IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
May 1, 2013
Lyle W. Cayce
Clerk

No. 12-40097

SOUTHWEST PHARMACY SOLUTIONS, INCORPORATED, doing business as American Pharmacies,

Plaintiff-Appellant

v.

CENTERS FOR MEDICARE AND MEDICAID SERVICES; DONALD M. BERWICK, solely in his official capacity as Administrator of The Centers for Medicare and Medicaid Services; KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, solely in her official capacity; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellees

Appeal from the United States District Court
for the Southern District of Texas

Before WIENER, CLEMENT, and PRADO, Circuit Judges.

EDITH BROWN CLEMENT, Circuit Judge:

The sole issue on appeal is whether the district court properly dismissed Southwest Pharmacy Solutions's claim for lack of subject matter jurisdiction. While 42 U.S.C. § 405(h) clearly requires a plaintiff to exhaust administrative remedies before filing a claim in federal court, the Supreme Court has provided a narrow exception to this rule in *Shalala v. Illinois Council on Long Term Care*,

Inc., 529 U.S. 1, 17–20 (2000). Southwest argues that its claim falls within this exception and therefore was dismissed erroneously. However, caselaw interpreting the application of § 405(h) to Medicare claims emphasizes that the *Illinois Council* exception is extremely narrow and appropriately applied only in cases where judicial review would be entirely unavailable through the prescribed administrative procedures. As Southwest has not carried its heavy burden of showing that the *Illinois Council* exception applies, we AFFIRM the district court's order dismissing the suit.

FACTS AND PROCEEDINGS

1. Medicare Part D

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Part D"). Pub. L. 108–173, codified at 42 U.S.C. §§ 1395w-101, *et seq*. Appellee Centers for Medicare and Medicaid Services ("CMS") is the agency within the Department of Health and Human Services ("DHHS") that is charged with the administration of the Medicare Program. Among other things, Medicare Part D added a new prescription drug benefit to the Medicare Program. Individuals eligible for Medicare but not enrolled in a separate Medicare Advantage Plan can obtain prescription drug benefits through a Prescription Drug Plan ("PDP").

Medicare Part D requires PDPs to permit enrollees to fill prescriptions at "any willing pharmacy," which includes "any pharmacy that meets the terms and conditions under the plan." *Id.* at § 1395w-104(b)(1). However, under the regulations promulgated pursuant to the statute, the Preferred Pharmacy Rule ("PPR") allows PDPs to charge enrollees different copayment amounts based on the pharmacy where they choose to have their prescriptions filled. 42 C.F.R. § 423.120(a)(9) ("A Part D sponsor . . . may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the

copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy.").

Although the PPR has been in effect since 2006, the first PDP to establish a preferred pharmacy network was the Humana Walmart-Preferred Rx Plan ("Walmart Plan") in 2011. The Walmart Plan designates Walmart-owned pharmacies as "preferred" and greatly reduces the copayments and coinsurance required at these pharmacies as compared to the copayments and coinsurance required at other, non-preferred pharmacies.

2. The Present Lawsuit

Southwest Pharmacy Solutions, Inc. ("Southwest") is a coalition of independent pharmacies operating in Texas, Arkansas, Louisiana, New Mexico, Oklahoma, Missouri, Mississippi, and Tennessee. Southwest filed this suit in district court on July 11, 2011 against CMS. Southwest alleged that the PPR allows a PDP to create a scheme that excludes independent pharmacies from participating in preferred pharmacy networks in direct contravention of the "any willing pharmacy" requirement. 42 U.S.C. § 1395w-104(b)(1)(A).[1] CMS moved to dismiss Southwest's claim for lack of subject matter jurisdiction.

In its motion to dismiss, CMS argued that the district court was precluded from exercising jurisdiction over claims arising under the Medicare statute unless such claims were first channeled through the administrative review process. *Id.* at § 405(h). Section 405(h) provides that "[n]o action against the United States . . . or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter."[2] *Id.* In other words, "[t]his means that §1331 (federal question) jurisdiction is categorically unavailable for claims arising under the Medicare

[1] At the time this suit was filed, the Walmart Plan remained the only PDP in operation.

[2] Section 405(h) of the Social Security Act has been adopted and incorporated into the Medicare Act. 42 U.S.C. § 1395ii; s*ee Ill. Council*, 529 U.S. at 9.

