FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

FOX INSURANCE COMPANY, INC., *Plaintiff-Appellant*, v. CENTERS FOR MEDICARE AND MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DONALD BERWICK, Administrator, Centers for Medicare and Medicaid Services; KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, *Defendants-Appellees*.	No. 11-16286 D.C. No. 2:10-cv-02154-RJB

FOX INSURANCE COMPANY INCORPORATED, *Plaintiff-Appellant*, v. CENTERS FOR MEDICARE AND MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DONALD BERWICK, Administrator, Centers for Medicare and Medicaid Services; KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, *Defendants-Appellees*.	No. 11-17890 D.C. No. 2:11-cv-00134-RJB OPINION

Appeal from the United States District Court
for the District of Arizona
Robert J. Bryan, Senior District Judge, Presiding

Argued and Submitted
November 6, 2012—San Francisco, California

Filed May 14, 2013

Before: Mary M. Schroeder, Andrew J. Kleinfeld, and Marsha S. Berzon, Circuit Judges.

Opinion by Judge Schroeder

SUMMARY*

Medicare

The panel affirmed the district court's judgments in favor of the federal government in an action challenging the government's immediate termination of a Medicare Part D services contract with a prescription drug insurance coverage provider.

The panel held that the Centers for Medicare and Medicaid Services properly terminated the Medicare Part D contract with prescription drug insurance provider Fox Insurance Company, Inc. The panel also affirmed the district court's ruling that governing regulations authorized the government's demand for immediate repayment of a prorated share of the funds that had been paid to Fox at the beginning of March 2010 and that Fox would not utilize after the contract's termination on March 9, 2010.

COUNSEL

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* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

Tony West, Assistant Attorney General, Stuart F. Delery, Acting Assistant Attorney General, Ann Birmingham Scheel, Acting United States Attorney, Mark B. Stern and Sarang V. Damle (argued), Appellate Staff, United States Department of Justice, Washington, D.C. for Defendants-Appellees.

OPINION

SCHROEDER, Senior Circuit Judge:

These are two appeals stemming from the government's immediate termination of a Medicare Part D services contract with a prescription drug insurance coverage provider, Plaintiff-Appellant Fox Insurance Company, Inc. The government terminated the contract in March of 2010 after it had warned Fox of delays in patients' access to needed medication. Fox had frequently delayed and sometimes completely denied patients' access to medically necessary drugs by subjecting its enrollees to improper hurdles, such as unnecessary tests and invasive medical procedures, as a condition to receiving their already delayed medications for serious medical conditions. This misconduct is not now disputed.

Medicare Part D was enacted in 2003. 42 U.S.C. § 1395w-101 *et seq*. The government administers the program through the Centers for Medicare and Medicaid Services, within the Department of Health and Human Services. This is the first Medicare Part D contract termination to reach a federal appeals court. The government acted pursuant to a statutory provision authorizing immediate termination, without pretermination hearing, upon a finding that delay would create an "imminent and serious risk" to the

health of plan enrollees. 42 U.S.C. § 1395w-27(h)(2). Following the termination, the government, pursuant to a related regulation, ordered Fox to immediately repay funds the government had paid to Fox at the beginning of the month of March and that were intended to cover the prescription payments that Fox would have been obligated to make had the contract remained in effect for the entire month. 42 C.F.R. § 423.509(b)(2)(i) (2008).

After an unsuccessful administrative appeal, Fox filed actions in the district court for the District of Arizona challenging both the termination and the order for immediate repayment. The district court had jurisdiction pursuant to 42 U.S.C. § 405(g), providing for judicial review of Social Security claims, and made applicable to Medicare provider disputes by 42 U.S.C. § 1395cc(h)(1). The court granted summary judgment for the government, holding that the immediate termination was valid. The district court also dismissed Fox's action challenging the order for immediate repayment, holding that the repayment order was authorized by the controlling regulations and rejecting Fox's contention that it was entitled to retain the funds pending a year-end reconciliation of all of the obligations between the parties.

