[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 02-10151

D. C. Docket No. 01-00356 CV-4-WS

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellant,

versus

RHONDA M. MEADOWS,
BOB SHARPE,
Deputy Secretary of Medicaid Agency for Health Care Administration of the State of Florida,

Defendants-Appellees.

Appeal from the United States District Court for the Northern District of Florida

(September 6, 2002)

Before BIRCH, MARCUS and CUDAHY[*], Circuit Judges.

[*] Honorable Richard D. Cudahy, U.S. Circuit Judge for the Seventh Circuit, sitting by designation.

CUDAHY, Circuit Judge:

The Florida legislature recently added another chapter in the ongoing efforts of states to hold down their Medicaid drug costs. The new Florida law enacted changes in its Medicaid program by creating a "preferred drug formulary" (also referred to as a "preferred drug list"), which exempts certain Medicaid-eligible drugs from a "prior authorization" requirement. If a drug is not on the preferred list, the prescribing doctor must call a state pharmacist to obtain approval of its use. In the course of this procedure, the pharmacist informs the doctor of the availability of other drugs (usually on the preferred drug list) that allegedly have comparable therapeutic value but are less expensive. The actual phone calls tend to be relatively brief (usually less than 10 minutes in length), and approval of the prescribing doctor's first-choice drug is guaranteed in 100 percent of all cases, provided only that he or she make the telephone call. During the first three months of the program, approximately 55 percent of all these calls have resulted in a change of the prescription to a drug on the preferred drug list. Naturally, because this procedure may tend to promote less profitable drugs at the expense of more profitable ones, it is not favored by the pharmaceutical manufacturers that brought this lawsuit.

The prior authorization program gives the state of Florida considerable leverage in negotiating with pharmaceutical companies. Following its enactment, the Medicaid market share for drugs not on the preferred drug list has shrunk significantly. Companies that have agreed to pay a "supplemental rebate" to reduce or offset the state's Medicaid expenditures are guaranteed the right to have their products considered for the preferred drug list. And, as noted, preferred drugs are *exempt* from the prior authorization program. Currently, slightly less than half of all Medicaid-eligible drugs are included on Florida's preferred drug list.

Shortly after the Florida law went into effect, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade group, sued the Agency for Health Care Administration (AHCA), which is the Florida agency that administers the state Medicaid program. The PhRMA alleged that the preferred drug provision was a "formulary" within the meaning of 42 U.S.C. § 1396r-8(d)(4). Since the Florida law did not satisfy all the requirements of that statute for a Medicaid formulary, the PhRMA argued that Florida's preferred drug list and prior authorization provisions were preempted by federal law. On cross-motions for summary judgment, the district court ruled that the Florida law was a permissible application of § 1396r-8(d)(1)(A), (d)(5), which expressly authorizes

prior authorization programs. The court therefore granted summary judgment for the AHCA. The PhRMA subsequently filed this appeal. We now affirm.

I.

Both the PhRMA and the AHCA agree that the material facts of this case are not in dispute. Therefore, this case ultimately turns on questions of statutory interpretation, which we review de novo. *See United States v. DBB, Inc.*, 180 F.3d 1277, 1281 (11th Cir. 1999); *Haynes v. Ambulance Svc., Inc. v. State of Alabama*, 36 F.3d 1074, 1075 (11th Cir. 1994). The central issue is whether there is a conflict between the recently enacted Florida law and the governing federal Medicaid statute, 42 U.S.C. § 1396r-8. The state of Florida argues that the new Florida law, ch. 2001-104, codified at Fla. Stat. § 409.91195, 409.912, provides for a "prior authorization program" within the meaning of 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5). In contrast, the PhRMA contends that the same provisions contemplates a "formulary" within the meaning of § 1396r-8(d)(1)(B)(iv), (d)(4).

Before commencing our analysis, we must discuss the relevant provisions of the federal Medicaid statutes and the new Florida law. We note at the outset that questions of statutory interpretation begin "by examining the text of the statute to determine whether its meaning is clear." *Harry v. Marchant*, 291 F.3d 767, 770 (11th Cir. 2002) (en banc) (citing *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432,

438 (1999)). "In construing a statute we must begin, and often should end as well, with the language of the statute itself." *United States v. Steele*, 147 F.3d 1316, 1318 (11th Cir. 1998) (en banc) (quoting *Merritt v. Dillard Paper Co.*, 120 F.3d 1181, 1185 (11th Cir. 1997)).

A.

Congress enacted the Medicaid program in 1965 in an effort to assist states with the cost of providing health care for the poor. Although the federal government provides approximately 56 percent of Florida's Medicaid funds, *see* 65 Fed. Reg. 69560-61, actual Medicaid relief is administered through state agencies pursuant to a Medicaid program that has been submitted to and approved by the U.S. Department of Health and Human Services. This cooperative venture between the federal and state governments is governed by the terms of Title XIX of the Social Security Act (SSA), §§ 1901-1935, codified at 42 U.S.C. §§ 1396-1396v. In addition, every state in the nation currently operates its own Medicaid program under its own statutes.

One large and growing part of the Medicaid program is the coverage of outpatient prescription drugs. Under 42 U.S.C. § 1396r-8, a drug is eligible for Medicaid coverage only if its manufacturer enters into an agreement with the Secretary of the Department of Health and Human Services to make a specified

rebate on each covered drug. With a few limited exceptions, this rebate is set by statute at 15.1 percent of the average manufacturer price. *See* § 1396r-8(c)(1) (setting 15.1 percent as the "minimum rebate percentage" for any rebate period commencing after December 31, 1995); § 1396r-8(k)(1) (defining the term "average manufacturer price"). The states, of course, are interested in securing additional rebates, and this is where the Florida legislature enters the picture.