Act." *GOS Operator, LLC v. Sebelius*, 843 F. Supp. 2d 1218, 1222 (S.D. Ala. 2012). Instead, any claims arising under the Medicare Act must be brought before DHHS prior to seeking judicial review of those claims under § 405(g).

In response to this argument, Southwest maintained that the district court had jurisdiction under *Illinois Council*, which provides a narrow exception to § 405(h) where "the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011). The district court disagreed and granted CMS's motion to dismiss after finding that the *Illinois Council* exception to § 405(h) did not apply. Southwest timely appeals.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's dismissal for lack of subject matter jurisdiction. *Nat'l Athletic Trainers' Ass'n v. U.S. Dept. of Health & Human Servs.*, 455 F.3d 500, 502 (5th Cir. 2006).

ANALYSIS

Title 42 U.S.C. § 405(h), which is incorporated into the Medicare Act by 42 U.S.C. § 1395ii, "severely restricts the authority of federal courts [to hear claims arising under the Medicare Act] by requiring [that] 'virtually all legal attacks' under the Act be brought through the agency." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 653 (5th Cir. 2012) (quoting *Ill. Council*, 529 U.S. at 13). Although the Supreme Court in *Illinois Council* acknowledged that this channeling requirement comes "at a price, namely, occasional individual delay-related hardship," it nonetheless determined that:

> In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated

> regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified.

529 U.S. at 13. The "net effect of § 405(h) is that it 'demands the channeling of virtually all legal attacks through the agency,' thereby assuring the Secretary [of the DHHS] 'greater opportunity to apply, interpret or revise policies, regulations, or statutes without possibly premature interference by different individual courts.'" *GOS Operator*, 843 F. Supp. 2d at 1223 (quoting *Ill. Council*, 529 U.S. at 13).

In *Illinois Council*, the Supreme Court created a very narrow exception to the channeling requirement "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." 529 U.S. at 19. Under this exception, a party may file a claim under the Medicare Act in federal court without first bringing it before the DHHS if further postponement of judicial review would have the effect of foreclosing judicial review entirely. *See id.* at 17. In other words, § 405(h) does not serve as a jurisdictional bar where the party challenging a regulation shows that "hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Id.* at 22–23.

The fact that a plaintiff would suffer great hardship if forced to proceed through administrative channels before obtaining judicial review is insufficient to warrant application of the *Illinois Council* exception. *See Physician Hosps.*, 691 F.3d at 657 (noting that the Supreme Court's language in *Illinois Council* "requires that a party go beyond showing its own hardship and indicate that the difficulty it encounters is sufficiently widespread as to threaten the loss of any judicial review"). Instead, a plaintiff must demonstrate "either a legal impossibility that any claimant would obtain judicial or administrative review,

or hardship from administrative channeling that was 'sufficiently widespread' to threaten the loss of any judicial review." *Vertos Med. Inc. v. Novitas Solutions, Inc.*, No. H-12-3224, 2012 WL 5943542, at *6 (S.D. Tex. Nov. 27, 2012). The second criterion applies only "when there [is] no third party with an interest and a right to seek administrative review. If [third parties have] an incentive, and [are] properly aligned to bring an administrative challenge, the [plaintiff's] inability or difficulty would not trigger the *Illinois Council* exception." *Id.* (citing *Physicians Hosps.*, 691 F.3d at 657–58).

Southwest provides three primary reasons why channeling its claims through the administrative process would effectively result in a total loss of judicial review: (1) Southwest would be foreclosed from appealing an adverse administrative decision in federal court since a claim challenging the PPR would likely be characterized by CMS as a grievance rather than a coverage dispute; (2) Southwest could not bring a claim challenging the PPR either directly or through its enrollees as proxies since the enrollees would not have sufficient financial incentive to vigorously pursue the regulatory challenge; and, (3) even assuming Southwest could bring a claim through its enrollees, those enrollees would not be able to satisfy the statutory amount-in-controversy requirement.