In an earlier Fox appeal, without expressing any views on the merits, we affirmed the denial of a preliminary injunction to reinstate the contract. *Fox Ins. Co. v. Ctrs. for Medicare & Medicaid Servs.*, 439 F. App'x 651 (9th Cir. 2011). We now affirm on the merits the district court's holding that the contract was properly terminated. We also affirm its ruling that governing regulations authorized the government's demand for immediate repayment of a prorated share of the funds that had been paid to Fox at the beginning of the month and that Fox would not utilize after the contract's termination

March 9, 2010. The government's actions were more than justified, as Fox had risked permanent damage to its enrollees by, inter alia, improperly denying coverage of critical HIV, cancer, and seizure medications, and having no compliance structure in place.

BACKGROUND

Title XVIII of the Social Security Act, known as the Medicare Act, establishes a federally subsidized health insurance program for the elderly and disabled. 42 U.S.C. § 1395 *et seq*. The Centers for Medicare and Medicaid Services ("CMS"), a component of the Department of Health and Human Services, administers the Medicare program. Medicare Part D provides prescription drug coverage through voluntary enrollment in plans offered by private insurers. 42 U.S.C. § 1395w-101(a). CMS contracts with insurance company plan sponsors to offer drug plans to Medicare beneficiaries. 42 U.S.C. § 1395w-112. These contracts incorporate the requirements of Medicare Part D. Under the statute, CMS is authorized to terminate a contract if the plan sponsor "has failed substantially to carry out the contract; is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or no longer substantially meets the applicable conditions of this part." 42 U.S.C. § 1395w-27(c)(2) (incorporated into Medicare Part D by 42 U.S.C. § 1395w-112(b)(3)(B)); 42 C.F.R. § 423.509(a) (2008).

The Act has two provisions concerning terminations. With respect to most terminations, where no emergency exists, CMS must give reasonable notice, an opportunity for a hearing, and a chance to cure defects. 42 U.S.C. § 1395w-27(h)(1) (incorporated by 42 U.S.C. § 1395w-112(b)(3)(F)).

Where a situation is urgent and patients are at risk, however, the Act provides that CMS may terminate a contract immediately. Such immediate termination is authorized if a delay "would pose an imminent and serious risk" to the health of plan enrollees. 42 U.S.C. § 1395w-27(h)(2).[1]

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[1] 42 U.S.C. § 1395w-27(h) provides as follows:

> (h) Procedures for termination
>
> (1) In general
>
> The Secretary may terminate a contract with a Medicare+Choice 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) of this section; 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.

In the event that CMS terminates a contract immediately, but after the beginning of the month, the provider will have already been paid for the entire month, and thus have received compensation for obligations it will never incur. The reason is that CMS subsidizes the prescription drug plan coverage by making regular payments called "capitation payments" to plan sponsors on a prospective, monthly basis. 42 U.S.C. § 1395w-115. These payments are based on a number of factors including the number of participants enrolled in the plan, participants' health status and income, the amount a plan sponsor pays for prescription drugs, and the plan sponsor's administrative costs. 42 C.F.R. §§ 423.315; 423.329. The payments are calculated on the basis of an estimate by CMS of the prospective monthly costs of the plan sponsor, after the plan sponsor submits a bid. 70 Fed. Reg. 4194, 4309–13 (Jan. 28, 2005); 42 C.F.R. § 423.315. In promulgating the regulations, CMS explained that the reason for the advance payments is that they prevent "cash flow problems" that would result if the plan sponsors had to front the costs. 70 Fed. Reg. 4194, 4313.

A regulation implementing the Act therefore provides that where CMS terminates a contract immediately and before the end of the month, it can recover the excess payment: "CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination." 42 C.F.R. § 423.509(b)(2)(i) (2008). The regulation further explains that the immediate termination provision is for situations when serious harm is threatened. The provision applies to terminations where CMS has determined that the plan sponsor is committing false, fraudulent or abusive activities, or is experiencing severe financial difficulties that impair its ability to provide necessary prescription drug

coverage "to the point of posing an imminent and serious risk to the health of its enrollees" or when the plan sponsor "otherwise fails to make services available to the extent that a risk to health exists." 42 C.F.R. § 423.509(a)(4)–(5) (2008).

