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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 04-2479

DOROTHY HARRIS, Legal Guardian of Willie M. Washington; SUZANNE K. BALIKCI, Legal Guardian of Jennie Lillian Schankowski; and MARY RUFFIN, Legal Guardian of Issac Ruffin, on behalf of themselves and all other similarly situated individuals [certified class action],

Plaintiffs-Appellees,

v.

JANET OLSZEWSKI, Director of the Michigan Department of Community Health,

Defendant-Appellant.

No. 05-1047

L.F., Legal Guardian of J.H., individually and on behalf of all other similarly situated individuals [certified class action],

Plaintiffs-Appellees,

v.

JANET OLSZEWSKI, Director of the Michigan Department of Community Health and PAUL REINHART, Director of Michigan's Medical Services Administration,

Defendants-Appellants.

Nos. 04-2479; 05-1047

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
Nos. 04-72386; 04-73248—Patrick J. Duggan, District Judge.

Argued: September 22, 2005

Decided and Filed: March 21, 2006

Before: SILER and SUTTON, Circuit Judges; SHARP, District Judge.*

COUNSEL

ARGUED: William R. Morris, MICHIGAN DEPARTMENT OF ATTORNEY GENERAL, Lansing, Michigan, for Appellants. Stephen M. Ryan, STEPHEN M. RYAN P.L.L.C., Bingham Farms, Michigan, Michael C. Levine, FRASER, TREBILCOCK, DAVIS & DUNLAP, Lansing, Michigan, for Appellees. **ON BRIEF:** William R. Morris, MICHIGAN DEPARTMENT OF ATTORNEY GENERAL, Lansing, Michigan, for Appellants. Stephen M. Ryan, STEPHEN M. RYAN P.L.L.C., Bingham Farms, Michigan, Michael C. Levine, FRASER, TREBILCOCK, DAVIS & DUNLAP, Lansing, Michigan, for Appellees. Joshua Waldman, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Amicus Curiae.

OPINION

SUTTON, Circuit Judge. In these consolidated appeals, Michigan's Department of Community Health (the "department" or "State") urges us to reverse the district court's entry of summary judgment against it in two cases brought under 42 U.S.C. § 1983 on behalf of a class of Michigan residents. The district court enjoined the department from enforcing a single-supplier contract for all incontinence products to Michigan's Medicaid recipients. On appeal, the department challenges the district court's holdings that: (1) Medicaid's freedom-of-choice provision, 42 U.S.C. § 1396a(a)(23)(A), confers a private right on individuals enforceable under § 1983 and (2) the State's single-source contract violates the freedom-of-choice provision because incontinence products are not "medical devices" as that term is used in the relevant statute, § 1396n(a)(1)(B). We agree that Medicaid's freedom-of-choice provision creates a private right that may be enforced under § 1983. But we disagree that the phrase "medical devices" is unambiguous and that the agency's interpretation—that medical devices may include incontinence products—is ineligible for *Chevron* deference. We thus reverse the judgment of the district court.

I.

A cooperative federal-state program, Medicaid authorizes the Federal Government to provide funds to participating States to administer medical assistance to individuals "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396. The State of Michigan participates in Medicaid and administers its program through the department.

At stake in these appeals is Michigan's method of supplying certain incontinence products through its Medicaid program. The relevant incontinence products include adult, child, and youth diapers and briefs as well as disposable incontinence shields, liners and underpads as well as incontinence catheters, accessories, syringes, skin barriers and enema units.

In 1997, the department and Binsons Home Medical Care signed a contract providing that Binsons would be the sole provider of incontinence products for some of Michigan's Medicaid recipients.

*The Honorable Allen Sharp, United States District Judge for the Northern District of Indiana, sitting by designation.

In 2004, after undergoing a competitive-bidding process, the department entered into a new contract designating J&B Medical as the single-source provider of incontinence products to all of Michigan's Medicaid recipients.

On June 28, 2004, Dorothy Harris filed a complaint in the United States District Court for the Eastern District of Michigan, seeking certification of a class consisting of all individuals who, like her, are eligible for Medicaid benefits in Michigan and may require use of incontinence products. Harris sought declaratory and injunctive relief under § 1983 and claimed that the department's single-source-provider contract violated Medicaid's freedom-of-choice provision. On July 1, 2004, another beneficiary, L.F., filed a similar complaint, after which the court consolidated the two cases.