Under 42 U.S.C. § 1396r-8(d)(1), state Medicaid agencies can impose additional "restrictions" on the coverage of Medicaid-eligible drugs. One provision of this statute, subsection (d)(1)(A), permits a "prior authorization program" for any covered outpatient drug. A second provision, subsection (d)(1)(B), permits various mechanisms for the exclusion or restricted coverage of outpatient drugs, including the creation of a "formulary" that meets certain statutory criteria.

The AHCA maintains that the new Florida law provides for a "prior authorization program." Under the applicable provision, "A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r-8(d)(1)(A) (emphasis added). Paragraph (5), entitled "Requirements of prior authorization programs," reads as follows:

> A State plan under this subchapter may require, *as a condition of coverage or payment* for a covered outpatient drug for which Federal

> financial participation is available in accordance with this section, ... the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval–
>
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
>
> (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 U.S.C. § 1396r-8(d)(5) (emphasis added). Under the plain language of this statute, *any* covered outpatient drug can be made subject to a prior authorization program if two requirements are met: (1) a response is provided within 24 hours of the request; and (2) a 72-hour supply of the drug is made available in emergency situations. In *Pharmaceutical Research & Manufacturers of America v. Concannon,* 249 F.3d 66, 76 (1st Cir. 2001), the First Circuit adopted this same interpretation of a § 1396r-8(d)(5) prior authorization program. At present, *Concannon* is the only other appellate opinion that has addressed this issue. However, during the pendency of this appeal, the Supreme Court granted a writ of certiorari in *Concannon*. *See Pharmaceutical Research & Mfgs. of Am. v. Concannon*, 122 S.Ct. 2657 (U.S. Jun. 28, 2002) (No. 01-188).

In contrast to the interpretation proffered by the AHCA, the PhRMA contends that the new Florida law contemplates a "formulary," which is therefore subject to a requirements of § 1396r-8(d)(1)(B), (d)(4). Under these provisions, "A

State may exclude or otherwise restrict coverage of a covered outpatient drug if ... (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)." § 1396r-8(d)(1)(B). The relevant parts of paragraph (4), entitled "Requirements for formularies," read as follows:

> A State may establish a formulary if the formulary meets the following requirements:
>
> (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State ... .
>
> (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section [which pertains to the rebate agreement required for Medicaid eligibility] ... .
>
> (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling ... the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
>
> (D) The State plan permits coverage of a drug excluded from the formulary ... pursuant to a prior authorization program that is consistent with paragraph (5).
>
> (E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

§ 1396r-8(d)(4).

One important feature of subsection (d)(4)(D) of the quoted text is that, for drugs excluded from the formulary, a state must permit coverage pursuant to "a

prior authorization program that is consistent with paragraph (5).” Paragraph (5) is the provision that outlines the 24-hour response and the 72-hour emergency drug-supply requirements of a prior authorization program. However, in order to clarify that a prior authorization program and a formulary are distinct methods of restricting coverage of outpatient drugs, the last sentence of subsection (d)(4) ends with the following proviso: “A prior authorization program established by a State under paragraph (5) *is not a formulary* subject to the requirements of this paragraph.” § 1396r-8(d)(4) (emphasis added).

When comparing the statutory requirements of a “prior authorization program” with the statutory requirements that apply to a “formulary,” one begins with the general principle that a state can impose, as a *condition* of Medicaid coverage or payment, that it be contacted prior to the dispensing of *any* covered outpatient drug. *See* § 1396r-8(d)(1)(A). If a state intends to operate a prior authorization program, that program must provide for (1) a response within 24 hours, and (2) the availability of 72-hour emergency supply. *See* § 1396r-8(d)(5). By way of contrast, a state can take the more stringent course of creating a “formulary,” which has the effect of *excluding* coverage of, or payment for, certain Medicaid-eligible drugs. *See* § 1396(d)(1)(B). In addition, the “formulary” must fully comply with five specific requirements set forth in § 1396r-8(d)(4), which,

among other things, generally limit an exclusion decision to issues of clinical safety and effectiveness. *See* § 1396r-8(d)(4)(C).

B.

In the spring of 2001, the Florida legislature passed the law that forms the basis of the present controversy. *See* Laws of Florida, ch. 2001-104 ("the 2001 amendments"), amending Fla. Stat. §§ 409.91195, 409.912.[1] After Governor Bush signed the bill, the Florida law went into effect on July 1, 2001. As a Medicaid reform measure that addressed the issue of covered outpatient drugs, the Florida law was presumably designed to operate against the existing backdrop of federal Medicaid statutes. In fact, the 2001 amendments explicitly reference the 42 U.S.C. § 1396r-8 – the provision that prescribes circumstances under which a state Medicaid plan can restrict coverage of Medicaid-eligible outpatient drugs.

Unfortunately, the terminology adopted by the Florida law has at least two ambiguities that have produced the current controversy. First, section 409.91195 mandates the creation of a "preferred drug formulary," which seems to be an imprecise parallel to a "formulary" within the meaning of § 1396r-8(d)(1)(B)(iv), (d)(4). Second, the term "preferred drug formulary" is used interchangeably

[1] The text of §§ 409.91195, 409.912(37) are reproduced in an appendix to this opinion.

throughout section 409.91195 with the term "preferred drug list."[2] The reference to a "preferred" drug list or "preferred" drug formulary appears to be unique to the Florida statute, since the term "formulary" in § 1396r-8 is not modified by any adjectives, much less a synonym for "preferred." Further, it is noteworthy that "formulary" is not a term of art that is specific to the requirements of § 1396r-8(d)(4). Webster's New Collegiate Dictionary (1994) defines a "formulary" as "a book listing medicinal substances and formulas."

