox coverage determination files, that Fox is failing to provide transition coverage of drugs without prior authorization pursuant to 42 CFR §423.120(b)(3) and the Medicare Prescription Drug Manual, Chapter 6, Section 30.4.5. This review uncovered claims that were inappropriately required to go through a PA process which included drugs used to treat hepatitis, pulmonary hypertension and diabetes. In addition, CMS discovered through a complaint that a beneficiary was unable to access her Pegasys (for hepatitis) due to an inappropriate PA, even though she had previously been on the drug during contract year 2009.

### **Basis of Intermediate Sanctions**

CMS has determined that Fox's compliance deficiencies, as described below, provide sufficient basis for the imposition of intermediate sanctions (42 C.F.R. §§423.752(a) and 423.752(b)). Furthermore, CMS has determined that a number of these deficiencies pose a serious threat to enrollees' health and safety, warranting imposing these sanctions effective immediately (42 C.F.R. §423.756(d)(2)).

CMS' determination to impose intermediate sanctions is based on the following regulatory bases for the imposition of intermediate sanctions, each of which provides an independent basis for the imposition of an intermediate sanction, and which are supported by examples of Fox's noncompliance, as described below:

***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 failed to provide access to Part D benefits as described in its 2010 approved bid by imposing impermissible PA and ST criteria not approved by CMS, failing to properly adjudicate coverage determinations on a timely basis, and failing to properly provide for refills of current medications as required under Part D transition requirements.
- Fox failed to disclose information to beneficiaries in the manner and the form specified by CMS under 42 C.F.R. § 423.128(b)(4), and in the Marketing Guidelines for Prescription Drug Plans, by posting PA criteria that were inconsistent with the CMS approved PA criteria, and by failing to post ST criteria that Fox was improperly applying.

***Fox substantially failed to provide medically necessary services that the organization is required to provide to Part D plan enrollees (42 C.F.R. §423.752(a)(1)).***

- Fox's non-compliance with PA and ST criteria, coverage determination, and transition fill requirements, improperly delayed therapies and/or prevented access to medically necessary drugs and therapies. Fox's delaying and/or preventing access to these types of drugs results in a failure to provide medically necessary services which adversely affects or has the substantial likelihood of adversely affecting enrollees.
- Fox's non-compliance as described above additionally poses a serious threat to enrollee health and safety as described 42 C.F.R. §423.756(d)(2), specifically with respect to non-compliant claims and coverage determinations involving protected class drugs, including: HIV, cancer, seizure, respiratory, and anti-diabetic medications.

***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.

**Opportunity to Respond to Notice**

Pursuant to 42 C.F.R. §423.756(a)(2), Fox has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by March 8, 2010. Please note that CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or overnight mail, or in this case, February 27, 2010.

**Right to Request a Hearing**

Fox may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§423.650 through 662. Pursuant to 42 C.F.R. §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 March 13, 2010. Please note, however, a request for a hearing will not delay the date specified by CMS when the sanction becomes effective. If the 15<sup>th</sup> day falls on a weekend or federal holiday, you have until the next regular business day to submit your request, which in this case is March 15, 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.

Mr. Kary Shankar  
February 26, 2010  
Page 5 of 6

Fox 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](mailto: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 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 & 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](mailto:Benjamin.Cohen@cms.hhs.gov)

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

If you have any questions about this determination, please do not hesitate to contact Jennifer Smith directly at (410) 786-1404.

Mr. Kary Shankar  
February 26, 2010  
Page 6 of 6

Sincerely,



Brenda J. Tranchida  
Director  
Program Compliance and Oversight Group

cc: Mr. Jonathan Blum, CMS/CPC  
Mr. Timothy Hill, 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  
Mr. Donald Kosin, DHHS/OGC  
Ms. Jennifer Smith, CMS/CPC/PCOG  
Dr. Jeffrey Kelman, CMS/CPC  
Mr. Thomas Hutchinson, CMS/CPC/MPPG  
Mr. Randy Brauer, CMS/CPC/MPPG  
Mr. Anthony Culotta, CMS/CPC/MEAG  
Ms. Mary A. Laurenno, CMS/OBIS  
Mr. Peter Ashkenaz, CMS/OEA  
Ms. Laura 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  
Ms. Jill Abrams, DHHS/OGC  
Ms. Nancy Brown, DHHS/OIG/OCIG  
Mr. Paul Collura, CMS/CMHPO  
Mr. Benjamin Cohen, CMS/OA