On November 1, 2004, the district court granted summary judgment for the plaintiffs. As pertinent here, the court held that Medicaid's freedom-of-choice provision "creates private rights" enforceable under § 1983. D. Ct. Op. at 9–17. It then held that the freedom-of-choice provision, 42 U.S.C. § 1396a(a)(23)(A), requires States to allow eligible individuals to obtain "medical assistance" from any qualified provider. Although the Medicaid statute contains an exception to the freedom-of-choice provision for providers of "medical devices," 42 U.S.C. § 1396n(a)(1)(B), the court held that this phrase does not include incontinence products. The department timely appealed.

II.

Section 1983 creates a cause of action against any person who, under color of state law, deprives "any citizen of the United States . . . of any rights, privileges, or immunities secured by the Constitution and laws." 42 U.S.C. § 1983. Although § 1983 authorizes lawsuits to enforce federal statutory rights, *Maine v. Thiboutot*, 448 U.S. 1, 4 (1980), it "does not provide an avenue for relief every time a state actor violates a federal law," *City of Rancho Palos Verdes v. Abrams*, 125 S. Ct. 1453, 1458 (2005). Consistent with the terms of § 1983, a claimant must demonstrate that the underlying statute creates enforceable "rights" because "it is *rights*" after all, "not the broader or vaguer 'benefits' or 'interests,' that may be enforced under" the statute. *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283 (2002).

In ascertaining "whether Congress intended to create a federal right" in the freedom-of-choice provision, *id*., the Court has directed us to look at three factors, *see Blessing v. Freestone*, 520 U.S. 329, 340–41 (1997); *see also Westside Mothers v. Haveman*, 289 F.3d 852, 862–63 (6th Cir. 2002). "First, Congress must have intended that the provision in question benefit the plaintiff." *Blessing*, 520 U.S. at 340. In answering this initial inquiry, courts look for a statutory right or "*individual* entitlement," *Gonzaga*, 536 U.S. at 287, that is "unambiguously conferred," *id*. at 283, by the use of "rights-creating language," *id*. at 284 n.3. An "aggregate focus" unconcerned "with whether the needs of any particular person have been satisfied," *id*. at 288 (internal quotation marks omitted), is insufficient; the statute must be "phrased in terms of the persons benefited," *id*. at 284, and use "individually focused terminology," *id*. at 287. "Second, the plaintiff must demonstrate that the right assertedly protected by the statute is not so vague and amorphous that its enforcement would strain judicial competence." *Blessing*, 520 U.S. at 340–41 (internal quotation marks omitted). "Third, the statute must unambiguously impose a binding obligation on the States. In other words, the provision giving rise to the asserted right must be couched in mandatory, rather than precatory, terms." *Id*. at 341.

These three inquiries do not end the matter, however. "Even after" a plaintiff demonstrates "that the federal statute creates an individually enforceable right in the class of beneficiaries to which he belongs[,] . . . there is only a rebuttable presumption that the right is enforceable under § 1983." *City of Rancho Palos Verdes*, 125 S. Ct. at 1458 (internal quotation marks omitted). "The defendant may defeat this presumption by demonstrating that Congress did not intend that remedy

for a newly created right" by pointing to "evidence of such congressional intent [that] may be found directly in the statute creating the right, or inferred from the statute's creation of a comprehensive enforcement scheme that is incompatible with individual enforcement under § 1983." *Id.* (internal quotation marks omitted); *see also Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 508 (1990).

Gauged by this test, Medicaid's freedom-of-choice provision creates enforceable rights that a Medicaid beneficiary may vindicate through § 1983. "A State plan for medical assistance," the provision says,

> *must* . . . provide that [ ] *any individual* eligible for medical assistance (including drugs) *may obtain such assistance* from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services.

42 U.S.C. § 1396a(a)(23) (emphasis added).

First, in giving "any individual eligible for medical assistance" a free choice over the provider of that assistance, the statute uses the kind of "individually focused terminology" that "unambiguously confer[s]" an "individual entitlement" under the law. *Gonzaga*, 536 U.S. at 283, 287. And by saying that "[a] State plan . . . must . . . provide" this free choice, the statute uses the kind of "rights-creating," *id.*, "mandatory language," *see Westside Mothers*, 289 F.3d at 863, that the Supreme Court and our court have held establishes a private right of action. It is also clear that the right is vested "in the class of beneficiaries to which [plaintiffs] belong[]," *City of Rancho Palos Verdes*, 125 S. Ct. at 1458, namely individuals eligible for Medicaid coverage. The freedom-of-choice provision, in other words, "gives recipients the right to choose among a range of qualified providers[] without government interference." *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 785 (1980) (emphasis removed); *cf. Gonzaga*, 536 U.S. at 279, 287 (holding that the Family Educational Rights and Privacy Act of 1974 (FERPA) does not "confer enforceable rights" under § 1983 because "[u]nlike the individually focused terminology of Titles VI and IX ('no person shall be subjected to discrimination'), FERPA's provisions speak only to the Secretary of Education, directing that 'no funds shall be made available' to any 'educational agency or institution' which has a prohibited 'policy or practice'"); *Blessing*, 520 U.S. at 333, 343 (holding that Title IV-D of the Social Security Act "does not give individuals a federal right to force a state agency to substantially comply with" its terms because "the requirement that a State operate its child support program in 'substantial compliance' with Title IV-D was not intended to benefit individual children and custodial parents, and therefore it does not constitute a federal right" enforceable under § 1983).

