CENTERS FOR MEDICARE AND MEDICAID SERVICES

Hearing Officer Decision

In the Matter of

Fox Insurance Company	*	
	*	Docket No. 2010 C/D Term 1
Immediate Termination of Prescription Drug Plan, S5557	*	
	*	
	*	

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §423.650(a)(2). The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated by the CMS Administrator to hear this case is the undersigned, Benjamin Cohen.

Issue

Whether CMS' immediate termination of Fox Insurance Company's Prescription Drug Plan was proper.

Statutory and Regulatory Background

The Social Security Act (the Act) authorizes CMS to enter into contracts with companies to provide private prescription drug benefits to their plan enrollees under Medicare Part D. See SSA §§1860D-11 and 1860D-12, 42 U.S.C. §§1395w-111 and 1395w-112. These companies are known as Part D sponsors. Section 1860D-12(b)(3) of the Act, (42 U.S.C. §1395w-112(b)(3)), provides that contracts with Part D sponsors will generally be subject to some of the same contract requirements as Medicare Advantage plans in Section 1857 of the Act, (42 U.S.C. §1395w-26). Relevant to the subject proceeding, subsections 1860 D-12(b)(3)(C) and (F) of the Act (42 U.S.C. §1395w-112(b)(3)(C) and (F)) specifically provide that Part D sponsors will be subject to the same requirements as those in Sections 1857(c) and (h) of the Act (42 U.S.C. §1395w-27(c) and (h)). The pertinent parts of Section 1857 states:

> (c) CONTRACT PERIOD AND EFFECTIVENESS
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> * * * *
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> (2) In accordance with procedures established under subsection (h), the Secretary may at any time terminate any contract if the Secretary determines that the organization-

(A) has failed substantially to carry out the contract

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

* * * *

(h) PROCEDURES FOR TERMINATIONS

(1) IN GENERAL. The Secretary may terminate a contract with the [Part D] organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which-

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH- Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(emphasis added).

Regulations governing Part D of the Medicare program are set forth at 42 C.F.R. §423.1 et seq. and include: application procedures, contract determinations (including terminations) and appeals. The specific regulation regarding termination of Part D sponsors is at 42 C.F.R. §423.509. At the time of the termination, the regulation at 42 C.F.R. §423.509(a) contained eleven subsections which provide grounds for which CMS may terminate a contract. Relevant to CMS allegations, 42 C.F.R.§423.509 (a)(1) provides that CMS may terminate a contract of a Part D sponsor that "failed substantially to carry out terms of its current or previous contract…" Similarly, 42 C.F.R.¶423.509(a)(2) indicates that CMS may terminate a contract if the Part D sponsor carries out its contract inconsistent with the effective and efficient implementation of the regulations. 42 C.F.R. §423.509(a)(6) indicates that CMS may terminate if a plan fails to comply with appeals and grievances requirements. Further, the regulatory framework of 42 C.F.R. §§423.509(b)(2) and (c)(1) and (2) provide that Part D plan sponsors will have the opportunity to submit corrective action plans (within specified timeframes) unless

CMS immediately terminates a contract based on "violations" or "the grounds" prescribed in 42 C.F.R. §423.509(a)(4)[1] or (a)(5).

Relevant to this dispute, the grounds for termination at 42 C.F.R. §423.509(a)(5)[2] permit ***immediate*** termination when the Part D Plan sponsor:

> Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists.[3] [4]

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[1] 42 C.F.R. §423.509(a)(4) (which is not the subject of this proceeding) indicates that CMS may immediately terminate a Part D sponsor who commits false, fraudulent or abusive activities.

[2] The Hearing Officer notes that 42 C.F.R. §423.509(a)(5) was officially established through the publication of the Proposed Rules at 69 Fed. Reg. 46631, 46714 (Aug. 3, 2004) and 70 Fed. Reg. 4193, 4337 (Jan. 28, 2005) (which established the Part D program). However, the text of 42 C.F.R §423.509(a) originated in the Proposed Rule and Final Rule (at parallel cite 42 C.F.R. §422.510(a)(5)) which established the Medicare Plus Choice Program, (a managed care Part C program which has been replaced by the Medicare Advantage program). 63 Fed. Reg. 34968, 35018 (June 26, 1998). The Part C regulations at 42 C.F.R. §422 et seq. and the Part D regulations at 42 C.F.R. §423 et seq. are largely parallel. *See* 69 Fed Reg. 46632, 46634 (Tues. Aug. 3, 2004).

[3] As the contentions below outline, the parties disagree regarding whether this regulatory provision as constructed prohibits CMS from immediately terminating Part D plans based upon a failure to make services available to the extent that a risk to health exists if such plan experiences no financial difficulties. The initial preamble (63 Fed. Reg. 34968, 35018-35019 (June 26, 1998)) explaining the parallel text of the original Part C regulation (at 42 C.F.R. §422.510(a)(5)) provides the most complete explanation regarding the Secretary's intention in implementing Section 1857(h)(2) of the Act. It states:

> "Section 1857(h)(2) provides authority for the Secretary to immediately terminate a contract with an M+C organization in instances where the Secretary determines that a delay in termination resulting from compliance with the procedures in section 1857(h)(1) discussed below would pose an imminent and serious risk to the health of enrolled Medicare beneficiaries.
>
> We have implemented this authority as follows. First, §422.510(a)(5) provides for termination when an M+C organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or when the organization otherwise fails to make services available to the extent that such a risk to health exists. Second, §422.510(b)(2) provides that a termination based on §422.510(a)(5) takes effect immediately. Third §422.510(c) provides that the opportunity for corrective action does not apply to a termination based upon §422.510(a)(5). And fourth, subpart N of part 422 provides that in the case of a termination based on §422.510(a)(5), a hearing is not provided until after the termination takes effect.
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> Section 1857(h)(1) specifies procedures that must be followed before a termination by HCFA can take effect (unless the exception for an imminent and serious risk to health applies, as discussed above). We specify these requirements at §422.50(b)(1). Section 1857(h)(1)(A) requires that the M+C organization be provided with a "reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies" that were the basis for a decision that grounds for termination existed under section 1857(c)(2). Section 422.510(c) provides for such a corrective action opportunity, consistent with time frames specified in Subpart N, except in cases in which the termination is based upon §422.510(a)(5), and the "imminent and serious" risk to health exception in section 1857(h)(2) applies.