That said, the amended Florida law obviously represents an attempt by the Florida legislature to conform a "preferred drug formulary" to at least *some* of the requirements of a "formulary" as defined by the federal Medicaid statutes. For example, the first sentence of Fla. Stat. § 409.91195 reads as follows: "There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of developing a preferred drug

---

[2] The Report and Recommendation of the federal magistrate judge, which was subsequently adopted by the district court, makes the following rather succinct observation:

> The Florida statutes use the phases "preferred drug formulary" and "preferred drug list" interchangably. *E.g.*, Fla. Stat. § 409.91195(1), (4), (6), (7), (8), (9), (11). Sometimes the first phrase is used (subsections (1), (5), and (6)), sometimes the second is used (subsections (7) and (8)), and sometimes both are used interchangeably in the same subsection (subsections (4) and (9)). Thus, while it would appear that the law intends a "preferred drug list" to be a "formulary," it would appear equally true that the Florida Statutes intend any "formulary" to be a "preferred drug list." Since the words are used so interchangeably, little can be inferred from the choice of words.

Pharmaceutical Research & Mfg. of Am. v. Medows, No. 4:01cv356-WS, Report and Recommendation of William C. Sherrill, Jr., U.S. Magistrate Judge, at 16 (N.D. Fla. Sept. 20, 2001) (footnote omitted).

formulary pursuant to 42 U.S.C. § 1396r-8." Paragraph (1) of this statute then defines the composition of the Medicaid Pharmaceutical and Therapeutics Committee in a way that is entirely consistent with a committee intended to develop a formulary within the meaning of § 1396r-8(d)(4). *Compare* § 1396r-8(d)(4)(A) ("The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State ... ."), *with* Fla. Stat. § 409.91195(1) ("The Medicaid Pharmaceutical and Therapeutics Committee [charged with the development of a preferred drug formulary] shall be comprised as specified in 42 U.S.C. § 1396r-8 and consist of 11 members appointed by the Governor. Four members shall be physicians, ... five members shall be pharmacists ... and one member shall be a consumer representative. ... At least one of the members shall represent the interests of pharmaceutical manufacturers.").

However, in addition to parallels between the federal Medicaid statute and the new Florida law, there are also important distinctions. For example, under the federal statute, *clinical* factors are the only permissible criteria for excluding a drug from the formulary. In contrast, the Florida law explicitly permits the Medicaid Pharmaceutical and Therapeutics Committee to consider *economic* factors when establishing the preferred drug list. *Compare* § 1396r-8(d)(4)(C) ("A covered

outpatient drug may be excluded ... only if ... the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion."), *with* Fla. Stat. § 409.91195(9) ("The Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and *cost-effectiveness* of a product." (emphasis added)), *and* Fla. Stat. § 409.91195(4) ("To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve *cost savings* contained in the General Appropriations Act." (emphasis added)). The Florida law, in contrast to § 1396r-8(d)(4)(C), also does not contain any requirement that the Medicaid Pharmaceutical and Therapeutics Committee provide a written public explanation for its decision to exclude a particular drug from its preferred drug list.[3]

[3] Note that the exclusion of a drug from the preferred drug list under the Florida law makes that drug subject to the prior authorization requirement. However, that same drug is *not* excluded from Medicaid coverage, which is the specific consequence of non-inclusion in a Medicaid formulary under § 1396r-8(d)(1)(B), (d)(4).

Differences between the Florida law and the federal Medicaid statute eventually became the topic of correspondence between Florida and federal administrators. On June 19, 2001, approximately three weeks after the Florida governor signed the 2001 amendments into law, AHCA submitted for approval the proposed revisions of Florida's Medicaid plan to the Center for Medicare & Medicaid Services (CMS).[4] In an e-mail dated July 27, 2001, an official of the CMS informed the AHCA of various potential problem areas in the state's plan and made the following observation and suggestion:

> Under the section titled Prescribed Drug Formulary with Prior Authorization, the state's use of the word "formulary" doesn't meet the definition of formulary in Section 1927 of the Act. Therefore, the state should strike all references to "formulary" from their state plan and replace them with another term/phrase such as "preferred drug list."

Sharpe Supplemental Affidavit, Doc. 33, Exh. C., at 1-2. On August 8, 2001, AHCA Deputy Secretary Bob Sharpe sent a letter to the CMS that specifically addressed the state plan's ambiguous terminology:

> AHCA is unclear as to CMS's rationale for the statement that Florida's use of the term "formulary" doesn't meet the definition of the term used in Section 1927 [codified at 42 U.S.C. § 1396r-8], and as to the legal effect of using another term.

* * *

[4] The CMS is the federal agency within the U.S. Department of Health & Human Services that oversees state Medicaid plans.

> If the Section 1927 use of "formulary" means a restrictive list designed to limit Medicaid coverage (i.e., to exclude certain drugs from coverage by the Medicaid program), then CMS is correct: the Florida "formulary" does not meet the definition of formulary in Section 1927. *The Florida formulary does not affect Medicaid coverage*; it merely establishes a preference for certain drugs, and submits all others (which remain covered services) to a prior authorization program.

Id., Exh. D., at 2 (emphasis added).

On September 14, 2001, Deputy Secretary Sharpe submitted to the CMS proposed revisions to the State's Medicaid Plan, including deletion of the phrase "preferred drug formulary," replacing it with "preferred drug list."[5] The new sentence reads, "In accordance with Florida Statute 409.91195 and pursuant to 42 U.S.C. § 1396r-8, there is created a preferred drug list with prior authorization for drugs not included on the preferred drug list." Four days latter, the CMS sent the AHCA a letter stating that Florida's Medicaid plan was now approved, retroactive to July 1, 2001, the day the 2001 amendments went into effect.

---

[5] Contrary to suggestions made by the PhRMA, the AHCA's current position on the structure and mechanics of the Florida law is consistent with its pre-litigation stance. In a public meeting held on May 31, 2001, the same day the Governor's signed the bill into law, George Kitchens, R.Ph., Bureau Chief, AHCA Medicaid Pharmaceutical Services, made the following remark to clarify the effect of the prior authorization provision: "The physician has the overriding ability to say, 'This is the therapy I want and this is the one I'm going to continue to use,' and it will be approved that way. [The prior authorization requirement is] more or less making the physicians aware that there are some options and have you considered [sic] this." AHCA Pharmaceutical Manufacturers Formulary & Supplemental Rebate Briefing, May 31, 2001 transcript, at 68. Kitchens made a similar statement during a public meeting of the Medicaid Pharmaceutical and Therapeutics Committee. P&T Committee meeting, June 26, 2001 transcript, at 37-38.