Second, while there may be legitimate debates about the medical care covered by or exempted from the freedom-of-choice provision, the mandate itself does not contain the kind of vagueness that would push the limits of judicial enforcement. Whether a state plan provides an individual with the choice specified in the provision is likely to be readily apparent, and the parties here do not dispute that the department's single-source contract fails to provide that choice.

Third, the "must . . . provide" language of the provision confirms that the statute is "couched in mandatory, rather than precatory, terms." *Blessing*, 520 U.S. at 341. The department does not argue otherwise.

Nor do other provisions of the Medicaid Act explicitly or implicitly foreclose the private enforcement of this statute through § 1983 actions. The Medicaid Act does not provide other methods for private enforcement of the Act in federal court. *Cf. Smith v. Robinson*, 468 U.S. 992, 1011–12 (1984) (recognizing that a § 1983 action "would . . . render superfluous most of the detailed procedural protections outlined in the statute"); *Middlesex County Sewerage Auth. v. Nat'l Sea*

Clammers Ass'n, 453 U.S. 1, 20 (1981) ("[W]hen a state official is alleged to have violated a federal statute which provides its own comprehensive enforcement scheme, the requirements of that enforcement procedure may not be bypassed by bringing suit directly under § 1983.") (internal quotation marks omitted); *see also City of Rancho Palos Verdes*, 125 S. Ct. at 1459 ("We have found § 1983 unavailable to remedy violations of federal statutory rights in two cases: *Sea Clammers* and *Smith.* Both of those decisions rested upon the existence of more restrictive remedies provided in the violated statute itself" and "in all of the cases in which we have held that § 1983 is available for violation of a federal statute, we have emphasized that the statute at issue, in contrast to those in *Sea Clammers* and *Smith*, did not provide a private judicial remedy (or, in most of the cases, even a private administrative remedy) for the rights violated.").

That the Federal Government may withhold federal funds to non-complying States is not inconsistent with private enforcement. *See Wilder*, 496 U.S. at 521–22 (holding that although the Medicaid Act "authorizes the Secretary to . . . curtail federal funds to States whose plans are not in compliance with the Act, . . . [t]his administrative scheme cannot be considered sufficiently comprehensive to demonstrate a congressional intent to withdraw the private remedy of § 1983"). Neither is the Act's requirement that States "grant[] an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the [State] plan is denied," 42 U.S.C. § 1396a(a)(3), inconsistent with a private action under § 1983, *cf. Wilder*, 496 U.S. at 520–22.

Our conclusion, moreover, comports with decisions of the Supreme Court, our court and other courts of appeals that have recognized privately enforceable rights under § 1983 stemming from similar statutory language in the Medicaid Act. *See, e.g.*, *id*. at 510, 524 (holding that 42 U.S.C. § 1396a(a)(13)(A)—requiring that a state plan for medical assistance must provide for "payment . . . of the hospital services, nursing facility services, and services in an intermediate care facility for the mentally retarded provided under the plan"—confers health-care providers with an enforceable right under § 1983 because it is expressly "phrased in terms benefitting health care providers"); *Westside Mothers*, 289 F.3d at 856 (holding that 42 U.S.C. § 1396d(a)(4)(B)—requiring States to provide certain periodic services "for individuals who are eligible under the plan"—creates a cause of action under § 1983 for eligible individuals); *Sabree v. Richman*, 367 F.3d 180, 190, 192 (3d Cir. 2004) (holding that 42 U.S.C. § 1396a(a)(8)—requiring that a state Medicaid plan must "provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals"—creates an enforceable right under § 1983); *Bryson v. Shumway*, 308 F.3d 79, 88 (1st Cir. 2002) (same); *Doe v. Chiles*, 136 F.3d 709, 715–16 (11th Cir. 1998) (same).