In this case, CMS awarded a contract to Fox on September 22, 2005, authorizing Fox to operate prescription drug plans starting on January 1, 2006. The contract was renewed each of the four subsequent years. In early 2010, however, CMS received complaints from plan enrollees and physicians regarding Fox's practices. The complaints stated that Fox had improperly denied coverage for certain critical medications, including medications for HIV, cancer, and seizures. On February 11, 2010, CMS contacted Fox for a response to these complaints. Fox replied to CMS, stating that it had fixed the system error that had caused the problem. After some investigation, however, CMS on February 26 suspended Fox's authorization to enroll new beneficiaries and to market its plan to potential beneficiaries. *See* 42 C.F.R. § 423.750. This action is not challenged.

On March 2–4, CMS conducted an on-site audit of Fox. *See* 42 C.F.R. § 423.505(e). Fox sent CMS a letter on March 8, listing the changes it had made or was making; most of those changes did not begin until after CMS's audit began on March 2. CMS determined that Fox had not only failed to provide required benefits, but had "expose[d] Fox's enrollees to imminent and serious risk to their health." On March 9, CMS terminated Fox's contract, effective immediately. In its letter, CMS detailed the reasons for the termination, concluding that Fox lacked the "necessary administrative capabilities and infrastructure to redress [its] severe deficiencies," and that it was not "in the public interest to give Fox time to attempt to ameliorate these deficiencies."

CMS's conclusions were supported by declarations executed on March 9 from Dr. Jeffrey Kelman, Chief Medical Officer of the Center for Drug and Health Plan Choice, and Dr. Cynthia Tudor, Director of the Medicare Drug Benefit and C&D Data Group of the Center. Dr. Kelman stated that Fox had "inappropriately denied drugs . . . for the treatment of cancer, HIV/AIDS, for the protection of transplants, and for the prevention of seizures, lack of access to which can be associated with immediate risks of major exacerbation of underlying health conditions." The inappropriate requirements imposed by Fox "impacted beneficiaries during courses of chemotherapy and in maintenance treatment for HIV/AIDS," forcing them "to leave the pharmacy without needed medications." Dr. Kelman further noted that the enrollees in the plan were "90% low income individuals, [who] had no option for cash payment access." The potential negative effects of Fox's actions were "likely to be life threatening for many of the enrollees impacted," and demonstrated "a blatant and reckless disregard for the health and welfare of the beneficiaries involved."

Dr. Tudor was similarly outraged by Fox's conduct. Dr. Tudor's review found that Fox's enrollees were required to obtain "unnecessary, invasive and/or costly medical procedures in at least some cases that resulted in significant delays in beneficiaries' receipt of necessary drugs." These unnecessary procedures included cardiac catheterizations, which involve passing a catheter into the heart from the groin or arm, and PET scans, which involve injecting a small amount of radioactive material into a patient's vein. *See* National Institutes of Health, MedlinePlus Medical Encyclopedia, *available at* http://www.nlm.nih.gov/medlineplus/encyclopedia.html. Dr. Tudor also stated that Fox's Compliance Officer "admitted that Fox has no

compliance plan or structure in effect and no internal auditing or monitoring of Fox's business operations is conducted."

Because CMS terminated the contract March 9, Fox had already been advanced funds for the entire month in the capitation payment received March 1. CMS, acting pursuant to 42 C.F.R. § 423.509(b)(2)(i) (2008), therefore promptly demanded repayment of the funds it had advanced to Fox and that had been intended to satisfy the now terminated insurance coverage. CMS endeavored to calculate the amount it was owed, sending a letter to Fox on August 19, 2010 demanding $21,399,603, which it described as the prorated amount of the March 2010 capitation payment of $30,153,987.