Notwithstanding ambiguities in the language of the Florida law, it is clear that the intended purpose of the preferred drug list is to reduce or offset the state's Medicaid expenditures. Under Fla. Stat. § 409.912(37), which is the other provision amended by the new Florida law, the establishment of the "preferred drug list" is directly tied to a "supplemental rebate" program. In most cases, the supplemental rebate is required to be at least 10 percent of the average manufacturer price over and above the § 1396r-8(a) federally mandated rebate. However, the statute provides a definite benefit to drug manufacturers: "Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug formulary." Fla. Stat. § 409.912(37)(a)7. Although some drugs, presumably because of product-specific clinical advantages, may make it onto the preferred drug list without agreeing to a supplemental rebate, other drugs make it onto the preferred list by providing comparable therapeutic benefits at a cost-effective price.[6] As noted, the preferred drug list in combination with the prior authorization provision has had a significant

[6] The statute reads in relevant part: "Agency decisions [on the preferred drug list] will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates." Fla. Stat. § 409.912(37)(a)7.

effect on the market share of various drug products among Florida's Medicaid population.[7]

C.

On August 7, 2001, the PhRMA filed this lawsuit. The PhRMA contended that Florida's "preferred drug formulary" was a "formulary" within the contemplation of federal law, but that the demands of the Florida law fell short of the narrow requirements set forth in 42 U.S.C. § 1396r-8(d)(4). Specifically, the PhRMA argued that the AHCA impermissibly relied on economic rather than clinical criteria when developing its preferred drug list. The case was assigned to a magistrate judge, and on September 20, 2001, he issued a report and recommendation, which concluded that the Florida law had created a "prior authorization program" pursuant to § 1396r-8(d)(1)(A), (d)(5). On December 28, 2001, the district court adopted the magistrate judge's report and recommendations in full and granted summary judgment to the AHCA. The PhRMA now appeals.

II.

[7] The PhRMA cites the AHCA's own statistics as evidence of this trend. For example, following the enactment of the Florida law, the market share for the antimigrane drug Imitrex fell from 60 to 6 percent. The market share of the proton pump inhibitor drug Prilosec fell from 38 percent to 4 percent, while the market share of Prevacid, which was included on the preferred drug list, increased from 43 to 65 percent. The PhRMA cites other equally large market shifts among various prescription drugs.

The central issue in this case is whether the Florida's system for covering Medicaid-eligible outpatient drugs conflicts in part with the governing federal statute, 42 U.S.C. § 1396r-8, and is therefore preempted under the Supremacy Clause, U.S. Const., art. VI, cl. 2. The Supreme Court has held that preemption may be differentiated into three discrete categories: (1) express preemption, where a federal statute contains "explicit preemptive language"; (2) field preemption, in which the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it"; and (3) implied conflict preemption, in which "compliance with both federal and state regulations is a physical impossibility" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade v. National Solid Wastes Mgmt.*, 505 U.S. 88, 98 (1992) (quotations and citations omitted); *accord This That and the Other Gift & Tobacco, Inc. v. Cobb County,* 285 F.3d 1319, 1322 (11th Cir. 2002); *Boyes v. Shell Oil Prods. Co.*, 199 F.3d 1260, 1267 (11th Cir. 2000).

Medicaid is a cooperative state-federal program, in which each participating state designs and implements its own Medicaid program subject to certain strictures established by federal law. 42 U.S.C. § 1396a (prescribing general requirements of state Medicaid plan); *cf. Harris v. McRae*, 448 U.S. 297, 309

(1980) (referring to the Medicaid program as a "system of 'cooperative federalism'" (quoting *King v. Smith*, 392 U.S. 309, 316 (1968)). As such, we readily conclude that the categories of express preemption and implied preemption are inapplicable here. Under § 1396r-8(d), the states are clearly given the authority to impose certain restrictions on the coverage of outpatient drugs, including a formulary for excluding coverage of certain outpatient drugs, or a distinct prior authorization program. Similarly, the federal government cannot "occupy the field" when no Medicaid relief is available unless a state designs and implements its own Medicaid program. Therefore, implied conflict preemption is the only category left standing and will be analyzed here.

In this circuit, a state statute is generally not entitled to a presumption against implied conflict preemption. *See Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no presumption exists against preemption."); *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997) (in a case involving implied conflict preemption under the Federal Boat Safety Act, noting that "we do not apply a presumption against preemption, even though common law tort claims are a mechanism of the police powers of the state"). However, Medicaid is one of several cooperative state-federal program covered by the Social Security Act, and the Supreme Court has suggested that

preemption for these types of programs may be difficult to establish. In *New York State Department of Social Services v. Dublino*, 413 U.S. 405 (1973), the Court addressed whether a New York welfare reform statute preempted another provision of the Social Security Act. In upholding the New York law, the Supreme Court observed, "Where coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one." *Id.* at 421 (reviewing possible preemption under the Federal Work Incentive Program); *accord Concannon*, 249 F.3d at 75; *New Mexico Dep't of Human Servs. v. Department of Health & Human Servs. Health Care Financing Admin.*, 4 F.3d 882, 886 (10th Cir. 1993); *Wash. Dep't of Soc. & Health Servs. v. Bowen*, 815 F.2d 549, 557 (9th Cir. 1987). We therefore believe there may be a presumption against preemption here.