In arguing to the contrary, the department urges us to follow two district court decisions. In the first of these decisions, *M.A.C. v. Betit*, 284 F. Supp. 2d 1298, 1307 (D. Utah 2003), the court concluded that "the freedom of choice provisions do not contain the unambiguous rights-creating language of *Gonzaga*" without explaining why the language discussed above is not "rights-creating." Because the district court did not explain why the mandatory "must . . . provide" language, 42 U.S.C. § 1396a(a)(23), and the "*individual* entitlement" language of the provision, *Gonzaga*, 536 U.S. at 287, do not satisfy *Gonzaga*'s requirements for a § 1983 action, we do not find the court's reasoning persuasive. Also unpersuasive is the second decision, *Watson v. Thorne*, No. 03-227-JE, 2004 U.S. Dist. LEXIS 12855 (D. Or. June 24, 2004), which is unpublished and which does not address the freedom-of-choice provision.

The department next argues that another provision of the Act, § 1396n(a), shows that Congress did not intend to create privately enforceable rights. "A State," that provision says, "shall not be deemed to be out of compliance with the requirements of . . . [the freedom-of-choice provision] solely" because it has taken various cost-saving measures, including entering into "arrangements through a competitive bidding process . . . for the purchase of laboratory services . . .

or medical devices." 42 U.S.C. § 1396n(a). That § 1396n(a) carves out services and products otherwise covered by § 1396a(a)(23), however, by no means establishes that the latter section does not create a right of action. One section (§ 1396a(a)(23)) creates an individual statutory entitlement, namely freedom of choice; the other (§ 1396n) creates exceptions to that right. *Compare Gonzaga*, 536 U.S. at 284 & n.3 (holding that Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681(a)(1), creates individually enforceable rights) *with* 20 U.S.C. § 1681(a)(3)–(9) (creating several statutory exemptions from these rights).

The department next contends that even if a private right of action exists to enforce the freedom-of-choice provision, that right extends only to *services* and does "not extend . . . to *items* that a health-care entity may use when providing services." Dep't Br. at 17 (emphasis added). "[O]n its face," the department reasons, § 1396a(a)(23) guarantees the right to choose among "providers of services" and concludes that because "suppliers of incontinence products are not providing services *per se*, Congress did not intend individuals to have free choice among suppliers of incontinence items." Dep't Br. at 17. But as other provisions and regulations show, the dichotomy proposed by the department does not exist. The "medical assistance" to which freedom of choice applies does not extend only to services, as § 1396a(a)(23) says the freedom-of-choice provision applies to and "includ[es] drugs." And the Act defines "medical assistance" as "payment of part or all of the cost of . . . home health care services," 42 U.S.C. § 1396d(a)(7), which the regulations define as including "medical supplies, equipment and appliances" that are required for use in the recipient's home, 42 C.F.R. § 440.70(b)(3). Incontinence products that patients use in their homes under their physicians' orders thus are fairly covered by § 1396a(a)(23)'s grant of freedom of choice over "medical assistance."

Finally, the department argues that *Caswell v. City of Detroit Housing Commission*, 418 F.3d 615 (6th Cir. 2005), compels a contrary conclusion. In *Caswell*, we held that because no "specific statutory provision" in the relevant Act, as opposed to a regulation implementing the Act, conferred the individual right the plaintiff sought to enforce, he could not pursue his claim under § 1983. *Id.* at 620. *Caswell* also recognized that recent Supreme Court precedent (particularly *Gonzaga* and *Sandoval*) had "cabined" our prior holding that § 1983 "creates a federal cause of action for the violation of a federal *regulation*." *Id*. at 618 (emphasis added); *see id.* ("'[L]anguage in a regulation may invoke a private right of action that Congress through statutory text created, but it may not create a right that Congress has not . . . . Agencies may play the sorcerer's apprentice but not the sorcerer himself.'") (quoting *Sandoval*, 532 U.S. at 291).

Seizing on this language from *Caswell*, the department submits that because plaintiffs have supported their position that the term in the statute ("home health services," 42 U.S.C. § 1396d(a)(7)) includes incontinence products by pointing to a term in a regulation ("medical supplies," 42 C.F.R. § 440.70), "only [the] regulation" establishes the necessary "bridge between 'services' and 'supplies,'" Dep't Resp. to Dep't of Health and Human Servs. (HHS) Amicus Br. at 4. The analogy is inapt. In *Caswell*, neither the plaintiff nor the court could identify any statutory provision that conferred the right at issue. Here, the authoritative regulation merely supplements the right identified in a specific *statutory* provision: the freedom-of-choice provision, § 1396a(a)(23)(A). A term in that provision, "medical assistance," is further defined in another *statutory* provision, § 1396d(a)(7), which states that "medical assistance" includes "home health care services." Plaintiffs' claim thus is not based on 42 C.F.R. § 440.70 *alone*; that regulation simply confirms that these *statutory* terms include incontinence supplies. The problem at issue in *Sandoval*, moreover, was that the regulations the parties sought to enforce did "not simply apply" statutory rights "since they indeed forb[ade] conduct that [the statute] permit[ted]." 532 U.S. at 285. Consequently, "the private right of action to enforce" the statute did "not include a private right to enforce the[] regulations," *id*., because "a private plaintiff may not bring a suit based on a regulation against a defendant for acts not prohibited by the text of the statute," *id*. at 286 (internal quotations marks and brackets omitted).