Fox requested that CMS review the demand. Fox argued that it was entitled to hold the entire March payment until completion of the "general reconciliation" that would not begin until the end of 2010, and that CMS also owed it money for various unreimbursed expenses. The "reconciliation" to which Fox referred is the term for the accounting CMS conducts after the end of each year with each of its contractors. This process reconciles all of the payments made to each plan with the actual subsidies to which the plan was entitled and any risk sharing adjustments. *See* 42 C.F.R. § 423.343. The plan "sponsors" or contractors have six months after the end of the year to provide CMS their relevant data, so the process is not completed until the following fall. Fox relied on the general regulation governing the annual accounting, or reconciliation, of all payments made to each sponsor. *Id.* The substance of Fox's position with respect to repayment was, therefore, that it could retain all of the amounts paid for March 2010 until the conclusion of the reconciliation expected in the fall of 2011.

CMS responded that it had acted on the basis of the more specific regulation relating to the situation where a contract is immediately terminated during a given month and the contractor has already been paid for the entire month. That regulation provides for a government recovery of the share of payments that would not be used: "CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination." 42 C.F.R. § 423.509(b)(2)(i) (2008).[2] CMS contended that this

[2] 42 C.F.R. § 423.509(b) (2008) in its entirety provided as follows:

> (b) *Notice*. If CMS decides to terminate a contract for reasons other than the grounds specified in § 423.509(a)(4) or § 423.509(a)(5), it gives notice of the termination as follows:
>
> (1) *Termination of contract by CMS*. (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.
>
> (ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.
>
> (iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.
>
> (iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

regulation, authorizing prompt action, necessarily applied because CMS had determined that Fox's actions created such an imminent and serious risk to the health of its enrollees that immediate termination was required. *See* 42 C.F.R. § 423.509(a)(5) (2008). CMS reviewed and upheld the demand for repayment as authorized under 42 C.F.R. § 423.509(b)(2).

Fox's appeal of the termination decision was then heard by a CMS Hearing Officer designated by the CMS Administrator. The Hearing Officer upheld CMS's

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> (2) *Immediate termination of contract by CMS*. (i) For terminations based on violations prescribed in § 423.509(a)(4) or § 423.509(a)(5), CMS notifies the Part D plan sponsor in writing that its contract will be terminated on a date specified by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.
>
> (ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.
>
> (iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

termination decision on the basis of CMS's authority under 42 U.S.C. § 1395w-27(h) and 42 C.F.R. § 423.509(a). He concluded that the deficiencies exposed by the audit "independently or together, warranted immediate termination." Fox then requested that the Administrator review the Hearing Officer's decision. The Administrator declined Fox's request, and Fox's administrative remedies were exhausted. *See* 42 C.F.R. § 423.666.

Fox filed its complaint in district court on October 7, 2010 challenging the demand for repayment. Fox then filed a separate suit on January 20, 2011 to challenge the termination decision. The same judge considered both.

The district court first heard Fox's challenge to the demand for repayment. Fox claimed that CMS violated the reconciliation regulations and further claimed that CMS in fact owed Fox significant sums of money that should be set off against CMS's demand. The district court granted without prejudice CMS's motion to dismiss the complaint. The district court stated that it would defer to CMS's reasonable interpretation of its own regulations. The district court noted that 42 C.F.R. § 423.509(b)(2), the provision cited by CMS in demanding repayment, creates an exception to the usual annual reconciliation process, and that it was appropriate for CMS to demand immediate repayment in this case. The district court also ruled that Fox had no right to setoff because it had shown no basis for a setoff and also because the regulation permits immediate recovery by CMS.

Fox filed its first amended complaint, alleging once again that CMS violated the reconciliation regulations, and that Fox was entitled to a setoff. The district court granted CMS's motion to dismiss the action, because Fox's contentions were

materially the same as those in the original complaint and barred by the law of the case.

In the meantime, the same district court judge heard Fox's challenge to the termination decision. Fox sought injunctive relief ordering the Secretary to reinstate the contract. The district court denied Fox's request, and this court affirmed in a brief unpublished decision. *Fox Ins. Co. v. Ctrs. for Medicare & Medicaid Servs.*, 439 F. App'x 651 (9th Cir. 2011).

On November 8, 2011, the district court granted CMS's motion for summary judgment on the merits of the termination. The district court stated that CMS had reasonably interpreted its regulation authorizing such a termination and that substantial evidence supported the finding that Fox failed substantially to comply with its obligations. The district court noted that Fox's misconduct could be distinguished from the problems of other plan sponsors, cited by Fox, whose contracts had not been terminated. Finally, the court ruled that Fox had no property interest on which it could base a due process claim.