42 C.F.R. §423.509(a)(5) (emphasis added).

If CMS terminates a Part D sponsor, the sponsor has the right to a hearing before a CMS Hearing Officer under 42 C.F.R §423.650(a)(2). The provision of 42 C.F.R.§423.650, sets the burden of proof for the hearing as follows:

> (b) The Part D sponsor bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the Part D program on the earliest of the following three dates:
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> (1) The date the sponsor received written notice of the contract determination or intermediate sanction,
> (2) The date of the most recent audit conducted by CMS,
> (3) The date of the alleged breach of the current contract or past substantial non-compliance as determined by CMS.[5]

> Section 1857(h)(1)(B) requires that the Secretary provide the M+C organization with "reasonable notice and opportunity for hearing," including "the right to appeal an initial decision … *before* terminating the contract." (Emphasis added.) Section 422.510(d) implements this provision by requiring that a notice of appeal rights under Subpart N be provided when a termination notice is sent to an M+C organization. This notice would specify that the termination would not be effective until after the hearing and appeal, except in the case of a termination under §422.510(a)(5)." Emphasis added.

Similarly, the August 2004 Proposed Rule at 69 Fed. Reg.46631, 46723 (Aug 3, 2004) states

> "As discussed above, §423.509 of Subpart K of this part implements the provisions of sections 1857(h)(1)(A) and 1857 (h) (2) of the Act that address reasons for our termination of contract opportunity for PDP sponsors to develop a corrective action plan before termination, and procedures for immediate termination if we identify an imminent and serious health risk to enrollees. (emphasis added).

[4] The hearing officer notes that pursuant to the Final Rule at 75 Fed. Reg. 19539, 19699 (Apr. 15, 2010 effective *June 7, 2010*) (see also Proposed Rule at 74 Fed. Reg. 54634, 54649 (Oct. 22, 2009)), CMS retained the expedited termination contract language at 42 C.F.R. §423.509(a)(5) with virtually identical language (now recodified at §423.509(b)(2)(i)(B)). Similarly, besides retaining the right to expeditious termination based on false, fraudulent or abusive activities as provided in recodified 423.509(b)(2)(i)(C), CMS added new text at 42 C.F.R. 423.509(b)(2)(i)(A) reiterating that CMS may also conduct an expedited termination if "CMS determines that a delay in termination, resulting from compliance with the procedure provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D sponsor plan."

[5] The implementing Proposed Rule at 72 Fed Reg. 29237, 29377 (May 25, 2007) states that "We believe our proposal to provide a framework for hearing officers to use in establishing a compliance date as a reference point will lessen the potential for such inconsistency. By requiring the compliance date to be the earliest of the three possible dates, the hearing will reflect that circumstances may differ on a case by case basis. For example, where an onsite audit was conducted or where a significant breach occurred, we think it is appropriate for us to base our decision to terminate a plan's contract on the date of either the audit or the breach. However, where an onsite audit did not occur, or where the basis of our termination is not one major breach, we think it is appropriate to use the date we notified the MA organization or Part D sponsor of our intent to terminate as a reference point. Without a specific date as a reference point for evaluating compliance, the hearing officer lacks the information necessary to arrive at a determination."

Factual and Procedural Background

Fox Insurance Company (Fox) is an Arizona corporation, with its principal place of business in, New York, NY 10010. In September of 2005, CMS awarded Fox a contract to operate Medicare Part D prescription plans beginning in 2006. At the time of contract termination, Fox offered plans in 20 different states.

In early February 2010, CMS contacted Fox in response to various complaints from physicians and beneficiaries stating that Fox had improperly delayed or denied claims for certain critical medication, including HIV, cancer and seizure medications.[6] CMS learned that Fox allegedly imposed improper prior authorization and step therapy requirements. CMS indicates it also learned that Fox was not complying with CMS requirements (see 42 C.F.R. 423.568 and 572) regarding coverage determination timeframes and failed to provide transition coverage of drugs that beneficiaries had taken in 2009 (see 42 CFR 423.120(b)(3) and Pub 100-18, Chapter 6 Section 30.4.5). CMS directed that Fox take immediate steps to cure its violations and directed Fox to provide its coverage determination files for review.[7]

Fox indicates that it immediately began an extensive review of its claim adjudication systems and it implemented substantial corrective measures. It asserts that by letters dated February 16 and 18, Fox notified CMS of remedial actions that it was undertaking and assured CMS that it was committed to comply with Part D requirements.[8]

By letter dated, February 19, 2010, Fox informed CMS that in addition to addressing specific concerns regarding Fox's requirement for prior authorization of antiretroviral medication for HIV patients, Fox had initiated changes in several operational areas. Those areas included removing high cost edits, reevaluating prior authorization forms, retaining clinical staff on CMS approved prior authorization criteria, and increasing oversight on its PBM pharmacy help desk activities. [9]