Customarily, by contrast, "regulations applying [a statute's ban on conduct] are covered by the cause of action to enforce that section" because "[s]uch regulations, if valid and reasonable, authoritatively construe the statute itself, and it is therefore meaningless to talk about a separate cause of action to enforce the regulations apart from the statute." *Id*. at 284 (citations omitted); *see also Ability Ctr. of Greater Toledo v. City of Sandusky*, 385 F.3d 901, 906 (6th Cir. 2004) ("[I]f the regulation simply effectuates the express mandates of the controlling statute, then the regulation may be enforced via the private cause of action available under that statute.") (citing *Sandoval*, 532 U.S. at 284). Because "[a] Congress that intends the statute to be enforced through a private cause of action intends the authoritative interpretation of the statute to be so enforced as well," *Sandoval*, 532 U.S. at 284, *Sandoval* does not undermine § 1983 enforcement here, *see id.* (citing cases "involv[ing] regulations of [this] type," including *National Collegiate Athletic Association. v. Smith*, 525 U.S. 459, 468 (1999) (regulation defining who is a "recipient" under Title IX) and *School Board of Nassau County. v. Arline*, 480 U.S. 273, 279–81 (1987) (regulations defining the terms "physical impairment" and "major life activities" in § 504 of the Rehabilitation Act of 1973)). Other courts, including this one, have reached a similar conclusion. *See Ability Ctr. of Greater Toledo*, 385 F.3d at 907 (holding that because the regulation at issue "effectuates a mandate" of a statute, it is "therefore enforceable through the private cause of action available under the statute"); *S.D. v. Hood*, 391 F.3d 581, 607 (5th Cir. 2004) (holding that because "the rights-creating language relied upon by the plaintiff is contained in the statute itself," because "the regulations implementing the statute, and defining 'home health care services' to include 'medical supplies,' [including 42 C.F.R. § 440.70] are authoritative interpretations of the statute and are enforceable by § 1983" and because "[HHS] has interpreted the 'home health care services' category as specifically including such supplies," "the federal statutory right asserted by the plaintiff is enforceable under § 1983").

III.

Having resolved the threshold right-of-action question against the State, we turn to the question whether the State permissibly treated incontinence products as "medical devices" under the exception to the freedom-of-choice provision, 42 U.S.C. § 1396n(a)(1)(B). "A State," the exception says, "shall not be deemed to be out of compliance with the requirements of . . . [the freedom-of-choice provision] solely by reason of the fact that the State . . . has entered into . . . arrangements through a competitive bidding process . . . for the purchase of . . . laboratory services . . .or *medical devices* if the Secretary has found that . . . adequate . . . devices will be available under such arrangements." *Id.* (emphasis added).

Chevron, U.S.A., Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), sets forth a familiar two-part inquiry for assessing an agency's construction of a statute that it administers. First: has Congress "directly spoken to the precise question at issue"? *Id*. at 842. If it has, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id*. at 842–43. Second: is "the agency's answer [] based on a permissible construction of the statute"? *Id*. at 843. If so and if Congress has given the agency authority to interpret the statute, a federal court will defer to the agency's interpretation. *Id.*

Congress, as an initial answer, has not "directly spoken" to the question at hand: Do "medical devices" include "incontinence products"? In establishing an exception to Medicaid's freedom-of-choice provision for "medical devices," Congress did not define the phrase and thus did not use the most natural means for eliminating ambiguity about it. *Cf. Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 125 S. Ct. 2688, 2699 (2005); *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 739 (1996).

Far from precluding incontinence products from coming within the exception to the freedom-of-choice provision, the "ordinary and natural meaning[]," *The Limited, Inc. v. Comm'r*, 286 F.3d 324, 333 (6th Cir. 2002), of "medical devices" extends to incontinence products. "Medical" means

"of, relating to, or concerned with physicians or with the practice of medicine often as distinguished from surgery" or "requiring or devoted to medical treatment." *Webster's Third New International Dictionary* 1402 (2002). And a "device" means "something that is formed or formulated by design and usu[ally] with consideration of possible alternatives, experiment, and testing: something devised or contrived." *Id*. at 618. Because incontinence products may fairly be described as "something devised" for "medical treatment," they come within the ordinary meaning of the phrase.