Fox filed timely notices of appeal of both the repayment case and the termination decision. We consolidated the appeals for briefing and argument. With respect to the termination, Fox's principal argument on appeal is that the regulation authorizing immediate termination is invalid as inconsistent with the statute, because it does not use identical language. With respect to the demand for repayment, Fox argues it was entitled to keep the March overpayment until completion of the annual reconciliation, despite the language of the specific regulation authorizing CMS's demand. We affirm.

DISCUSSION

I. The Lawfulness of the Contract Termination

The district court rejected all of Fox's numerous contentions challenging the lawfulness of the government's termination. In this appeal, Fox makes three arguments. It contends that the regulation relied upon by the government to authorize such a termination, 42 C.F.R. § 423.509(a)(5) (2008), was itself unlawful. Second, Fox contends that, even if the regulation was valid, the termination was unlawful because Fox had in fact achieved substantial compliance with all the legal requirements it had to meet. Third, Fox contends that the government could not terminate its contract because it had not earlier terminated contracts of other providers that Fox contends had engaged in even more egregious misconduct. We deal with each of these contentions in turn and conclude that none has merit.

A. CMS Acted Pursuant to a Lawful Regulation

Fox claims there is an inconsistency between the statute and the regulation by comparing the language of the statute with the language of the regulation in effect at the time of the termination. Under the statutory scheme, when terminating a contract, CMS ordinarily must give reasonable notice, an opportunity for a hearing, and a chance to cure defects. 42 U.S.C. § 1395w-27(h)(1) (incorporated by 42 U.S.C. § 1395w-112(b)(3)(F)). CMS, however, is authorized to terminate a contract immediately if a delay "would pose an imminent and serious risk" to the health of plan enrollees. 42 U.S.C. § 1395w-27(h)(2).

The regulation implementing this statutory scheme, 42 C.F.R. § 423.509(a)(5), as it existed in 2010, authorized CMS to terminate a contract immediately in situations where the sponsor's financial difficulties create a risk to health or the sponsor is not delivering services for other reasons that create a risk to health. The relevant regulatory language provides that CMS may terminate if the sponsor

> [e]xperiences 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.

42 C.F.R. § 423.509(a)(5) (2008). In such situations, "[i]mmediate termination of [the] contract by CMS" is authorized. 42 C.F.R. § 423.509(b)(2) (2008).

Fox's argument, in comparing the statute with the regulation, focuses on the last phrase of the regulation that refers to "a risk to health." The statute provides that CMS may terminate a contract immediately where delay "would pose an imminent and serious risk to the health of individuals enrolled." 42 U.S.C. § 1395w-27(h)(2). According to Fox, because the last phrase of the regulation omitted the words "imminent and serious," the regulation purported to give the agency power the statute does not: to terminate upon a finding of a risk to health, not a risk that is "imminent and serious" as provided in the statute.

This, however, is not the way that the agency has interpreted or applied the regulation. CMS has explained that

it has interpreted the regulation's reference to a "risk to health" as incorporating the statutory standard of "imminent and serious" risk as set forth in 42 U.S.C. § 1395w-27(h)(2) and in the preceding clause of the regulation. More important, this is the interpretation CMS actually used when it terminated Fox's contract in this case. CMS, in its termination letter to Fox, said that Fox's deficiencies "expose[d] Fox's enrollees to *imminent and serious* risk to their health, thus warranting the immediate termination of Fox's contract with CMS." (emphasis added).

The language of the disputed last phrase of the regulation has now been changed, perhaps as a result of this litigation, and now expressly contains the same words as the statute. The regulation thus now permits CMS to terminate a contract immediately where CMS determines that "a delay in termination . . . would pose an *imminent and serious* risk to the health of the individuals enrolled with the Part D plan sponsor," or where the "plan sponsor 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 otherwise fails to make services available to the extent that *such* a risk to health exists." 42 C.F.R. § 423.509(b)(2)(i) (emphasis added).