A. Classification of Southwest's Claim

Under the Medicare Part D regulations, only claims that CMS has characterized as "coverage determinations," as opposed to "grievances," are appealable to the federal courts after being channeled through the administrative review process. *See* 42 C.F.R. § 423.562(b). Claims that are characterized as grievances do not receive either administrative or judicial review. *See id.*; *see also id.* at § 423.564. A "coverage determination" is defined as including a "decision on the amount of cost sharing for a drug." *Id.* at § 423.566(b)(5). A "grievance," on the other hand, includes "any complaint or dispute, other than one that involves a coverage determination, expressing

dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested." *Id.* at § 423.560.

According to Southwest, any claim challenging the PPR would be treated as a grievance rather than a coverage determination by CMS and thus would not be subject to judicial review. Southwest continues to press this point even though CMS submitted a declaration written by Anthony Culotta, the Director of Medicare Enrollment and Appeals Group at CMS, to the district court, admitting that an enrollee's complaint regarding the disparity in copayments or coinsurance between preferred and non-preferred pharmacies would be treated as a coverage determination (the "Culotta Declaration"). Southwest's refusal to accept CMS's interpretation of a coverage determination stems from its speculation that CMS has adopted this interpretation solely to advance its position in the instant litigation and its contention that the interpretation conflicts with CMS's past practices.

Generally, we defer to an agency's interpretation of its own regulations absent plain error or inconsistency with those regulations. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997). While we have declined to extend deference under *Auer* to an agency's "interpretation [that] is a novel litigating position 'wholly unsupported by regulations, ruling, or administrative practice,'" *Tex. Clinical Labs Inc. v. Sebelius*, 612 F.3d 771, 777 (5th Cir. 2010) (quoting *Brown v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988)), that is not the case here. Southwest has not provided any evidence that CMS has previously applied the Medicare Part D regulations in a manner inconsistent with its proffered interpretation—in fact, CMS has not even had the opportunity to characterize a challenge to the PPR as a grievance rather than a coverage determination. Absent such an inconsistency, we decline to hold that the agency's interpretation "is merely a litigating position" rather than a "fair and considered judgment on

the matter in question." *Id.* at 778 (quoting *Auer*, 519 U.S. at 462). This is simply not a case where the agency's interpretation is so lacking in the "hallmarks of thorough consideration" that we should decline to grant it *Auer* deference. *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2169 (2012).

Southwest has also failed to convince us that CMS's interpretation is merely a "*post hoc* rationalization advanced by an agency seeking to defend past agency action against attack." *Id.* at 2166 (alteration omitted) (quoting *Auer*, 519 U.S. at 462). As CMS has yet to characterize a claim challenging the PPR as either a grievance or a coverage determination, there is no past action to defend. Moreover, unlike previous cases where courts have declined to defer to an agency's interpretation when doing so would impose liability, *see, e.g., id.* at 2167 ("Petitioners invoke the [agency's] interpretation of ambiguous regulations to impose potentially massive liability on respondent for conduct that occurred well before that interpretation was announced."), or unfair surprise, *see, e.g., Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 171 (2007) ("[A]s long as interpretive changes create no unfair surprise . . . the change in interpretation alone presents no separate ground for disregarding the Department's present interpretation."), on a party without sufficient warning, CMS's interpretation in fact benefits Southwest by promising to allow its challenges to the PPR to proceed as coverage determinations rather than grievances. Nor is this conclusion undermined by the fact that CMS advanced this position in a document drafted in response to the present litigation, *see id.*, 551 U.S. at 171; *Tex. Clinical Labs*, 612 F.3d at 778, or by the fact that CMS is a party to this case, *see generally Tex. Clinical Labs*, 612 F.3d 771.

As Southwest has not shown that CMS's interpretation of its own regulations is merely a litigating position or a *post hoc* rationalization, we must look to see if this interpretation is consistent with the regulatory text. *See Chase*

Bank USA, N.A. v. McCoy, 131 S. Ct. 871, 880 (2011) ("Because the interpretation the [Board of Governors of the Federal Reserve System] presents in its brief is consistent with the regulatory text, we need look no further in deciding this case."). Since an agency's interpretations "are creatures of its own regulations," CMS's interpretations of the Medicare regulations are "controlling unless plainly erroneous or inconsistent with the regulations being interpreted." *Castellanos-Contreras v. Decatur Hotels LLC*, 622 F.3d 393, 409 (5th Cir. 2010) (citing *Long Island Care at Home*, 551 U.S. at 171). CMS's interpretation of the Medicare Part D regulations' characterization of claims as coverage determinations or grievances is neither plainly erroneous nor inconsistent with the text of the regulations.[3] Southwest has not given us a compelling reason to doubt CMS's explicit commitment to characterize claims challenging the PPR as coverage determinations that dispute the amount of cost sharing for a particular enrollee purchasing a particular drug.[4]