Bearing this presumption in mind, we turn to the preemption analysis. Implied conflict preemption occurs when (a) compliance with both federal and state regulations is a physical impossibility, or (b) when a state law is an obstacle to execution and accomplishment of the objectives and purpose of a Congressional enactment. *See Gade*, 505 U.S. at 98; *This That and the Other Gift & Tobacco,* 285 F.3d at 1322; *Boyes*, 199 F.3d at 1267. If the Florida law created a *Medicaid*

"formulary," we would agree with the PhRMA that Florida officials developing the preferred drug list could not consider a drug's "cost-effectiveness," as required under Fla. Stat. § 409.91195(9), when the governing federal statute clearly limits such decisions to clinical issues of safety and drug effectiveness. *See* § 1396r-8(d)(4)(C).

However, we need not belabor the issue of physical impossibility because we agree with the magistrate judge and the district court that a reasonable reading of the Florida law suggests that the state has created a "prior authorization program" within the meaning of § 1396r-8(d)(1)(A), (d)(5). Subsection (d)(1)(A) permits a state Medicaid plan to "subject to prior authorization *any* covered outpatient drug." (emphasis added). Further, the text of the Medicaid statute contains only two specific limitations on prior authorization: a response within 24 hours and the availability of an emergency 72 hour supply of the drug. *Cf. Concannon,* 249 F.3d at 76 (stating that the only two requirements for a prior authorization program under § 1396r-8(d)(5) are "the 24-hour response and the 72-hour drug-supply requirements"). Because the Florida law satisfies both of these requirements, *see* Fla. Stat. § 409.912(37)(a)1, compliance with both federal and state law is certainly possible.

Our determination that the Florida law creates only a prior authorization program, and not a "formulary" in the federal sense, is further buttressed by substantial record evidence that the State's preferred drug list does not actually "exclude" any Medicaid-eligible outpatient drug from coverage.[8] Under the federal Medicaid statute, exclusion of a drug from a "formulary" has the effect of actually denying coverage of, or payment for, certain Medicaid-eligible drugs. As the PhRMA correctly points out, a decision to remove a drug from a § 1396r-8(d)(4) formulary must be based solely on clinical factors. Because the statutory

---

[8] The issue of exclusion is an important one. *PhRMA v. Concannon, supra*, is the only case that has addressed the legal contours of a Medicaid prior authorization program, and it is currently pending before the Supreme Court. In *Concannon*, the First Circuit held that a similar supplemental rebate program under Maine law satisfied the requirements of a prior authorization program under § 1396r-8(d)(a)(A), (d)(5). However, the disputed Maine law actually has a greater potential for interfering with a prescribing doctor's medical judgment. In *Concannon*, Maine acknowledged "that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant, but [the state] insists that the Medicaid recipient will always receive medically necessary drugs." 249 F.3d at 77. Recognizing the possibility that a prescribing doctor's first choice medication may not be covered, the First Circuit specified that its ruling was limited to a facial attack on the Maine law: "This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement as 'as applied.'" *Id.* at 78.

Under the Florida law, the prescribing physician retains the final authority to prescribe a Medicaid-eligible outpatient drug. *See* note 5, *supra*. On the record before us, we have no reason to believe that a prescribing physician would compromise the medical care of his patient in order to avoid making a telephone call to obtain a 12-month authorization of a medication not on the preferred drug list. From July 1, 2001 to September 30,2001, the AHCA agent pharmacist received 6,565 requests for non-preferred drugs; 2,874 prescriptions were authorized and 3,691 resulted in the physician's changing the prescription to a drug on the preferred list. These statistics suggest that in over 55 percent of these cases, the prescribing physicians received additional information from the AHCA pharmacist that persuaded them that a drug on the preferred list was medically appropriate. In short, it appears that the Florida law permits a clinical dialogue between a doctor and a pharmacist that can reduce the state's Medicaid costs without jeopardizing patient care.

requirements of such a formulary also mandate a prior authorization program, *see* § 1396r-8(d)(4)(D) (specifying as one of the requirements of a formulary is that "[t]he State plan permits coverage [of an excluded drug] ... pursuant to a prior authorization program that is consistent with paragraph (5)"), we construe this requirement to mean that a state must *consider* coverage for an excluded drug on a case-by-case basis. The decision to provide coverage would presumably be based on medical information conveyed by the prescribing doctor to the state agency that administers the Medicaid program.[9] However, the AHCA maintains that the Florida law actually creates a prior authorization program that covers all Medicaid-eligible drugs, provided that the prescribing doctor contacts the state pharmacist. The AHCA has consistently advanced this interpretation since the enactment of the

[9] Based on our interpretation of § 1396r-8, we note that the prior authorization requirement of a federal Medicaid formulary, pursuant to subsection (d)(4)(D), is likely to serve a different function than a prior authorization program authorized under subsections (d)(1)(A), (d)(5). Since a federal formulary *excludes* from coverage Medicaid-eligible outpatient drugs, *see* subsection (d)(1)(B)(iv), the prior authorization provision specified by subsection (d)(4)(D) permits the prescribing doctor to obtain an exception to this exclusion, presumably because of medical factors specific to his or her patient. In contrast, a prior authorization program under subsections (d)(1)(A), (d)(5), such as that provided in the Florida law, can be used to inform doctors about the availability of drugs with comparable therapeutic properties that are also more cost-effective for the state. Presumably, some doctors will learn to avoid the prior authorization program by routinely looking for a suitable drug on the "preferred drug list," Fla. Stat. § 409.91195(4); hence, the shifts in market share following the enactment of the Florida law. *See* note 7, *supra*. Based on the record before us, it is clear that prescribing physicians retain the authority to override any suggestions made by the AHCA state pharmacist. However, if the Florida law had actually created a federal formulary, and complied with all the requirements of subsection (d)(4), it would be permissible for the state to retain the final authority over coverage of, or payment for, non-formulary drugs.