The key point for our purposes is that CMS's interpretation of the regulation as it applied it in this case is fully consistent with the relevant statutory language. CMS told Fox its conduct exposed its enrollees to "imminent and serious risk." 42 U.S.C. § 1395w-27(h)(2). Fox cannot legitimately complain that it is a victim of governmental overreaching.

B. When CMS Terminated Its Contract Fox Had Not Brought Itself Into Substantial Compliance With the Contractual and Statutory Requirements

Medicare Part D insurance providers must remain in substantial compliance with all of their contractual and legal obligations or risk termination. The statute gives the Secretary authority to terminate a contract if the organization "has failed substantially to carry out the contract; is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or no longer substantially meets the applicable conditions of this part." 42 U.S.C. § 1395w-27(c)(2). To carry out this statutory authority, the Secretary promulgated 42 C.F.R. § 423.650(b) (2008), which stated that the plan sponsor "bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the Part D program."

CMS gave Fox the opportunity to show substantial compliance. On February 11, 2010, CMS contacted Fox, in response to complaints from patients and doctors that Fox had improperly denied coverage for critical medications, thus putting Fox on notice of a problem. Fox told CMS that it was taking remedial measures in response to these complaints. After an initial investigation, however, CMS suspended Fox's authorization to enroll new beneficiaries and to market its plan to potential beneficiaries. CMS followed up with an on-site audit of Fox on March 2–4. *See* 42 C.F.R. § 423.505(e). CMS concluded that Fox had failed to provide required benefits and could not address its compliance deficiencies because it lacked any compliance infrastructure.

Fox takes issue with the agency's conclusion. It contends that it had taken steps to bring itself into "substantial

compliance" by the completion of the audit. The evidence supporting CMS's noncompliance conclusion, however, is more than substantial. CMS found that Fox imposed unauthorized prior-authorization and step-therapy as conditions on various drugs up through the audit that took place March 2–4. These additional conditions could only properly have been imposed if CMS had pre-approved them. *See* 42 C.F.R. § 423.272(b)(2) (2008). In addition, a plan sponsor may not condition access to certain "protected" classes of drugs. 42 C.F.R. § 423.120(b)(2)(v). Despite these regulations, Fox, according to Dr. Kelman's March 9 findings on behalf of CMS, imposed unauthorized restrictions on many drugs, which led to the denial of claims for drugs for "cancer, HIV/AIDS, for the protection of transplants, and for the prevention of seizures." Dr. Kelman in his declaration further stated that "[t]he potential negative effects to patients with cancer, HIV/AIDS, as well as many other chronic diseases is clearly significant in terms of clinical exacerbations, and is likely to be life threatening for many of the enrollees impacted."

Dr. Tudor reported that Fox also lacked the required internal compliance mechanisms. The "Compliance Officer" at Fox admitted to Dr. Tudor during the onsite audit that Fox "has no compliance plan or structure in effect." CMS found that Fox had "not developed any written compliance policies or procedures and Standards of Conduct," and did "no internal auditing or monitoring of Fox's business operations." All of these failures were violations of CMS regulations. *See* 42 C.F.R. § 423.504(b)(4)(vi) (2008). Based on this evidence, CMS correctly concluded on March 9 that Fox's performance suffered from "serious [] deficiencies" and that a delay would create an "imminent and serious risk to the health" of the Medicare beneficiaries enrolled in Fox's plans.

CMS was justified in terminating the contract with Fox because it was not in substantial compliance.

Fox's legal argument to us amounts to no more than the assertion that it was in substantial compliance so long as it indicated it had taken steps to improve. It adopts as its legal standard for substantial compliance a factual statement from an Eleventh Circuit decision. That court said that the company at issue in the case before it "had already taken steps to rectify the problem and would be clearly compliant soon after." *Emerald Shores Health Care Assocs., LLC v. U.S. Dep't of Health & Human Servs.*, 545 F.3d 1292, 1299 (11th Cir. 2008). We do not agree with Fox that this language constitutes the Eleventh Circuit's definition of "substantial compliance," or even that Fox had satisfied it. Nor can we agree that it would create a workable definition. The phrase "substantial compliance" is defined elsewhere in the Medicare regulations as the situation where "identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimum harm." 42 C.F.R. § 488.301. This is the definition of substantial compliance under Medicare Part A, which is part of the same statutory framework as Part D. The term should have the same meaning under both Parts. *Cf. Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."). "Substantial compliance" means the risk of harm is minimal. It cannot be equated with "still making needed improvements," where the risk of harm in the interim is not minimal.