---

[3] Several provisions in the regulations and CMS's Medicare Prescription Drug Benefit Manual support this interpretation. A coverage determination includes, for example, a "decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary [or] because the drug is furnished by an out-of-network pharmacy . . .) that the enrollee believes may be covered by the plan." 42 C.F.R. § 423.566. If uncertainty arises as to whether the claim should be considered a grievance, the Manual directs the plan sponsor to "process the complaint as a request for a coverage determination." CTRS. FOR MEDICARE AND MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, ch. 18, § 20.2 (2013).

[4] Although Southwest contends that the interpretation of Medicare Part D regulations advanced in the Culotta Declaration contradicts CMS's interpretation set forth in its Prescription Drug Benefit Manual, *supra* note 3, none of the examples provided by Southwest directly cover the hypothetical claims at issue here. Southwest's examples from the Prescription Drug Benefit Manual instead address situations where an enrollee contests the characterization of a particular drug as a "non-preferred" versus a "preferred" drug, or where an enrollee chooses between copayment and coinsurance, and not the imposition of different prices for drugs purchased at a "non-preferred" versus a "preferred" pharmacy. Accordingly, Southwest cannot claim that the Culotta Declaration is materially inconsistent with any previously promulgated policies on this specific issue.

We find it appropriate to extend *Auer* deference to an agency's interpretation of its own regulations "where, as here, the regulation is ambiguous as to the precise issue in contest," *Wells Fargo Bank of Tex. N.A. v. James*, 321 F.3d 488, 494 (5th Cir. 2003) (citing *Auer*, 519 U.S. at 452), the agency's interpretation is consistent with the regulations, and there is no indication that the interpretation was adopted to further the agency's litigating position. *See Tex. Clinical Labs*, 612 F.3d at 778. If, at some point in the future, CMS were to refuse to process a challenge to the PPR as a coverage determination, Southwest could reassert its right to judicial review by filing a new claim with that new evidence. But on the evidence before us, we hold that CMS's interpretation of the Medicare Part D regulations, as set forth in the Culotta Declaration, is deserving of courts' deference. The district court did not err in finding that the administrative process would be available to Southwest and other similarly situated parties seeking a determination on this issue.

B. Ability to Bring a Claim Directly or Through a Proxy

Southwest's second argument posits that, even if CMS were to characterize a challenge to the PPR as a coverage determination, Southwest would still be unable to obtain judicial review since the Medicare Part D regulations do not allow providers to bring coverage determination claims. *See* 42 U.S.C. § 1395w-104(h)(1) ("[O]nly the part D eligible individual shall be entitled to bring [a coverage determination] appeal."). The regulations do, however, allow for an enrollee to appoint a representative to navigate the appeals process on his behalf. *See* 42 C.F.R. § 423.566(c). Consequently, in order to obtain judicial review of a regulatory challenge to the PPR, a provider must seek to be appointed as the representative of an enrollee. *See id.* at § 423.562(b)(4)(vi) (noting that enrollees may request judicial review of a claim if the Medicare Appeals Council affirms an adverse Administrative Law Judge decision). Southwest argues that, since it cannot challenge the regulation

directly or as an assignee, its claim falls within the *Illinois Council* exception. Although Southwest acknowledges that its enrollees could appoint a member pharmacy to act as their representative in a challenge to the PPR, it maintains that this is not sufficient to satisfy the requirement of judicial review because representatives do not have the same rights as assignees and because the enrollees would have little incentive to bring these claims in the first place.