Florida law. *See* note 5, *supra*. As the state agency that administers the state Medicaid plan, and because its construction is reasonable, we believe that the AHCA's interpretation of the Florida law is entitled to substantial deference. *See Enterprise Leasing Co. v. Metropolitan Airports Comm.*, 250 F.3d 1215, 1223 (8th Cir. 2001) (holding that "substantial deference is afforded to a state agency's interpretation of a statute the agency administers" and that the agency's interpretation cannot be set aside "unless it is arbitrary, capricious, an abuse of discretion, or otherwise not supported by law"); *see also National RR Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 417 (1992) ("Judicial deference to reasonable interpretations by an agency of a statute that it administers is a dominant, well-settled principle of federal law.").

Turning to the second species of implied conflict preemption, we do not believe that the Florida law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade*, 505 U.S. at 98. As noted by the First Circuit in *Concannon*, the "primary purpose of Medicaid is to enable states to provide medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services.'" 249 F.3d at 75 (quoting 42 U.S.C. § 1396 (2000)). In this case, the Florida law operates to drive down the cost of prescription drugs under the Medicaid program by providing drug

manufacturers with a strong economic incentive to offer the state a supplemental rebate. Moreover, these rebates do not necessarily have to be cash adjustments that can be applied to other, unrelated general fund expenditures. Rather, the supplemental rebates can directly improve the coverage and efficiency of the state Medicaid program by being applied to "disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act." Fla. Stat. § 409.912(37)(a)7. By stretching its Medicaid dollars, the Florida law has the potential for providing more and better medical services to the target population. Finally, because Florida's preferred drug list is based on *both* clinical and cost-related factors, *see* Fla. Stat. § 409.91195(9) (requiring that preferred drug list recommendations be based on "clinical efficacy, safety, and cost-effectiveness of a product"), the Florida law leaves open the possibility that a medically superior drug will be included on the list even without a supplemental rebate.

In its effort to demonstrate that the Florida law frustrates the objectives of the federal Medicaid legislation, the PhRMA contends that the state of Florida has

created a "de facto" formulary that sidesteps the clinical safeguard requirements of § 1396r-8(d)(4). The PhRMA constructs its rather complex argument by discussing a series of revisions to the prescription drug provisions of the Social Security Act. The PhRMA's contentions can be summarized in the following manner.

In 1990, Congress banned Medicaid formularies because states were using them to eliminate coverage for expensive but medically necessary drugs. *See* Pub. L. No. 101-508, § 4401(a)(2)(C), 104 Stat. 1388-143 (1990) (amending 42 U.S.C. § 1396a(a)(54)). According to the legislative debate cited by the PhRMA, the then predominant patterns of using formularies had been compromising the quality of medical care for Medicaid patients, and the formularies were therefore eliminated by Congress. In 1993, Congress enacted the current version of § 1396r-8(d). *See* Pub. L. No. 103-66, § 13602(a), 107 Stat. 616-17 (1993) (amending 42 U.S.C. § 1396r-8 and adding the current subsection (d)(4)). Although the new law once again permitted the creation and use of formularies, it included stringent clinical safeguards to reduce the potential for abuse. However, as the PhRMA points out, the prior authorization provision survived all of these changes (i.e., it was part of the pre-1990 law and remained largely unchanged by the 1990 and 1993 amendments), thus giving rise to the inference (according to the PhRMA) that Congress never intended that a prior authorization program under this provision

would be used to impose significant restrictions on prescribing doctors. Therefore, because the present Florida law, deemed to authorize a "prior authorization program," essentially replicates the abuses that crept in under the pre-1990 formularies (or so the PhRMA alleges), the PhRMA contends that the Florida law cannot be squared with the Congressional intent motivating the 1990 and 1993 reforms. To support its theory, the PhRMA refers us to copious volumes of legislative history.[10]

---

[10] To make its case, the PhRMA has assiduously plumbed the sprawling legislative history of the Medicaid prescription drug statute. For example, the PhRMA directs our attention to a 1990 Senate hearing on proposed changes to the Medicaid prescription drug provisions, in which Representatives Wyden and Cooper testified that approximately 20 states had established formularies that restricted, primarily on the basis of cost, the number of covered outpatient drugs available to Medicaid patients. *See Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Subcomm. on Health for Families and the Uninsured of the Comm. on Finance*, S. HRG. 101-1261, 101st CONG. 10, 19 (1990). Although these debates contained some reference to existing flaws in the prior authorization programs, *see id.* at 17 (statement by Rep. Wyden that "under the status quo there are prior authorization programs where no one even answers the phone"), the PhRMA maintains that these debates suggest that the problems with prior authorization programs were relatively minor compared to the widespread abuse of the formulary provisions – hence the scope of the 1990 amendments, which preserved the former but eliminated the latter.

Three years later, the tenor of congressional discourse had apparently changed. As an example of what motivated the 1993 amendments to the Medicaid prescription drug statute, the PhRMA invites our attention to a statement made by William Toby, Jr., Acting Administrator of the Health Care Finance Administration, requesting that states once again be permitted to establish formularies in order that they might have "greater flexibility to ensure the effective use of Medicaid funds." *Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce*, H. HRG. 103-61, 103rd CONG. 7 (1993). Once again relying on legislative debates, the PhRMA argues that the 1993 amendments were carefully designed to preserve the patient access to drugs that was achieved through the 1990 amendments. *See id.* at 453 (quoting Rep. Waxman that the 1990 amendment represented a "government-industry compact" that expanded the availability of Medicaid of drugs while simultaneously extracting rebates from manufacturers). As a result, the post-1993 incarnation of the Medicaid formulary is subject to the strict clinical safeguards of § 1396r-8(d)(4).