By email dated February 22, 2010 CMS indicated that it "continues to identify serious deficiencies" in Fox's administration of the Part D program. CMS stated that in addition to the requirements for prior authorization for some antiretroviral drugs, it noted examples of failure to provide timely coverage determinations, requiring prior authorization and step therapy for drugs within the protected classes for which beneficiaries are actively taking,[10] and failing to appropriately transition members for

[6] Fox Brief (Initial) at 6; CMS Brief at 7-8, CMS Ex. 1 (Declaration of B. Tranchida at ¶4 and 5).
[7] CMS Brief at 7-8; CMS Exhibit (Ex.). 1 (Declaration of B. Tranchida at ¶5-9).
[8] Fox Brief (Initial) at 6 (The record does not contain the February 16 and 18 letters referenced in the brief)
[9] *See* Fox Brief (Initial) Ex. A, See also CMS brief at 7, CMS Ex 2.
[10] CMS determined that at least 333 members had prior authorization and step therapy inappropriately applied. In addition CMS discovered that all of the coverage determination (requested as a result of the denial) for these beneficiaries were subsequently and inappropriately denied. (CMS Ex.5 Declaration of Kelman at ¶8, CMS Ex. 8, Tudor Declaration at ¶10.)

formulary changes occurring across contract years. [11] CMS indicated that Fox "must immediately correct" these areas and requested that Fox provide CMS with a corrective plan by the next day.

By memorandum delivered via email dated February 26, 2010, CMS notified Fox of areas of non-compliance and immediately imposed intermediate sanctions on Fox.[12] Specifically, pursuant to its authority under 42 C.F.R. §423.756, CMS immediately suspended Fox's entire marketing and new beneficiary enrollment. The memorandum stated that CMS believed the issues "to be of such a serious nature that if left uncorrected, CMS will consider taking action to immediately terminate your contract."[13]

Due to the nature of the alleged deficiencies, on March 2 through March 4, CMS conducted on-site audits of Fox's principal place of business in New York, New York, and ProCare Rx[14] located in Duluth, Georgia. At the audit, CMS determined that the violations which had been the subject of directives and warnings from CMS in February continued to exist. In addition, CMS found four more violations including: the inappropriate use of high cost edits to deny coverage (see 42 C.F.R.§423.272(b)(2)) which resulted in thousands of rejected claims,[15] failure to ensure Independent Review of Denial Appeals (see 42 C.F.R. §423.590(f)),[16] use of inferior sources to make coverage decisions (see Social Security Act §1860D-2(e)(1)(B) and §1927 (g)(1)(B)(i)),[17] and lack of infrastructure and oversight sufficient to operate a national prescription drug plan consisting of approximately 120,000 members (see 42 C.F.R.§423.504(b)(4)(vi) (A) through (G)).[18]

By letter dated March 5, 2010, Fox conveyed deep concern regarding the significant issues that were identified by CMS and informed CMS that it was taking steps to ultimately obtain compliance with the Part D requirements within one month.[19] On March 8, 2010, Fox sent a letter to CMS in response to the February 26 intermediate

[11] CMS Ex.5 Declaration of Kelman at ¶8, CMS Ex. 8, Tudor Declaration at ¶10..In assessing the impact of the violation, CMS found that there were approximately 50 drugs for which prior authorization was improperly added and 5600 beneficiaries who had claims for these drugs during the last quarter of 2009. CMS contends that each of these beneficiaries was not afforded the transition benefit during 2010 and instead was subjected to PA requirement which had the effect of delaying and/or denying their access to needed drugs

[12] CMS Ex. 6. Areas of alleged non-compliance cited by CMS included those violations cited in CMS' February 22, 2010 e mail..

[13] *Id*. at 5.

[14] ProCare Rx was Fox's subcontracted pharmacy benefits manager (PBM).

[15] A "high cost edit" is a red flag raised when a drug is expensive or exceeds a certain cost threshold. *See* CMS Ex. 5 (Declaration of Kelman at¶ 8 *).*

[16] Fox, allegedly, was sending beneficiaries' coverage requests back to the same doctors who originally denied them, in violation of CMS regulations. *See* CMS Ex. 5 *(*Tudor Decl. At ¶ 14).

[17] Fox allegedly failed to use the statutorily required compendia called "DrugDex" when making its coverage determinations. *See* CMS Ex. 5 (Tudor Decl. at ¶ 16; Kelman Decl. at ¶8)

[18] Fox allegedly lacked the basic structure and policies to insure proper oversight and compliance with CMS requirements. *See* CMS Ex. 5 (Tudor Decl. at ¶ 18-19).

[19] Fox Ex. C.

sanctions, and explained steps Fox had/would take to address the identified problems.[20] In the letter, Fox acknowledged that it had a range of issues that it needed to address but outlined the steps it had taken to address the most immediate CMS concerns relating to the health and safety of enrollees.