In arguing that the type of representation allowed under the Medicare Part D regulations is inadequate, Southwest attempts to distinguish precedent declining to extend the *Illinois Council* exception where a third party could bring a claim as an assignee of the aggrieved provider. *See, e.g.*, *Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816–17 (D.C. Cir. 2005) (finding that judicial review was not completely foreclosed since the aggrieved chiropractors could bring their challenge as the enrollees' assignee). According to Southwest, assigning rights to a provider—thereby allowing the provider to become a party to the administrative proceeding—is not the same as merely appointing a provider as a representative. However, the only meaningful distinction identified by Southwest between appointment as a representative and assignment is that an appointment can be revoked by the enrollee whereas an assignment cannot. Southwest provides no compelling explanation why this minor difference leads to the conclusion that enrollees would be inadequate proxies for pharmacies in a challenge to the PPR. And we see no reason why it would. That a representative's appointment can be revoked is not relevant to whether a representative whose appointment has not been revoked can vindicate its claim in the courts.

Furthermore, as CMS notes, the Medicare Part D regulations would allow Southwest's member pharmacies to pursue these claims on behalf of their customers immediately after obtaining authorization from them. *See* 42 C.F.R. § 423.560 ("Unless otherwise stated [in the rules described in

subpart M of part 423], the appointed representative has all of the rights and responsibilities of an enrollee in . . . obtaining a coverage determination, or in dealing with any of the levels of the [Medicare Part D] appeals process."). The enrollees would not have to navigate the process of bringing an administrative claim or shoulder any of the expenses associated with that process. In this way, Southwest could shield enrollees from the cost and inconvenience of bringing a claim challenging the PPR, thereby making it easier to attract potential litigants.

Even assuming that the assignment of rights to providers by the enrollees differs from the appointment of providers as representatives of the enrollees for the purposes of § 405(h), Southwest has not demonstrated that the enrollees would be ineffective or unwilling proxies. In spite of Southwest's efforts to compare the instant facts to those in *Council for Urologicial Interests*, 668 F.3d at 713 (applying the *Illinois Council* exception where the provider's proposed proxies had no reason initiate the litigation), we find important distinctions between the two cases. In *Council for Urological Interests*, the only parties that could bring a challenge to the regulation at issue "were at best neutral and at worst stood to gain from the new regulation." *Physician Hosps.*, 691 F.3d at 657 (citing *Council for Urological Interests*, 668 F.3d at 713). "Thus, the third parties [in *Council for Urological Interests*] lacked the incentive to bring a challenge because they were *categorically misaligned* with the plaintiffs." *Id.* (emphasis added). The D.C. Circuit ultimately concluded that, "[i]n cases where the only entities able to invoke Medicare Act review are highly unlikely to do so, their unwillingness to pursue a Medicare Act claim poses a serious 'practical roadblock' to judicial review." *Council for Urological Interests*, 668 F.3d at 712.

The facts of this case are, however, more akin to those in *National Athletic Trainers*, where we held that third-party physicians were sufficient proxies for

aggrieved athletic trainers since the physicians had adequate financial incentive to pursue a regulatory challenge on the trainers' behalf. 455 F.3d at 507. Like the physicians in *National Athletic Trainers*, the enrollees stand to gain financially as they could reduce their future prescription copayments or coinsurance by challenging the PPR. *See id.* at 507. Both Southwest and the enrollees could receive a financial benefit from overturning the PPR—albeit of different magnitudes—and have similar incentives to initiate a regulatory challenge.

Moreover, precedent from this circuit and our sister circuits merely requires that the proxies have some incentive to bring a regulatory challenge on behalf of the aggrieved party. *See, e.g., Nat'l Ath. Trainers.*, 455 F.3d at 507 (discussing economic incentives); *Am. Chiropractic Ass'n*, 431 F.3d at 816–17 (discussing non-economic incentives). While the enrollees may not stand to gain a fortune from challenging the PPR, they also have some non-financial stake in the outcome of the case, as evidenced by their continued patronage of independent pharmacies even after the introduction of the Walmart-Humana Plan discount. There is no indication that "the absence of any relationship between [Southwest] and the [enrollees]" would prevent an "alignment of interests" such that the practical effect of § 405(h) would be a complete preclusion of judicial review.[5] *See Council for Urological Interests*, 668 F.3d at

[5] The United States District Court for the Eastern District of North Carolina has recently reached a similar conclusion, finding that the plaintiffs:

> [F]ailed to show that the interests of non-preferred pharmacies and PDP enrollees are so misaligned that judicial review is precluded. PDP enrollees have the incentive to patronize a non-preferred pharmacy for all the normal, non-economic reasons customers prefer one business to another, such as location, product selection, and customer service. . . . Furthermore, a PDP enrollee's non-economic incentive to bring a challenge dovetails with the enrollee's financial incentive. An enrollee patronizing a non-preferred pharmacy naturally would be interested in paying the lower preferred pharmacy co-payment for a medication and therefore would be inclined to bring a challenge.