An analogous use of "device" in the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*., supports this view. That Act defines "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory." 21 U.S.C. § 321(h). This broad definition of the term would itself cover incontinence products. Confirming the point, the Food and Drug Administration has promulgated regulations establishing that incontinence products like those at issue in this case are "devices" within the FDCA's definition. *See* 21 C.F.R. § 876.5920 ("A protective garment for incontinence is a *device* that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta.") (emphasis added). In 1981, when Congress enacted § 1396n(a)(1)(B), *see* Pub. L. No. 97-35, 95 Stat. 809–10 (Aug. 13, 1981), and used the undefined phrase "medical devices," it seems unlikely that Congress meant to preclude an interpretation of the term that was consistent with a definition it had provided for "device" just six years before, when it enacted § 321(h) of the FDCA, *see* Pub. L. No. 94-295, 90 Stat. 575 (May 28, 1976); *see also Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) ("When administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well.").

The Medicare Act points in the same direction. It contains a definition of "medical devices" that incorporates the definition of "devices" found in the FDCA. *See* 42 U.S.C. § 1395y(m)(2); 42 C.F.R. § 405.201(b).

Having failed to enact a definition of "medical devices" that precludes the phrase from covering "incontinence products," having used a phrase that has a range of meanings, including one that naturally extends to incontinence products, and having deployed a phrase that it has used in analogous statutory and regulatory settings to cover incontinence products, Congress cannot be said to have limited the agency's authority to include incontinence products within this freedom-of-choice provision.

As to step two of *Chevron*, at least one of the natural meanings of "medical devices" includes incontinence products, and the agency's interpretation therefore represents a permissible one entitled to deference. *Chevron*, 467 U.S. at 843. HHS has implemented its interpretation in three settings. On May 19, 1997, the agency responded to an inquiry from the department, stating that "a medical device can be considered something used for a specific purpose in the practice of medicine" and that "adult diapers, catheters, etc. qualify as medical devices" because those items "would be used to manage the medical condition of incontinence." JA 172. *See Lukhard v. Reed*, 481 U.S. 368, 378 (1987) (plurality) (noting that authoritative expression of agency's view in memoranda and letters "is entitled to deference"); *id*. at 383 (Blackmun, J., concurring) (same).

After HHS expressed this view in its May 1997 letter, the department certified that Michigan's single-source contract for incontinence products complied with statutory and regulatory requirements for an exemption to the freedom-of-choice provision. When HHS accepted the department's certification, it was required to find that the amendment satisfied all statutory requirements, *see* 42 U.S.C. § 1396a(b), including that the department's single-source contract for incontinence products complied with § 1396n(a)(1)(B). In carrying out that responsibility, HHS was

exercising Congress's "express delegation of specific interpretive authority," *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001), and accordingly the agency's approval of the state plan amendment is entitled to *Chevron* deference, *see Pharm. Research & Mfrs. of Am. v. Thompson*, 362 F.3d 817, 821 (D.C. Cir. 2004) (holding that when the agency approves a state plan amendment under Medicaid, "the Secretary's decisions are entitled to *Chevron* deference"); *S.D. v. Hood*, 391 F.3d at 596 (same); *see also, e.g.*, *Rosen v. Goetz*, 410 F.3d 919, 927 (6th Cir. 2005) (holding that "we owe substantial deference" to the federal agency's approval of a state's proposed disenrollment process under Medicaid) (internal quotation marks omitted); *Alaska Dep't of Health & Soc. Servs. v. Ctrs. for Medicare & Medicaid Servs.*, 424 F.3d 931, 939 (9th Cir. 2005) (holding that *Chevron* deference to the agency's denial of a state plan amendment to its Medicaid program "is required" and collecting cases); *Georgia, Dep't of Medical Assistance ex rel. Toal v. Shalala*, 8 F.3d 1565, 1572–73 (11th Cir. 1993) (applying *Chevron* deference to the denial of a state plan amendment).

"[A]t our invitation," the United States also "filed an amicus curiae brief in this case, explaining that [the department's] proposed procedures are consistent with [HHS's] regulations." *Rosen*, 410 F.3d at 927. In that brief, "HHS [ ] recognized that incontinence products 'can be considered as medical devices.' The agency, however, did not rigidly interpret the statute to require this approach, but simply acknowledged it as one interpretation within a range of permissible constructions." HHS Amicus Br. at 17–18 (quoting JA 172).