On March 9, 2010, CMS sent Fox's CEO a letter immediately terminating the contract for prescription drug plan services. As described above, the letter further detailed the bases presented in February leading to intermediate sanctions, as well as the additional violations (described above) discovered at the March 2-4 audit.[21] The letter also noted that during the onsite audit, Fox's Compliance Officer (Mr. Sandip Mukherjee)[22] admitted that Fox had no compliance plan or structure in effect and no internal auditing or monitoring of Fox's business operation was conducted, (including no processes to oversee first tier downstream or related entities). CMS indicated this lack of internal controls is in direct violation of CMS regulatory and contract requirements.[23]

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[20] *See* Fox Ex. B. The hearing officer notes that Fox did not formally appeal the imposition of the February 26, 2010 intermediate sanctions to the hearing officer. Specifically, Fox's March 8 letter indicated that in lieu of providing a rebuttal to CMS' allegation, Fox had/would take the following steps: 1) Fox removed prior authorization, step therapy and utilization management requisites for protected class drugs. Fox revoked denials for 2010 in the protective class drugs actively and was actively calling beneficiaries notifying them that they could collect medications. 2) Fox attached an new formulary with all protective class drugs 3) Fox is entering system overrides to ensure that members are given a transition supply 4) Fox hired a new compliance officer who is already engaged, 5) Fox terminated its arrangements with CH Health regarding clinical functions and hired new staff to begin work on March 10. Fox planned to immediately train such staff on CMS rules including the use of statutorily required compendia (Drugdex) and claim adjudication requirements. 5) Fox attached a report on all member rules that were added that were previously denied.

[21] CMS Ex. 3.

[22] CMS' March 9, 2010 letter (CMS Ex. 3, footnote 1) indicated that the compliance-oriented reviews and document reviews were conducted on the first day (March 2) of the three day audit. The March 9 termination letter also indicated that toward the end of the three day site visit, Fox introduced Mr. Kerry Mc Donald, who CMS was told had been hired earlier that day to serve as Chief Compliance Officer.

[23] Specifically, CMS noted (CMS Ex.3 at 9-10) that " (1) Fox had 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, (2) 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 (3)Fox does not have a Compliance Committee or a Board Compliance Oversight Committee (4) Fox has no compliance education and training program for its employees and/or their first tier, downstream or related entities (5) Fox has not established lines of communication for employees, first tier, downstream or related entities to report suspected compliance violations (6) Fox has not established any disciplinary guidelines for its employees, first tier, downstream or related entitles. Fox does not have a non- retaliation policy for those who report instances of non-compliance (7) Fox has not established any monitoring or auditing activity to test and confirm compliance with the Part D benefit regulations (8) 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 (9) 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, Paragraph 18 and 19)."

In support of the immediate termination pursuant to 42 C.F.R. 423.509(a)(5) the letter summarized:

> CMS had 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.
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> 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.
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> * * *
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> 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.[24]

On March 9, CMS also notified Fox's enrollees that Fox was being terminated, and arranged to transfer all of Fox's enrollees to other prescription drug plans. On March 12, 2010, CMS notified Fox's enrollees that they had been transferred to the LI-NET program and instructed pharmacies to discontinue billing ProCare Rx on behalf of Fox and instead to process claims through LI-NET Rx.

On March 15, 2010, Fox challenged its termination by filing a complaint in the United States District Court for the Southern District of New York contending that the Federal Courts were the appropriate forum to challenge CMS determination. By letter dated March 22, 2010, Fox concurrently filed for administrative review without prejudice to the rights it was asserting before the District Court. On March 24, 2010, the District Court issued a bench order granting CMS' motion to dismiss for lack of summary judgment and denying Fox's motion for a preliminary injunction as moot. (Fox Ins. Co. v. Sebelius 10 CV 2218, Hearing Tr. at 29-39 (S.D.N.Y. Mar. 24, 2010)) Fox appealed to the United States Court of Appeals, Second Circuit which on June 22, 2010, upheld the District

[24] The letter also cited as an additional basis for supporting [non-immediate] termination of Fox's contract the provision at 42 C.F.R. §§423.509(a)(1), 423.509(a)(2) and §423.509(a)(6)

Court's determination that it lacked jurisdiction over Fox's claim on the basis that Fox failed to administratively exhaust its claims through the CMS Hearing Officer.[25]

Issue 1:

Did CMS exceed its statutory and regulatory authority when it *immediately* terminated Fox's contract?

Fox's Contentions

Fox claims that because CMS did not demonstrate that Fox was experiencing financial difficulties, CMS exceeded its regulatory authority by terminating Fox's contract under 42 C.F.R. §423.509(a)(5) which permits ***immediate*** termination when the Part D Plan sponsor:

> Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists.

Fox contends that the introductory phrase of such provision which reads "*Experiences financial difficulties so severe…*" qualifies the following two conditions set forth in the provision. Essentially, Fox argues that the provision provides that CMS may terminate if the part D sponsor *either*:

1. *Experiences financial difficulties so severe, that* its ability to provide prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, *OR*
2. *Experiences financial difficulties so severe, that* the sponsor otherwise fails to make services available to the extent that a risk to health exists.[26]

Fox contends that the regulations under 42 C.F.R. §423.509(a) contain eleven independent bases for termination and each is given its own paragraph (except for subparagraph (9) which is distinctly divided into subparagraphs). Accordingly, when viewed together, it is clear that paragraph (a)(5) as a whole was meant to cover one independent basis [involving financial difficulties].[27] Additionally, CMS has not cited any regulatory history, nor did the August, 2004 rule implementing the Part D program

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[25] Fox Insurance Company v Sebelius, 2010 WL 2539653(C.A.(N.Y.) See also, Hearing Officer Administrative Record Correspondence. While the parties were provided the opportunity to appear in-person before the CMS Hearing Officer within thirty days of the termination in accordance with the regulations, the parties mutually elected to set a briefing schedule for the hearing officer beyond such timeframe. Additionally the parties elected to waive the right to appear for a live hearing before the hearing officer in lieu of presenting argument strictly on- the record.

[26] *See* Fox Reply Brief at 3.