713–14. Because Southwest could shoulder the administrative and financial burdens of bringing an administrative claim and its enrollees stand to gain some financial or other benefit from overturning the PPR, the *Illinois Council* exception does not apply.

C. Satisfaction of the Amount-in-Controversy Requirement

Finally, Southwest argues that, assuming its claim is characterized as a coverage determination and assuming that it found enrollees who would allow a member pharmacy to represent them, it still would be foreclosed from judicial review by the amount-in-controversy requirement. The Medicare Part D regulations provide that an enrollee may only obtain judicial review of an adverse coverage determination if the enrollee has at least $1,300 in controversy. 42 C.F.R. §§ 423.1976(a)–(b), 423.2136(a); 75 Fed. Reg. 58407–01 (Sept. 24, 2010) (setting the minimum amount in controversy as $1,300 at the time Southwest's complaint was filed). The amount in controversy in this case consists of the difference in copayment or coinsurance for a particular drug at preferred pharmacies versus non-preferred pharmacies. Under the regulations, an enrollee may aggregate his claims for multiple medications in order to satisfy the amount in controversy. 42 C.F.R. § 423.1970(c)(1). An enrollee may also aggregate his appeal with the appeals of other enrollees in order to satisfy the amount in controversy.[6] *Id.* at § 423.1970(c)(2). However, the power to

---

Farmville Drug Discount, Inc. v. Sebelius, No. 4:12–CV–109–D, 2013 WL 1246815, at *9 (E.D.N.C. Mar. 27, 2013) (citations omitted).

[6] CMS contends that the amount in controversy could also be satisfied by accounting for an enrollee's projected annual costs for a particular prescription drug or set of drugs. We reject this methodology since, as Southwest notes, the projected value of an enrollee's prescriptions can only be used to satisfy the amount in controversy when the basis for the enrollee's appeal is the provider's refusal to provide prescription drug benefits. *See* 42 C.F.R. § 423.1970(b). Because a claim challenging the PPR is based on an objection to the amount of cost sharing for a particular prescription drug, and not the refusal to provide prescription drug benefits, the enrollees would not be able to use the projected value formula to satisfy the amount in controversy.

aggregate claims under this provision is limited by the requirement that all claims be brought within 60 days of filling the prescriptions, *id.* at §§ 423.582(b), 423.1970(c)(2), and the requirement that the aggregated claims involve the same prescription drugs, *id.* at § 423.1970(c)(2)(iii).

Southwest argues that these restrictions completely preclude it from challenging the PPR. In its brief, Southwest makes numerous calculations to demonstrate that "it is mathematically impossible for any [single] enrollee of the Walmart Humana-Preferred Rx Plan to reach the $1,300 amount in controversy utilizing the differences [in copayment or coinsurance] between preferred and non-preferred pharmacies." Southwest further insists that it would be "impossible, if not virtually impossible, to have a sufficient group of individuals submitting their administrative appeals virtually simultaneously concerning the identical prescription drug such that they can collectively achieve the minimum amount in controversy for judicial review." According to Southwest, it would be mathematically and practically impossible to find a sufficient number of enrollees whose claims could be aggregated to satisfy the amount-in-controversy requirement.

The district court disagreed with this argument, citing Southwest's failure to refute CMS's contention that some prescription drugs are so costly that meeting the amount-in-controversy threshold would not be preclusively difficult for a group of enrollees. Neither party has provided definitive calculations on this issue; Southwest refers generally to the testimony of two pharmacists who maintained that it would be difficult for any single individual to satisfy the amount-in-controversy requirement, while CMS counters that Southwest need only identify four enrollees with prescriptions for the same expensive drug who would be willing to allow Southwest to represent them in court.[7] Both

[7] CMS's assertion is based on the following analysis: during the second stage of the Walmart Plan's prescription drug coverage (the "Initial Coverage Stage"), a single enrollee

Southwest's and CMS's calculations are based on hypothetical drug costs, and neither give any concrete estimate of how many enrollees' claims would need to be aggregated to reach $1,300 in controversy given a particular drug or set of drugs.