Moreover, the record in this case, as summarized above, demonstrates that Fox did not meet even its own definition of substantial compliance, much less the controlling agency

definition. There is no indication that Fox could have become compliant in the foreseeable future. What it did was too little, too late.

C. CMS Was Not Required to Treat Fox the Same Way It Had Earlier Treated Other Companies in Different Cases

Fox's next contention is that CMS's immediate termination decision was inconsistent with CMS's treatment of other nonperforming sponsors, against whom CMS imposed various sanctions, including termination, but only after affording those sponsors an opportunity to develop and implement a plan to correct the deficiencies CMS had identified. Fox urges that, as a matter of administrative law, CMS had to provide a legitimate reason for treating Fox differently.

With regard to this argument, the district court ruled that Fox's case was not materially similar to the six previously terminated sponsors. Five of the six involved situations of fiscal insolvency not comparable to Fox's situation. The sixth, Health Net, did expose enrollees to imminent and serious health risks because of deficient administration, but the possibility of improvement was at least in sight. The district court quoted CMS's March 9 termination letter, in which CMS observed in Fox's case that it had "no confidence that Fox has the necessary administrative capabilities and infrastructure to redress the severe deficiencies . . . uncovered." In other words, CMS concluded that Fox, unlike other non-compliant sponsors, could not fix the problems.

In this court Fox makes a similar contention that it cannot be treated in a manner that differs from the way CMS treated

others in the past. The only authority Fox cites to support its position here are three D.C. Circuit cases in which an agency arguably made a ruling with respect to particular evidence or particular parties that differed without explanation from an earlier ruling. *County of Los Angeles v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999) involved a ruling that data were unreliable when the same data had been considered reliable in an earlier year; *Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248 (D.C. Cir. 1996) involved treatment of certain settlement payments as subject to royalties despite earlier adherence to a Fifth Circuit opinion that these payments were not; *Caiola v. Carroll*, 851 F.2d 395 (D.C. Cir. 1988) involved treating some corporate officers differently from others in the same case. These cases all focused on comparing specific legal or factual rulings. They do not create any principle that a court should second guess an agency's result in light of the result the agency may have reached in an earlier case that is not now before the court. Our review must be of the lawfulness of the agency's action according to the record before us, giving deference to the agency's interpretation of the statutory standards. Administrative Procedure Act, 5 U.S.C. § 706(2); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984).

Fox also contends that the contract termination violated its constitutional rights. This contention essentially rehashes its previous arguments, but dresses them in constitutional garb. At best, Fox contends that it was deprived of its property, in the form of its contract with the government, without due process of law. Even if we were to accept the questionable proposition that Fox has a protectable property interest in its government contract, *see Erickson v. United States*, 67 F.3d 858, 862 (9th Cir. 1995) (holding that

physicians do not have a property interest in their continued participation in Medicare and related programs), Fox's argument still would fail. CMS notified Fox of the complaints about its performance, completed an on-site audit, and conducted an administrative hearing which reviewed the termination decision. CMS was authorized to terminate Fox's contract immediately, and Fox received the process it was due. *See Morrissey v. Brewer*, 408 U.S. 471, 481 (1972).

II. CMS's Demand for Immediate Repayment of the Prorated Portion of the Monthly Advance Was In Accord With the Controlling Regulation and Resort to Common Law Setoff Was Not Required

Fox contends that even if the immediate termination was proper, CMS was not entitled to demand immediate repayment of advanced funds. It challenges CMS's action in demanding repayment of the prorated portion of the amount CMS had advanced to Fox for obligations Fox would have incurred in March had its contract not been terminated. Demand was made pursuant to 42 C.F.R. § 423.509(b)(2)(i) (2008). That regulation provides as follows: "If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination." 42 C.F.R. § 423.509(b)(2)(i) (2008).