[27] *See* Fox Initial Brief at 13-14

discuss the intent of 42 C.F.R. §423.509(a)(5).[28] Additionally, Fox alleges that CMS made statements in the October 2009 Federal Register which, in Fox's opinion, effectively confirmed that 42 C.F.R. 423.509(a)(5) required a Part D sponsor to experience financial difficulties before authorizing contract termination.[29]

Fox posits that CMS statements in the Federal Register regarding 42 C.F.R. §423.509(a)(4)-(5) authority for immediate terminations show that the statutory authority only allows the Secretary to immediately terminate under circumstances leading to "an imminent and serious risk to health," whereas the regulation's second section calls for an immediate termination where merely a "risk to health" exists. Therefore, when reading the second section of the regulation in isolation from the first, the regulatory authority to immediately terminate for a "risk to health" is broader than the statutory authority to immediately terminate for "an imminent and serious risk to health."

Fox argues that CMS' past uniform practices of statutory interpretation of 42 C.F.R. §423.509(a)(5) when dealing with similar enforcement action illustrate that immediately terminating Fox without prior notice or procedural safeguards (e.g., opportunity to be heard) is now inconsistent with the previous reading of the regulations.[30]

Finally, Fox claims that reading the two clauses of 42 C.F.R.§423.509(a)(5) in complete isolation from each other, so that the financial difficulties language does not impact the second clause, should be disfavored because the second clause would then clearly exceed CMS' statutory authority. If the second clause read in isolation is a basis for contract termination, then CMS is claiming the authority to immediately terminate a contract "whenever a "risk to health exists." Fox believes this is contrary to the statutory authority at Section 1857 of the Social Security Act for immediate termination which extends only to situations where procedural delays "would pose an imminent and serious risk to the health of [enrollees]." Allowing CMS to immediately terminate contracts under the looser "risk to health" standard would allow CMS to immediately terminate contracts that Congress had specifically provided should be terminated only with notice and an opportunity to cure.[31]

Finally, as opposed to CMS's contention of the "or otherwise" language in the regulation, such language ties two alternative and non-overlapping bases together and makes either a basis for termination. CMS reading renders the language in the regulation superfluous because there is no possible circumstance where a sponsor's financial difficulties could be impairing "its ability to provide necessary prescription drug coverage…to the point of posing an imminent and serious risk to the health of its enrollees without the second clause, as interpreted by CMS in this dispute, also being satisfied (i.e. the sponsor would necessarily be "fail[ing] to make services available to the extent that a risk to health exist[ed].")[32]

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[28] *See* Fox Initial Brief at 14.
[29] *See* Fox Initial Brief at 14-15.
[30] Fox Brief (Initial) at 15-19. Fox Reply Brief at ft. note 2.
[31] Fox Brief (Initial) at 19.
[32] Fox Reply Brief at 3-4.

Fox also contends that its reading of 42 C.F.R. §423.509(a)(5) implements the purpose of the Social Security Act and CMS' regulations better than CMS' reading. The statute and regulations generally protect beneficiaries' health by allowing plan sponsors to correct their deficiencies under CMS' guidance. Fox explains that Congress and CMS have determined that beneficiaries are best served not by immediate terminations whenever plan sponsors deviate from requirements but by reserving immediate terminations for a narrow set of circumstances—those related to evidence of fraud or those stemming from financial difficulties. , Fox argues that plan sponsors experiencing financial difficulties are unlikely to have the resources to fix problems quickly. Accordingly, the better reading of the regulation does not subject plan sponsors who have financial resources but experience administrative difficulties to be subject to immediate termination.[33]

CMS' Contentions

CMS contends that it had the regulatory authority to *immediately* terminate Fox's contract as Fox endangered the health of its enrollees and continued to place its enrollees' health under imminent and serious risk.

First, CMS argues that Fox's interpretation that 42 C.F.R. §423.509 (a) requires that a company experience financial difficulties in order for CMS to invoke immediate termination is contrary to the plain language of the regulation. The inclusion of the phrase " or otherwise fails," in the second clause would render the term "otherwise" to be superfluous under Fox's interpretation. Similarly, Fox's interpretation would clearly undermine the obvious purpose of the statute and regulation (protection against endangerment of health) by requiring CMS to provide ninety days advance notice of termination in cases in which beneficiaries' health was at risk unless financial difficulties also existed. Moreover, the fact that CMS elected not to use subparagraphs to list separate bases of termination within 42 C.F.R. §423.509(a) is irrelevant.[34]

Second, no Federal Register statements have stated that "financial difficulties" are required for CMS to pursue an immediate termination. Similarly, contrary to Fox's contentions, CMS has never interpreted 42 C.F.R. §423.509(a)(5) as granting it broader authority than that conveyed by statute.[35]

Finally, CMS' termination was consistent with its past practices and its authority regardless of the frequency that such authority is exercised. CMS' election to not terminate past sponsors was not because of either a lack of authority, or a reflection of unfair or unequal treatment towards Fox.[36] While other Part C or Part D plans may have experienced problems similar to Fox, the response of each organization is so unique that CMS would be entirely hamstrung if it had to proceed in lockstep fashion with each organization that had alleged deficiencies. The Secretary has delegated to CMS the

[33] Fox Reply Brief at 5-8.
[34] *See* CMS Brief at 24-27.
[35] *See* CMS Brief at 27-29.
[36] *See* CMS' Brief at 29-32.

authority to utilize a variety of compliance and enforcement tools to determine which is most appropriate for individual situations.