At the very least, both parties seem to agree that it would take multiple enrollees who have been prescribed expensive drugs to satisfy the amount-in-controversy requirement. Nonetheless, without more, this burden does not warrant the application of the *Illinois Council* exception, which requires complete preclusion of judicial review rather than mere postponement of review based on hypothetical, unconfirmed difficulties in bringing a claim. *See Puerto Rican Ass'n of Physical Med. & Rehab., Inc. v. United States*, 521 F.3d 46, 49–50 (1st Cir. 2008) (declining to apply the *Illinois Council* exception where plaintiffs had not attempted to bring a test case through the administrative review process in order to challenge the regulation at issue). Accordingly, Southwest's hypothetical illustration that reaching the amount in controversy would be mathematically impossible is insufficient to trigger the *Illinois Council* exception.

Moreover, as discussed above, Southwest cannot prevail on its conclusory assertion that "enrollee[s] [have] no incentive to engage in the collective coordinated action necessary to aggregate all such claims to meet a minimum amount in controversy over a single prescription drug in order to obtain judicial review" such that the aggregation of enrollees' claims would be a practical impossibility. To apply the *Illinois Council* exception to this set of facts would

---

using a non-preferred pharmacy could pay up to a total of $430.10 more in co-insurance (for either a single prescription drug or multiple prescription drugs) than an enrollee using a preferred pharmacy. Since the Initial Coverage Stage is the only stage during which an enrollee's amount in controversy can increase, the maximum amount in controversy that any single enrollee could achieve under the Walmart Plan is $430.10. Thus, it would require a minimum of four enrollees to reach the $1,300 amount in controversy under the Medicare Part D regulations.

open the door to a myriad of challenges based on hypothetical impossibilities. While Southwest may ultimately be unable to successfully recruit multiple enrollees to challenge the PPR, we should not assume that the hypothetical facts before us would necessarily culminate in a complete preclusion rather than a mere postponement of judicial review.[8]

Southwest asks us to apply the *Illinois Council* exception based purely on speculation that finding a group of enrollees who would be willing to pursue their claims would be an impossible task. Although no enrollee or group of enrollees has yet challenged the PPR, this does little to bolster Southwest's argument as the first plan promulgated under the PPR went into effect on January 1, 2011. At the time this case was brought in district court, the regulations had not even been in effect for a year.[9] *See Nat'l Athletic Trainers*, 455 F.3d at 507 (holding that, under the circumstances of the case, one year was not a "sufficient period of time . . . for us to infer from the lack of a challenge that there will be no challenge"); *cf. Council for Urological Interests*, 668 F.3d at 713 (finding that no third party had an incentive to bring a claim where there was an absence of any administrative challenge to the regulations at issue in the three-year period following the promulgation of those regulations). The fact that a relatively short period of time has passed without challenge to the PPR does not necessarily indicate that, given the appropriate information and guidance, the enrollees could not or would not bring those claims in the future. As a result, Southwest has not convinced us that its enrollees would be unwilling or unable

[8] Southwest admits that it has not attempted to recruit enrollees who could aggregate their claims in order to challenge the PPR. Such an attempt, while not always necessary to successfully invoke the *Illinois Council* exception, would provide us with some concrete basis on which to determine that obtaining judicial review would be practically impossible.

[9] Southwest filed its original complaint in the United States District Court for the Southern District of Texas on July 11, 2011.

to reach the amount-in-controversy threshold such that it should be granted an exception to § 405(h)'s channeling requirement.

CONCLUSION

While Southwest may have shown that it faces obstacles in finding enrollees who would file claims challenging the PPR which would satisfy the amount-in-controversy requirement, it has not shown that those obstacles are insurmountable. The question asked by the Supreme Court in *Illinois Council* is not whether compliance with § 405(h)'s channeling requirement would be merely inconvenient or expensive, but instead whether it would result in a "*complete* preclusion of judicial review." *Council for Urological Interests*, 668 F.3d at 708. Because Southwest has failed to demonstrate that its challenge to the PPR falls within the very narrow reach of the *Illinois Council* exception, we AFFIRM the district court's dismissal for lack of subject matter jurisdiction.