HHS's interpretation, moreover, arises in the context of a federal statute that relies on state and federal cooperation (and state and federal money) and that HHS has long sought to implement in a way that permits local innovation. When Congress first enacted § 1396n, HHS issued interim and final rules to implement the new statutory provision, *see* 46 Fed. Reg. 48,524; 48,527 (Oct. 1, 1981) (interim rules); 48 Fed. Reg. 23,212; 23,221 (May 24, 1983) (final rules), including a regulation to implement the process for competitive bidding of "medical devices," *see* 42 C.F.R. § 431.54(d). In the preamble to the interim rules, HHS stated that it intended to "afford States the greatest possible flexibility and opportunity for innovation in administering their Medicaid programs, consistent with the statutory requirements." 46 Fed. Reg. at 48,524. To do so, the agency "decided to minimize Federal prescription of definitions and procedures in implementation of these provisions." *Id*. HHS reaffirmed this intent in the preamble to its final rules, noting that it "has exercised its administrative discretion by determining to regulate less, thereby reducing administrative burdens on the States to the extent possible" because its "policy is to afford States maximum flexibility within statutory constraints" and that "this policy is both proper and reasonable and reflects Congressional intent." *Id*. at 23,215.

"[R]eliance on [the] Secretary's significant expertise [also is] particularly appropriate in the context of a complex and highly technical regulatory program" like Medicaid. *Wis. Dep't of Health & Family Servs. v. Blumer*, 534 U.S. 473, 497 (2002) (internal quotation marks omitted). "Perhaps appreciating the complexity of what it had wrought, Congress conferred on the Secretary exceptionally broad authority to prescribe standards for applying certain sections of the [Medicaid] Act." *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981); *see also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) ("[W]e must defer to the Secretary's interpretation unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation. This broad deference is all the more warranted when, as here, the regulation concerns a complex and highly technical regulatory program" that "require[s] significant expertise and entail[s] the exercise of judgment grounded in policy concerns.") (internal quotation marks and citation omitted).

Because the phrase "medical devices" is at a minimum ambiguous and because the agency's construction of it is at a minimum reasonable, the agency's interpretation is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. We hold that HHS has reasonably construed

the term to allow participating States the discretion to include incontinence products within its scope.

In seeking to fend off this conclusion, plaintiffs counter that the dictionary definition of "device" is "distorted" and that a better definition of the word is "'a piece of equipment or a mechanism designed to serve a special purpose or perform a special function.'" Harris Resp. to HHS Amicus Br. at 2–3 (quoting *Webster's New International Dictionary (Unabridged)* 618 (3d ed. 1993)). That *one* of *Webster's* five "subsenses" of "device" might preclude incontinence products, however, does not establish that the term has a monochromatic meaning that confined the agency here.

Plaintiffs next claim that other parts of the Medicaid statute support a narrow (or at least narrower) interpretation of "medical devices." While the freedom-of-choice provision applies broadly to "medical assistance," they point out that Congress identified just two types of medical assistance to which the exception applies: "medical devices" and "laboratory services." But it should come as no surprise that a freedom-of-choice rule and a freedom-of-choice exception will overlap. The very nature of an exception is to carve out matters otherwise covered by the rule. Nor does the agency's implementation of the exception swallow the rule. The agency has never deployed a definition of "medical devices" that applies to *all* medical assistance—consider the many *medical services* not covered by "medical devices" or "laboratory services"—and as shown the words of the exception reasonably may be construed to cover incontinence supplies. Keep in mind, moreover, that the question is not whether "medical devices" *must* mean incontinence supplies but whether the phrase *may* fairly be given that meaning. A definition of "medical devices" that permits the federal agency (or, as here, permits the States) to extend the freedom-of-choice exception to incontinence supplies hardly eliminates the many settings covered by "medical assistance" in which freedom of choice will exist and, most importantly, does not compel, or in some instances even permit, the agency (or States) to extend the exception to these other settings.