Finally, Fox was in the process of developing and implementing a formal compliance plan on March 4 and had taken steps to ensure that full compliance would be achieved within days. Fox explained that it had hired a compliance officer with significant experience on March 4, and Fox had begun the process of developing formal written compliance policies, formal training programs, and rigorous monitoring. Fox explains that these policies would have been in place within days if CMS had not terminated Fox's contract on March 9.[37]

Issue 2:

Did Fox sufficiently meet its burden of proof and demonstrate that it was in substantial compliance with the contract requirements as of the relevant timeframe outlined in 42 C.F.R. §423.650(b)?

Fox's Contentions:

In response to deficiencies CMS had identified, Fox explains that it had taken major efforts to achieve substantial compliance with CMS requirements on March 4, 2010,[38] and was on the cusp of full compliance when its contract was terminated on March 9.[39] Fox disputes CMS' assertion that its beneficiaries' health was at risk at the time its contact was terminated.[40] To the extent that CMS rests its arguments on allegations that immediate termination was necessary to prevent further risk to beneficiary health, Fox contends that those assertions are based on incomplete information because they fail to take into account the considerable remedial efforts that Fox undertook by March 4, 2010.

Fox also contends that despite its admitted temporary failures, Fox is a capable organization with the resources necessary to effectively provide Part D coverage to its enrollees and CMS depiction of Fox is inaccurate. Specifically, CMS has overlooked Fox's four years of successful plan operations

Fox also alleged that by March 3 and March 4, it either corrected, or took steps to correct, the violations that lead to improper imposition of prior authorization and step therapy requirements.[41] Fox alleges that by March 4, it instituted measure to adhere to coverage determinations and on March 5, it concluded a contract with Pharmacy on the Go that immediately made pharmacists available to Fox to increase the speed with which coverage determinations were resolved, and it verified that by March 9 all first level

[37] Fox Initial Brief at 27-28.
[38] Fox Brief at 20. Fox contends that the relevant date for attaining compliance under 42 C.F.R. 423.650 does not include the entire audit period, but rather, the last day only.
[39] Fox Reply Brief at 10. Fox Brief at 7-9, 19-28. Fox
[40] Fox Reply Brief at 10, Fox Brief at Attachment G ¶15.
[41] Fox Initial Brief at 24-25. Fox Brief at Attachment G (Arloro Declaration) ¶25. The declaration also indicated that Fox analyzed all the member rules on Protected Class drugs to make sure they were entered properly in the system and between March 3 and March 10 modified all rules resulting on coverage denials into approvals.

determinations were made within 24 hours.[42] Likewise, on March 3 and 4, Fox took measures to ensure that errors preventing transitioning beneficiaries from receiving continued coverage of drugs not on Fox's formulary had been resolved; and these correction were finalized on March 9.[43] Fox explained that although February, 2010 efforts to correct technical problems causing the improper high cost edits to appear as prior authorization requirements had not been completely successful, removal of all prior authorization and step therapy restrictions on March 3 and 4 completely resolved this problem.[44] Fox alleges it took steps to ensure that beneficiaries had access to an independent level of review during the coverage determination process on March 3 and 4.[45]

Moreover, CMS assertion that Fox's contract with DRUGDEX would only be effective on March 15 is incorrect. Fox explains that it was given a full version of DRUGDEX to use free for ten days (March 5 to March 15). Therefore, Fox had a resource in place (immediately following March 4) and immediately following March 4, enrollees would have experienced the full benefits associated the use of DRUGDEX.[46] Additionally, CMS' description of Fox as a fourteen person operation and its characterization of its compliance department was misleading because it failed to consider employees of Fox's vendors. Similarly, although CMS argues that after Fox terminated its relationship with its offshore clinical partner, it would no longer have qualified personnel to perform coverage determination is misleading. While Fox would have a temporarily reduced capacity, it still maintained internal staff to conduct coverage determinations. [47]

CMS' Contentions:

CMS contends that it immediately terminated Fox because the company was preventing its Medicare beneficiaries from receiving critical, and in some cases lifesaving, prescription medications. CMS contends that Fox was not in "substantial compliance with the requirements of the Part D program" by the earliest of the three dates outlined in 42 C.F.R. §423.650(b), therefore; CMS had the authority to immediately terminate Fox due to the imminent and serious risk to the health of the Medicare enrollees. CMS views the relevant window to review comprises the entire audit period (March 2-4, 2010).[48] CMS argues, however, that even if the relevant window is the confined to the last day of the audit (March 4), most of Fox's system changes occurred after that date, and there was serious question as to whether any of the claimed system changes would have been sufficient.[49]

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[42] Fox Initial Brief at 25, Attachment G (Arloro Declaration) ¶25. The declaration also noted that Fox revised its formulary to add all Protected Class drugs, whether branded or generic, between March 4 and March 11, 2010.
[43] Fox Brief at 25-26.
[44] Fox Initial Brief at 26. Fox Brief at Attachment G (Arloro Declaration) ¶32-37.
[45] Fox Brief at 26-27.
[46] Fox Reply Brief at 8-10.
[47] Fox Reply Brief at 8-9; Fox Brief at 5; Fox Reply Brief, Attachment A.
[48] *See* CMS' Brief at note 7.
[49] CMS Brief at 17.