The PhRMA contends that the Florida law upsets this carefully calibrated equilibrium. However,

The primary flaw in the PhRMA's analysis is that the statutory interpretation problem here arises from an ambiguity in the Florida law, *not* in the federal Medicaid statute. The text of § 1396r-8(d) clearly authorizes: (1) a "prior authorization program," which requires as a *condition* of Medicaid coverage or payment, that the relevant state agency be contacted prior to the dispensing of *any* covered outpatient drug; and (2) a "formulary," which permits the more stringent consequence of excluding coverage or payment with respect to certain Medicaid-eligible drugs if certain *clinical* criteria are adhered to. But the last sentence of § 1396r-8(d)(4), which is the provision that specifies the minimum requirements for a formulary, also contains the following unequivocal proviso: "A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph." As we have observed on many previous occasions, when an enactment of Congress has spoken with this level of clarity, recourse to legislative history is unnecessary. *See Federal Reserve Bank of Atlanta v. Thomas,* 220 F.3d 1235, 1239 (11th Cir. 2000) (stating that statutory language must be ambiguous before "courts may examine extrinsic materials, including legislative history, to determine Congressional intent"); *United States v.*

---

we decline the PhRMA's invitation to scour the legislative history in order to improve upon a clearly drafted federal statute.

Orozco, 160 F.3d 1309, 1313 (11th Cir. 1998) ("Review of the legislative history is not necessary unless a statute is inescapably ambiguous'" (quotations omitted)); *United States v. Veal*, 153 F.3d 1233, 1245 (11th Cir. 1998) (same); *see also United States v. Rush*, 874 F.2d 1513, 1514 (11th Cir. 1989) (stating that legislative history cannot be relied upon to create an ambiguity when the statutory text is clear).

The PhRMA further argues that Congress intended the prior authorization provision of § 1396r-8(d)(5) to serve as an "adjunct" to the requirements of a formulary under § 1396r-8(d)(4). However, this construction of the Medicaid statute by the PhRMA renders meaningless the proviso in subsection (d)(4) that a "prior authorization program established ... under paragraph (5) is not a formulary subject to the requirements of [paragraph (4)]." The PhRMA's interpretation also cannot be reconciled with the unequivocal language contained elsewhere in the statute: "A State may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5)." § 1396r-8(d)(1)(A) (emphasis added).

The PhRMA attempts to dodge these inconsistencies by arguing that "the precise contours of a state's prior authorization powers under [paragraph (5)] are not at issue in this case" and that, notwithstanding these ambiguities, the Florida

law undermines the explicit clinical safeguard requirements of a § 1396r-8(d)(4) formulary. This line of reasoning is unconvincing. The Florida law does not *exclude* coverage for any Medicaid eligible drugs, which is the literal effect of a § 1396r-8(d)(4) formulary. *See* § 1396r-8(d)(1)(B)(iv) (permitting a State to "*exclude* or otherwise restrict coverage of a covered outpatient drug if ... the State has *excluded coverage* of the drug from its formulary established in accordance with paragraph (4)" (emphasis added)). Instead, the Florida law merely *conditions* coverage for non-preferred drugs on whether the prescribing physician has followed the prior authorization procedure.

If this case presents us with difficult issues of statutory interpretation, this difficulty arises from the confusing phraseology of the Florida law. Section 409.91195 begins with the sentence, "There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration [AHCA] for the purpose of developing a *preferred drug formulary* pursuant to 42 U.S.C. § 1936r-8." (emphasis added). However, the term "preferred drug formulary" does not appear in the governing Medicaid statute, and the reference to § 1396r-8 resolves nothing; a prior authorization program is defined in subsections (d)(1)(A) and (d)(5), while a "formulary" is defined in subsections (d)(1)(B) and (d)(4). Further, section 409.91195 of the Florida law uses the term "preferred drug

formulary" interchangeably with "preferred drug list": subsections (1) and (6) refer to "preferred drug formulary"; subsections (7) and (8) refer to "preferred drug list"; and subsections (4) and (9) refer to "formulary" and "preferred drug list"as if they were synonyms. As noted in the report and recommendation submitted by the magistrate judge, "while it would appear that the law intends a 'preferred drug list' to be a 'formulary,' it would appear equally true that the Florida Statutes intend any 'formulary' to be a 'preferred drug list.' Since the words are used so interchangeably, little can be inferred from the choice of words."

The PhRMA contends that the use of the word "formulary" effectively eliminates any resulting ambiguity and requires anything designated as a "formulary" to be subject to the clinical safeguards of § 1396r-8(d)(4). However, this argument is unpersuasive. As previously noted, "formulary" is not a term of art that is exclusive to federal Medicaid law. The dictionary definition of "formulary" is a "book listing medicinal substances and formulas." Webster's New Collegiate Dictionary (1994). The PhRMA also argues that the Florida legislature intended to create a § 1396r-8(d)(4) formulary because it mandated a committee of physicians and pharmacists that satisfied the specific requirements of subsection (d)(4)(A). Yet, if the Florida legislature were carefully conforming the Florida statutes to the requirements of the governing Medicaid statute, it is puzzling that it failed to

include a provision for a "written explanation (available to the public)" of a decision to exclude a particular drug from the formulary, as required by § 1396r-8(d)(4)(C). The AHCA insists that the Florida law permits the state to implement a conforming Medicaid formulary at a later date, and that the Medicaid Pharmaceutical and Therapeutics Committee, created pursuant to section 409.91195, would already be in place to assume this additional duty. As the agency charged with administering the Florida law, we must defer to its reasonable construction of an ambiguous state statute. *See Enterprise Leasing Co.*, 250 F.3d at 1223 (according substantial deference to state agency charged with the administration of a statute when its construction is reasonable).

III.

In summary, we hold that the 2001 amendments to the Florida law provide for a prior authorization program within the meaning of 42 U.S.C. § 1396r-8(d)(1)(A), (d)(5). The AHCA has adopted a reasonable construction of the Florida law that comports with the requirements of the governing federal Medicaid statute. The judgment of the district court is therefore AFFIRMED.