The regulation applies specifically to the termination of a contract where there is an imminent and serious risk to enrollees' health, and thus tracks the circumstances under which CMS may terminate a contract immediately without notice or hearing. *See* 42 U.S.C. § 1395w-27(h)(2). The regulation authorizes CMS to recover, and hence to demand,

immediate repayment of funds that will not be utilized by the contractor after the termination.

Fox essentially denies that § 423.509 applies and, not surprisingly, would prefer to keep the funds over the period of many months before there is a final reconciliation of the obligations of the parties. Fox says the applicable regulation is the one that applies to the final reconciliation, 42 C.F.R. § 423.343.[3] The substance of that regulation constitutes technical instructions for accountants who manage the reconciliation process. It applies generally to all Medicare contractors who have performed during the course of the year and must settle their financial relationship with CMS at the end of each year.

We deal with a situation, however, that the Medicare statute regards as exceptional. The provision for repayment after immediate termination is expressly directed to a specific situation in which a contractor has been paid in anticipation of services that it will not perform as a result of the termination. The fundamental problem with Fox's position is that it ignores the specific regulation that applies to its situation. That regulation authorizes repayment.

Our law requires this court to give effect to all of a regulation's sections where possible. *Barboza v. Cal. Ass'n of Prof'l Firefighters*, 651 F.3d 1073, 1078 (9th Cir. 2011); *Boeing Co. v. United States*, 258 F.3d 958, 967 (9th Cir. 2001). In doing so, we favor the application of a specific provision over a general one. *See Crawford Fitting Co. v. J.T. Gibbons, Inc.*, 482 U.S. 437, 445 (1987) (stating that

[3] 42 C.F.R. § 423.343 provides the procedures for "Retroactive adjustments and reconciliations."

absent clear intention otherwise, "a specific statute will not be controlled or nullified by a general one") (internal quotation and citations omitted).

We cannot accept Fox's interpretation of the general provision without ignoring the existence of the more specific provision. Fox's misinterpretation is evidenced by its reliance on the preamble to the general regulation, which states that reconciliation includes "any difference between the actual number . . . of enrollees and the number . . .on which [CMS] had based the organization's advance monthly payments." 70 Fed. Reg. 4194, 4315 (Jan. 28, 2005). This does not refer to a mid-month termination, and therefore does not by its terms delay the contractor's repayment of the prorated amount until an end of the year reconciliation. The language of the preamble contemplates the routine month-by-month reconciliation process for all contractors, independent of the demand for immediate repayment of prorated amounts from a contractor that has been terminated.

Indeed it would make little sense for a government concerned about the expenditure of taxpayer funds to permit a delinquent contractor to keep overpayments for a period of months, without demanding repayment. This is particularly true when a contractor who has been paid for the entire month is terminated before the month is over, so that some overpayment is virtually certain to have been made.

Fox also contends that CMS cannot rely on § 423.509(b)(2)(i) because the regulation does not apply the common law principle of setoff. Courts read statutes and regulations to preserve common law principles, like setoff, absent an evident statutory purpose to the contrary. *See United States v. Texas*, 507 U.S. 529, 533–34 (1993).

Fox's argument is unconvincing. The annual reconciliation process provides an opportunity for Fox to assert any claims that the government owes it money. *See* 42 C.F.R. § 423.343. That administrative process is ongoing as to Fox. This case therefore does not present the issue whether the Medicare regulations broadly abrogate the common law setoff principle. The only question here is more limited: who holds the excess capitation payments when CMS terminates a contract mid-month pending the final results of the reconciliation process. The applicable regulation, 42 C.F.R. § 423.509(b)(2), answers that circumscribed question clearly and in the government's favor, reflecting Congress's intent to bring a quick end to the government's relationship with contractors whose malfeasance has created a serious risk to the health of Medicare enrollees.

CONCLUSION

The district court correctly held that the immediate termination was valid and the repayment order was authorized by the controlling regulations. Its judgments are **AFFIRMED**.