Similarly, Fox was not within substantial compliance as of March 4, 2010, because there was an ongoing risk to the health and safety of the Medicare enrollees. Where the health and well-being of individuals are put at risk by a Part D sponsor, the notion of substantial compliance must necessarily be closely tied to whether the health and well-being is not in jeopardy.[50]

In its brief, CMS reiterated the deficiencies[51] outlined in the March 9, 2010 letter, and in its legal argument, summarized and highlighted several examples of deficiencies that existed throughout the audit period. Fox failed to correct the error that lead to improper imposition of prior authorization and step therapy throughout the audit period, even though Fox informed CMS that these requirements were removed on February 28, 2010.[52] Similarly, Fox neglected to remedy its coverage determination process during the audit.[53] CMS reiterated that Fox did not guarantee adherence to required coverage determinations by March 4, 2010. Likewise, Fox did not complete execution of its contract with Pharmacist on the Go, USA, Inc. until March 5, 2010, and there is no evidence that the contract would have immediately (or within days) remedied the deficiencies.[54] CMS also noted that Fox did not begin using the DRUGDEX compendium until March 5, 2010 (and the subscription was not effective until March 15).[55]

CMS contends that Fox's promises and attempts to correct the compliance issues after the audit are irrelevant. [56] CMS argues that it owed no duty to Fox to allow for additional cure time after the March 4, 2010 audit end, but rather, it owed a duty to Medicare beneficiaries to address the situation immediately. CMS contends that it does have statutory authority to immediately terminate without opportunity to cure for these exact situations.

Decision

Issue 1: Did CMS exceed its statutory and regulatory authority when it *immediately* terminated Fox's contract?

The Hearing Officer finds that CMS had the legal authority to immediately terminate the contract pursuant to §§1857(c) and (h) [and §1860 D-12(b)(3)(C)and (F)] of the Social Security Act and the regulatory authority provided in 42 C.F.R. §423.509(a)(5). Fox's

[50] CMS Brief at 22-24.
[51] CMS Brief at 7-16. *See infra*, Factual and Procedural section.
[52] CMS Brief at 17-18. In contradiction to Fox's explanation in its initial brief at 24-25, CMS also specifies that prior authorization policies were still in place on March 5, 2010. *See* CMS Ex. 10 (Declaration of Judith A. Geisler) at ¶9-11.
[53] CMS Brief at 19; *supra*, note 16.
[54] CMS Brief at 19-20. CMS alleges this is particularly troubling given that the required timeframe for providing notice to an enrollee is only 24 hours. CMS alleges that the contract scope was for healthcare professional recruiting, and staffing services, not for services that would have clearly included conducting coverage determinations.
[55] CMS Brief at 20.
[56] *See* CMS Brief at 20-22 (citing CMS Ex. 11 / Fox Ex C). *Supra*, note 19.

reading of 42 C.F.R.§423.509(a)(5) (that plan sponsors who have financial resources but experience administrative difficulties are not subject to immediate termination) is without merit

First, the Social Security Act at §1857(h)(2) provides the Secretary an exception to the general rule at §1857(h)(1) which requires that deficient Sponsors be given the opportunity to develop and implement a corrective action plan before termination. The exception at §1857(h)(2) neither focuses upon or mentions the existence of "financial difficulties" as a core factor in determining whether it is appropriate for CMS to bypass the corrective action plan process and issue an immediate termination. As cited previously such section focuses on ultimate health concerns:

> 2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH- Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization

Similarly, a review of the relevant historical preambles to the regulatory text in no way indicates that the existence of financial difficulties is required for CMS to immediately terminate a plan under 42 C.F.R. 423.509(a)(5). Although the preamble to the original Medicare Plus Choice regulation (63 Fed. Reg. 34968, 35018-35019 (June 26, 1998)) and the preamble to the subsequent Medicare Advantage regulation (69 Fed. Reg. 46631, 46723 (Aug 3, 2004)) reiterate the "financial difficulties" language, such language is merely quoting the actual regulatory provision for contextual background. The Hearing Officer finds no preamble history to support Fox's interpretation that plan sponsors who have financial resources but experience administrative difficulties are not subject to immediate termination. Rather, the hearing office finds that the essence of the text, and a whole, is clearly focused upon the concept of health risk.[57]

Moreover, even disregarding the focus of the statutory language and regulatory preamble, a close reading of the regulatory text in isolation does not support Fox's interpretation, but rather, discusses two related, yet separate ideas and criteria. The financial difficulties clause refers to a prospective risk while the failure to make services available refers to an actual risk. The provision at 42 C.F.R. §423.509(a)(5) states:

> Experiences financial difficulties so severe that its *ability* to provide necessary prescription drug coverage is impaired to the point of *posing* an *imminent* and *serious* risk to the health of its enrollees, or *otherwise fails to make services available* to the extent that a risk to health exists.

Clearly an organization that has failed to make services available to the extent that an actual risk to health indeed exists is subject to immediate termination. Likewise, if an organization experiences financial difficulties so severe that its *ability* to provide necessary prescription drug coverage is impaired to the point of *posing an imminent* and

[57] *See* underscored text *supra* notes 2 and 3.

serious risk to the health of its enrollees, immediate termination is appropriate and consistent with the statute. As the regulation provides for immediate termination for financial difficulties which may potentially pose harm, it reasons that the text sets a threshold that the risk is imminent and serious. [58]

Issue 2: Did Fox sufficiently meet its burden of proof and demonstrate that it was in substantial compliance with the contract requirements as of the relevant timeframe outlined in 42 C.F.R. §423.650(b)?

The Hearing Officer upholds CMS determination to immediately terminate Fox pursuant to §§1857(c) and (h) (2) [and §§1860 D-12(b)(3)(C)and (F)] of the Social Security Act and the regulatory authority provided in 42 C.F.R. §423.509(a)(5).[59]
The record indicates that Fox required a significant number of enrollees to endure unnecessary and invasive medical procedures in order to obtain drugs. Fox failed to meet numerous CMS requirements in a manner consistent with professionally recognized standards of care.

