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Medicare Part D—"Any Willing Pharmacy" v. Preferred Pharmacies

Southwest Pharmacy Solutions, Inc. v. United States Department of Health and Humans Services et al.

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On July 11, 2011, an independent pharmacy cooperative operating in Texas and surrounding states filed suit in federal court against the U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services ("CMS"). With little fanfare to date, the basis for this case will most certainly have meaningful implications on the practice and business of community pharmacy. The suit alleges that CMS created certain regulations that are contrary and in conflict with the underlying Medicare Part D statute in which the regulations were based. The catalyst for the Complaint centers around the Humana Walmart-Preferred RX Plan's ("the Humana Plan") formation of preferred pharmacy networks under its Medicare Part D plan.

On January 1, 2011, the Humana Walmart-Preferred Rx Plan took effect. Under the Humana Plan, Walmart-owned stores serve as the preferred retail pharmacy. Consequently, if a patient under the Humana Plan goes to a non-preferred pharmacy, he or she will have a co-pay significantly higher than that of the preferred retail pharmacy—Walmart. As one might expect, a co-pay disparity such as this would likely have a rather negative business impact on non-Walmart pharmacies. The Complaint provides that this type of arrangement under Medicare Part D, although likely consistent with regulation, is contrary to statute.

As most of you know, in 2003 and after much debate, Congress added a drug benefit plan to Medicare under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, codified under 42 U.S.C. §1395w-101, et seq. (known as and referred to herein "Medicare Part D"). As a very brief primer on administrative law, Congress creates statutes, but it is up to the administrative agency to create the detailed regulations necessary for implementation of the statute—so statutes and regulations are two different creatures. The legal standard for the validity of regulations requires that the regulation fit within the scope and purpose of the statute under which Congress created authority for the regulation. Hence, in this case, CMS cannot create a regulation that is contrary to the statute from which Medicare Part D is based, which is the primary allegation of Plaintiffs' Complaint.

Under Medicare Part D, Congress provided an "Any Willing Pharmacy" provision:

Participation of any willing pharmacy. A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

In implementing Part D through regulation creation, Plaintiffs allege that "[i]n direct contravention of this mandate, CMS promulgated the Preferred Pharmacy Rule which permits a [prescription drug plan] to refuse a willing pharmacy from participation in a preferred network."[2] The Regulation reads as follows:

Differential cost-sharing for preferred pharmacies. A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage 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.[3]

Plaintiffs argue that the underlying Statute states that no pharmacy shall be excluded from a prescription drug plan ("PDP") network. In allowing a preferred

[1] *42 U.S.C. §1395w-104(b)(1)(A).*
[2] *Plaintiffs' Complaint at 6, Southwest Pharmacy Solutions, Inc. v. U.S. Department of Health and Human Services, et al. (S.D. Texas 2011) (Case No. 2:11-cv-227).*
[3] *42 C.F.R. §423.120(a)(9).*

network with tiered co-pays, CMS is practically sanctioning the exclusion of non-preferred pharmacies, who would otherwise be more than willing to participate upon the terms and conditions of the preferred pharmacies[4]. Plaintiffs assert that the regulation and its application in the Humana Plan is in direct conflict with the statutory "Any Willing Pharmacy" provision by not allowing participation under the same terms and conditions given to the preferred pharmacy. Hence, Plaintiffs state, "Such a network-within-a-network model plainly subverts the Any Willing Pharmacy Requirement of the Act." [5] and conclude that CMS' Preferred Pharmacy Rule "is contrary to the plain language of the Medicare Part D Act, contrary to the clearly express Congressional intent, exceeds [CMS'] legislative authority and is arbitrary, capricious, an abuse of discretion and not in accordance with law . . . ." [6]

In its request for relief, Plaintiffs asked the Court to declare that the Preferred Pharmacy Rule is unlawful and should therefore be set aside, which would, for all intents and purposes, end the preferred component of the Humana Plan.

In lieu of an answer to the Complaint, Defendants filed a motion to dismiss for lack of subject-matter jurisdiction. Under 42 U.S.C. §405(h), judicial review for a matter of this nature is only available after the administrative procedures have been exhausted; thus, Defendants contend that Plaintiffs have not utilized the administrative channels offered by CMS. In response, Plaintiffs asserted that the administrative channels are designed for coverage issues rather than benefit design, which is the issue-at-hand. Further, Plaintiffs state that judicial review through administrative appeals must involve claims of $1,300 or greater over 60 days, which would be impossible to achieve for one person over the time period.

In the end, the Court found the Defendants arguments more persuasive and dismissed the Complaint for lack of jurisdiction, leaving the Plaintiffs limited options. In all likelihood, Plaintiffs will appeal the ruling and/or another group could pursue a similar claim in a different jurisdiction with the hope of obtaining a more favorable ruling on this procedural issue.

In the end, the underlying issues of this case represent another pivotal moment for the practice and profession of pharmacy. With the Humana Plan, the continued trend of limitations on patient choice sails in the uncharted waters of Medicare Part D. Unchecked, I imagine more similar alliances will continue to form, which is a development arguably outside of Congressional intent in the creation of Medicare Part D.

Jon Wallace received his pharmacy degree from the University of North Carolina and his law degree from the University of South Carolina. Mr. Wallace serves as General Counsel for the South Carolina Pharmacy Association and is a Clinical Associate Professor in the Department of Clinical Pharmacy and Outcome Sciences at the South Carolina College of Pharmacy. He is in private practice with Green Ford & Wallace, LLC in Charleston, South Carolina engaged in pharmacy and health law issues.

[4] *Plaintiffs' Complaint at 6.*
[5] *Id. at 3.*
[6] *Id. at 10.*