Appendix

The following is the text of Fla. Stat. § 409.91195:

> There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of developing a preferred drug formulary pursuant to 42 U.S.C. s. 1396r-8.
>
> (1) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised as specified in 42 U.S.C. s. 1396r-8 and consist of 11 members appointed by the Governor. Four members shall be physicians, licensed under chapter 458; one member licensed under chapter 459; five members shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative. The members shall be appointed to serve for terms of 2 years from the date of their appointment. Members may be appointed to more than one term. The Agency for Health Care Administration shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that at least some of the members of the Medicaid Pharmaceutical and Therapeutics Committee represent Medicaid participating physicians and pharmacies serving all segments and diversity of the Medicaid population, and have experience in either developing or practicing under a preferred drug formulary. At least one of the members shall represent the interests of pharmaceutical manufacturers.
>
> (2) Committee members shall select a chairperson and a vice chairperson each year from the committee membership.
>
> (3) The committee shall meet at least quarterly and may meet at other times at the discretion of the chairperson and members. The committee shall comply with rules adopted by the agency, including notice of any meeting of the committee pursuant to the requirements of the Administrative Procedure Act.
>
> (4) Upon recommendation of the Medicaid Pharmaceutical and Therapeutics Committee, the agency shall adopt a preferred drug list.

To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

(5) Except for mental health-related drugs, antiretroviral drugs, and drugs for nursing home residents and other institutional residents, reimbursement of drugs not included in the formulary is subject to prior authorization.

(6) The Agency for Health Care Administration shall publish and disseminate the preferred drug formulary to all Medicaid providers in the state.

(7) The committee shall ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter, have an opportunity to present public testimony to the committee with information or evidence supporting inclusion of a product on the preferred drug list. Such public testimony shall occur prior to any recommendations made by the committee for inclusion or exclusion from the preferred drug list. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the Medicaid Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting. To the extent possible, upon notice by a manufacturer the agency shall also schedule a product review for any new product at the next regularly scheduled Medicaid Pharmaceutical and Therapeutics Committee.

(8) Until the Medicaid Pharmaceutical and Therapeutics Committee is appointed and a preferred drug list adopted by the agency, the agency shall use the existing voluntary preferred drug list adopted pursuant to s. 72, chapter 2000-367, Laws of Florida. Drugs not listed

on the voluntary preferred drug list will require prior authorization by the agency or its contractor.

(9) The Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product. When the preferred drug formulary is adopted by the agency, if a product on the formulary is one of the first four brand-name drugs used by a recipient in a month the drug shall not require prior authorization.

(10) The Medicaid Pharmaceutical and Therapeutics Committee may also make recommendations to the agency regarding the prior authorization of any prescribed drug covered by Medicaid.

(11) Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Department of Children and Family Services.

The following is the text of Fla. Stat. § 409.912(37):

(37)(a) The agency shall implement a Medicaid prescribed-drug spending- control program that includes the following components:

1. Medicaid prescribed-drug coverage for brand-name drugs for adult Medicaid recipients is limited to the dispensing of four brand-name drugs per month per recipient. Children are exempt from this restriction. Antiretroviral agents are excluded from this limitation. No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder may be imposed on Medicaid recipients. Medications that will be available without restriction for persons with mental illnesses include atypical antipsychotic medications, conventional antipsychotic medications, selective serotonin reuptake inhibitors, and other medications used for the treatment of serious mental illnesses. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply. The agency shall continue to provide unlimited generic drugs, contraceptive drugs and items, and diabetic supplies. Although a drug

may be included on the preferred drug formulary, it would not be exempt from the four-brand limit. The agency may authorize exceptions to the brand-name-drug restriction based upon the treatment needs of the patients, only when such exceptions are based on prior consultation provided by the agency or an agency contractor, but the agency must establish procedures to ensure that:

a. There will be a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation;

b. A 72-hour supply of the drug prescribed will be provided in an emergency or when the agency does not provide a response within 24 hours as required by sub- subparagraph a.; and

c. Except for the exception for nursing home residents and other institutionalized adults and except for drugs on the restricted formulary for which prior authorization may be sought by an institutional or community pharmacy, prior authorization for an exception to the brand-name-drug restriction is sought by the prescriber and not by the pharmacy. When prior authorization is granted for a patient in an institutional setting beyond the brand-name-drug restriction, such approval is authorized for 12 months and monthly prior authorization is not required for that patient.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the average wholesale price less 13.25 percent.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include

initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full- service status, location, size, patient educational programs, patient consultation, disease-management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8, and, pursuant to the establishment of such formulary, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 10

percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 25 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug formulary. However, a pharmaceutical manufacturer is not guaranteed placement on the formulary by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term " supplemental rebates" may include, at the agency's discretion, cash rebates and other program benefits that offset a Medicaid expenditure. Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act. The agency is authorized to seek any federal waivers to implement this initiative.

8. The agency shall establish an advisory committee for the purposes of studying the feasibility of using a restricted drug formulary for nursing home residents and other institutionalized adults. The committee shall be comprised of seven members appointed by the Secretary of Health Care Administration. The committee members shall include two physicians licensed under chapter 458 or chapter 459; three pharmacists licensed under chapter 465 and appointed from a list of recommendations provided by the Florida Long-Term Care Pharmacy Alliance; and two pharmacists licensed under chapter 465.

9. The Agency for Health Care Administration shall expand home delivery of pharmacy products. To assist Medicaid patients in securing their prescriptions and reduce program costs, the agency shall expand its current mail-order- pharmacy diabetes-supply program to include all generic and brand-name drugs used by Medicaid patients with diabetes. Medicaid recipients in the current program may obtain nondiabetes drugs on a voluntary basis. This initiative is limited to the geographic area covered by the current contract. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

(b) The agency shall implement this subsection to the extent that funds are appropriated to administer the Medicaid prescribed-drug spending-control program. The agency may contract all or any part of this program to private organizations.

(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.