The Hearing Officer finds that Fox is incorrect in its contention that the last date of the audit (March 4), is the relevant reference point for determining substantial compliance. 42 C.F.R. §423.650 states, in relevant part:

> (b) The Part D sponsor bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the Part D program on the earliest of the following three dates:
>
> (1) The date the sponsor received written notice of the contract determination or intermediate sanction,
>
> (2)The date of the most recent audit conducted by CMS,
>
> (3)The date of the alleged breach of the current contract or past substantial non-compliance as determined by CMS.

The Hearing Officer notes that pursuant to subsection (b)(3), CMS could have elected to utilize (and the Hearing Officer could have considered) reference dates as early as Fall

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[58] *Supra*, note 4. The Hearing Officer notes that pursuant to the Final Rule at 75 Fed. Reg. 19539, 19699 (Apr. 15, 2010 effective *June 7, 2010)* CMS retained the expedited termination contract language at 42 C.F.R. §423.509(a)(5) with virtually identical language (now recodified at 42 C.F.R.§423.509(b)(2)(i)(B)). Similarly the new text at 42 C.F.R. §423.509(b)(2)(i)(A) reiterating that CMS may also conduct an expedited termination if "CMS determines that a delay in termination, resulting from compliance with the procedure provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D sponsor plan" Accordingly, although this new regulation is not controlling as it was published and effective after the termination, it is consistent with such analysis as it explicitly provides CMS the ability to immediately terminate plans for a prospective imminent and serious risk [consistent with the statute] for reasons other than financial difficulties.

[59] The Hearing Officer also finds that the record indicates that some of Fox's deficiencies also individually and separately supported other regulatory bases for non-immediate termination [(i.e. Fox substantially failed to carry out the terms of its contract with CMS (42 C.F.R. §423.509(a)(1)); Fox carried out its contracts with CMS in a manner inconsistent with the effective and efficient implementation of the program (42 C.F.R.423.509(a)(2)); Fox failed to comply with the requirements of subpart M of Part 423 related to appeals and grievances (42 C.F.R. §423.509(a)(6))].

2009 to measure compliance given the number of serious breaches that occurred during such period (e.g. improper use of prior authorization, step therapy, coverage determination and transition requirements resulted in thousands of rejected/delayed or denied access to drugs (including critical HIV, cancer and seizure medications). [60] Instead, the Hearing Officer notes that CMS based its argument on a certain timeframe for which it made first-hand observations that Fox was not in substantial compliance with the requirements of the Part D program. This timeframe, due to the very nature of a compliance audit, was comprised of multiple days (March 2-4, 2010.) The Hearing Officer therefore accepts CMS' position that for this hearing, a subsection (b)(2) analysis is appropriate utilizing the later March 2-4, 2010 reference window.

Moreover, the Hearing Officer rejects Fox's argument that 42 C.F.R. §423.650(b)(2) limits the reference window to the final closing date of an on-site audit. Considering the statutory and regulatory framework[61] which is logically structured to provide CMS the necessary ability to immediately terminate a plan if an actual or imminent and serious risk to health occurred or exists, and given that multi-dimensional audits may occur over multiple days, CMS' explanation that the audit dates contemplated by 42 C.F.R. §423.650(b)(2) may comprise the entire audit period is reasonable and compelling.[62]

Specifically, the Hearing Officer notes that the on-site audit exposed deficiencies which, independently or together, warranted immediate termination: Fox imposed improper prior authorization and step therapy requirements. Fox did not comply with CMS requirements (see 42 C.F.R. §§423.568 and 572) regarding coverage determination timeframes and failed to provide transition coverage of drugs that beneficiaries had taken in 2009 (see 42 C.F.R.§423.120(b)(3)). Fox also inappropriately used high cost edits to deny coverage (see 42 C.F.R.§423.272(b)(2)) which resulted in thousands of rejected claims, failed to ensure Independent Review of Denial Appeals (see 42 C.F.R. §423.590(f)), used inferior sources to make coverage decisions (see Social Security Act §1860D-2(e)(1)(B) and §1927 (g)(1)(B)(i)), and lacked proper infrastructure and oversight sufficient in operating its national prescription drug plan (see 42 C.F.R.§423.504(b)(4)(vi) (A) through (G)).

The Hearing Officer notes that CMS originally used its discretion to provide Fox the opportunity to take corrective action pursuant to its Feb 26, 2010 letter. During the audit, however, it became evident that not only did many of the serious violations which had been the subject of the February, 2010 directives and warnings remain (despite Fox's promises to remedy), but that additional serious violations existed. It was apparent, therefore, that allowing Fox even more time to correct the violations would have unnecessarily continued to expose Fox's enrollees to imminent and serious risk to their health. Considering its audit findings and observations, CMS' lack of confidence that Fox had the necessary administrative capabilities and infrastructure to redress the existing

[60] CMS Ex. 3.
[61] Supra, note 5.
[62] Moreover, the Hearing Officer notes that even after the audit closed on March 4, Fox was continuing to address compliance issues to fix deficiencies and compliance issues. Supra, note 19 and 20.

deficiencies was certainly warranted. CMS, which owes a duty to Medicare beneficiaries to address situations in which health and safety is compromised, utilized a methodical and responsible approach in deciding to immediately terminate the organization. Fox failed to meet its burden of proof and demonstrate that it was in substantial compliance with the contract requirements as of the relevant timeframe outlined in 42 C.F.R. §423.650(b)(2) [or (b)(3)].

Conclusion

CMS' termination is sustained.

Benjamin Cohen
Hearing Officer

Date: December 7, 2010