Plaintiffs next claim that Congress's use of the phrase "medical devices and supplies" in another part of § 1396n shows that "medical devices" cannot include incontinence products. Subsection (e) of that section, which concerns waivers for children suffering from AIDS or drug dependency at birth, says that "the Secretary shall grant a waiver to provide that a state plan approved under this subchapter shall include as 'medical assistance' under such plan payment for part or all of the cost" of certain expenses, including "medical devices and supplies." 42 U.S.C. § 1396n(e)(1)(A). Even assuming that the phrase "medical devices and supplies" suggests that Congress envisioned two categories (that of "medical devices" and "medical supplies") and even assuming that Congress meant this dichotomy to persist throughout § 1396n, the phrasing raises as many questions as it answers. Most pertinently, the subsection does not clarify whether these two categories are mutually exclusive, or whether they overlap, or whether one is to be understood as a subset of the other—and if so, which one is broader and which one is narrower. And even if we could determine which one of these options Congress meant to embrace, the undefined phrase does not specify in which category incontinence products belong. Under these circumstances, we cannot say that the phrase establishes that Congress "directly" spoke to the issue before us, *Chevron*, 467 U.S. at 842, or that the agency's interpretation has rendered meaningless other words in the section.

Plaintiffs next argue that HHS's approval of the State's contract does not deserve deference because "administrative action with the effect of law should be subjected to the formal administrative procedure, not simply signed by an associate regional administrator." Harris Br. at 24. But the Supreme Court has already "rejected [the] argument" that when an "interpretation was not made after a formal adjudication or notice-and-comment rulemaking, [ ] it does not warrant *Chevron*-style deference." *Cleveland Nat'l Air Show, Inc. v. United States DOT*, 430 F.3d 757, 763–64 (6th Cir. 2005). *Mead* itself, the principal case upon which plaintiffs rely in making this

argument, acknowledged that while "the overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication," the absence "of that procedure here does not decide the case, for we have sometimes found reasons for *Chevron* deference even when no such administrative formality was required and none was afforded." 533 U.S. at 230–31 (footnote omitted). In the end, "[w]hile a formal process is one signal that an agency deserves *Chevron* deference, it is not the only one." *Cleveland Nat'l Air Show, Inc.*, 430 F.3d at 763–64. As noted, our court and other courts of appeals have applied *Chevron* deference to HHS's approval or denial of state Medicaid plans. *See Rosen v. Goetz*, 410 F.3d 919, 927 (6th Cir. 2005); *Pharm. Research & Mfrs. of Am. v. Thompson*, 362 F.3d 817, 821 (D.C. Cir. 2004); *S.D. v. Hood*, 391 F.3d 581, 596 (5th Cir. 2004); *Alaska Dep't of Health & Soc. Servs. v. Ctrs. for Medicare & Medicaid Servs.*, 424 F.3d 931, 939 (9th Cir. 2005); *Georgia, Dep't of Med. Assistance ex rel. Toal v. Shalala*, 8 F.3d 1565, 1572–73 (11th Cir. 1993).

Plaintiffs next claim that the agency's interpretation "is contrary to the HHS's published interpretation in the Federal Register," Harris Br. at 24, pointing to the following preamble in HHS's interim regulations: "Medical devices means items such as durable medical equipment, home health appliances, eyeglasses, hearing aids, or prosthetics that are covered under the State's Medicaid program." 46 Fed. Reg. at 48,524. By its terms, however, this 1981 definition does not purport to be exhaustive; the phrase "such as" makes that clear. And even if the agency had meant the list to be exhaustive in 1981, *Chevron* does not prohibit an agency from altering its definition of an ambiguous term in carrying out its responsibility to implement a federal statute. *See Brand X*, 125 S. Ct. at 2700 ("Agency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework" because "'[a]n initial agency interpretation is not instantly carved in stone. On the contrary, the agency . . . must consider varying interpretations and the wisdom of its policy on a continuing basis,' for example, in response to changed factual circumstances, or a change in administrations.") (quoting *Chevron*, 467 U.S. at 863–64) (internal citation omitted); *id.* ("[I]n *Chevron* itself, this Court deferred to an agency interpretation that was a recent reversal of agency policy."); *Smiley*, 517 U.S. at 742 ("[C]hange is not invalidating, since the whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agency.").

Plaintiffs, lastly, assert that HHS's May 1997 letter is contradicted by an earlier letter that informs the State that the writer has "requested formal consultation from the Medicaid Bureau" to determine whether incontinence products are medical devices. JA 169. The author of the letter expressed doubt that "'medical devices' . . . includes the items that are covered in [the department's] proposed contract." *Id.* The copy of the letter contained in the record is undated, but the request of formal consultation that the letter mentions resulted in the May 1997 letter in which HHS expressed its final, authoritative and controlling interpretation. *See also* HHS Amicus Br. Addendum at 6. That a single Medicaid program representative, in the course of responding to a state inquiry, expressed a tentative view contrary to HHS's ultimate official determination does not undermine the deference owed to the official agency determination.

IV.

For these reasons, we reverse and remand for further proceedings consistent with this opinion.