Catholic Health Initiatives, et al v. Kathleen Sebelius Doc. 919691231

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 10, 2010 Decided August 13, 2010

No. 09-5377

CATHOLIC HEALTH INITIATIVES, ET AL.,
APPELLANTS

v.

KATHLEEN SEBELIUS, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:07-cv-00555-PLF)

Paul D. Clement argued the cause for appellants. With him on the briefs were *Christopher L. Keough* and *J. Harold Richards*.

Irene M. Solet, Attorney, U.S. Department of Justice, argued the cause for appellee. With her on the brief was *Michael S. Raab*, Attorney. *Dana L. Kaersvang*, Attorney, and *R. Craig Lawrence*, Assistant U.S. Attorney, entered appearances.

Before: SENTELLE, *Chief Judge*, BROWN, *Circuit Judge*, and RANDOLPH, *Senior Circuit Judge*.

Dockets.Justia.com

Opinion for the Court filed by *Senior Circuit Judge* RANDOLPH.

Opinion concurring in the judgment filed by *Circuit Judge* BROWN.

RANDOLPH, *Senior Circuit Judge*: This is an appeal from an order of the district court granting summary judgment to the Secretary of Health and Human Services. Catholic Health Initiatives, a nonprofit charitable corporation, and a group of its affiliated nonprofit hospitals brought an action under the Medicare Act to recover premiums the hospitals had paid for malpractice, workers' compensation, and other insurance. The hospitals paid the premiums to First Initiatives Insurance Ltd. from 1997 through 2002. Catholic Health wholly owns First Initiatives, which is based in the Cayman Islands.

In general, the Secretary considers malpractice, workers' compensation, and other liability insurance premiums to be part of a hospital's "reasonable costs" incurred in providing services to Medicare beneficiaries. As such, the costs are reimbursable. The Medicare Act defines the "reasonable cost of any services" to be "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services . . .." 42 U.S.C. § 1395x(v)(1)(A). The "reasonable cost" "shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services . . .." *Id.*

The regulations describe reasonable costs as "related to the care of Medicare beneficiaries," 42 C.F.R. § 413.9(c)(3), and "determined in accordance with regulations," *id.* § 413.9(b). Reasonable costs include "all necessary and proper costs incurred in furnishing" Medicare services. *Id.* § 413.9(a).

Necessary and proper costs are those direct and indirect costs "that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities," and that are not "substantially out of line with" the costs of similar institutions. *Id.* § 413.9(b)(2), (c)(2).

The Secretary has issued a Provider Reimbursement Manual. The Manual contains "guidelines and policies to implement Medicare regulations which set forth principles for determining the reasonable cost of provider services," but it "does not have the effect of regulations." Centers for Medicare and Medicaid Services, Provider Reimbursement Manual, Part 1, Foreword, at I ("PRM"). The Manual does bind Medicare's "fiscal intermediaries" – private firms under contract with the Secretary to review provider reimbursement claims and determine the amount due. *See* 42 U.S.C. § 1395h; *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 80-81 (2d Cir. 2006); *St. Mary of Nazareth Hosp. Ctr. v. Schweiker*, 718 F.2d 459, 463 (D.C. Cir. 1983).[1]

Rather than purchasing insurance in the market, some Medicare providers have established their own insurance companies – known as "captives" – for the purpose of insuring themselves against malpractice and certain other claims. PRM § 2162.2.A. If the captive is a domestic corporation, and if the premiums it charges are comparable to those of other insurance companies, the Manual states that the affiliated provider is entitled to reimbursement for premiums paid to the captive. *Id.* But if the captive is offshore, the Manual prohibits reimbursement for premiums if the captive's investments do not comply with the following rule:

---

[1]In 2005, fiscal intermediaries were replaced by "medicare administrative contractors." *See* 42 U.S.C. 1395h; 42 C.F.R. § 413.24(f).

In the case of offshore captives, investments by a related captive insurance company are limited to low risk investments in United States dollars such as bonds and notes issued by the United States Government; debt securities issued by United States corporations or governmental entities within the United States rated in the top two classifications by United States recognized securities rating organizations at the time of investment; debt securities of foreign subsidiaries of United States corporations rated in the top two classifications by United States recognized securities rating organizations at the time of investment where the parent United States corporations guaranteed (on the face of the securities) payment of the subsidiaries' securities; and deposits (including Certificates of Deposit) in United States banks or their foreign subsidiaries, and foreign banks rated in the top two short term classifications by United States recognized securities rating organizations. Low risk investments may also include investments of non-United States issuers including foreign governments and corporations and supranational agencies rated in the top two classifications by United States recognized securities rating organizations (effective with investments made on or after 10/11/91). Effective for investments made on or after 10/06/95, the limitation on related offshore captive insurance company investments is extended to include the above described low risk investments rated in the top three classifications by United States recognized securities rating organizations. Additionally, investments may include dividend paying equity securities listed on a United States stock exchange provided that the investment in equity securities does not exceed 10 percent of the company's admitted assets, with the investment in any specific equity issue further limited to 10 percent of the total equity security investment. (All such captives are required to annually submit to a designated intermediary a certified

> statement from an independent certified public accountant or actuary attesting to compliance or non-compliance with these requirements for the previous period.) These investments cannot be pledged or used as collateral for loans obtained by the captive or parties related to the captive either directly or indirectly, nor may investments be made in a related organization.

PRM § 2162.2.A.4. First Initiatives Insurance did not satisfy these requirements. During the contested period it invested as much as forty to fifty percent of its assets in equity securities.

In light of First Initiatives' noncompliance with the Manual, the hospitals disallowed their premium payments on the annual cost reports they submitted to Medicare's fiscal intermediaries. *See* 42 C.F.R. § 405.1801(b)(1). The hospitals then sought to recover those premiums by challenging § 2162.2.A.4 at a hearing before the Provider Reimbursement Review Board, a five-member panel with authority to affirm, modify, or reverse an intermediary's decision. 42 U.S.C. § 1395*oo*(a), (d), (h). (Here the intermediary decision was merely to accept the hospitals' own disallowance of their premium costs.) The Board must give the Manual "great weight," but – unlike an intermediary – is not bound by it. 42 C.F.R. § 405.1867.

In a three to two decision, the Board held that the investment limitations in § 2162.2.A.4 of the Manual were a "valid extension" of the statute and the regulations governing "reasonable cost." Therefore the Board majority treated the provision as "compulsory." *Catholic Health Initiatives v. Mutual of Omaha Ins. Co.*, PRRB Decision No. 2007-D14 (Jan. 24, 2007) ("Board Decision"). The majority explained that, unlike domestic captive insurance companies, offshore captives present an "inherent risk": "offshore captives are under the control of foreign governments and are not subject to the same level" of

regulation as domestic insurers, which are regulated by the states. In addition, the ten percent limit on equity investments "is in line with the asset allocations found among domestic insurance companies." The two dissenting Board members believed that § 2162.2.A.4 of the Manual was not an "appropriate application of Medicare statutory reasonable cost principles," that it was "devoid of any link to the standards expressed in the regulations," and that it could not be justified as an interpretive rule "exempt from the notice and comment provisions of the Administrative Procedure Act . . .." The ten percent provision was, the dissenters stated, an example of "why the rulemaking process is critical to establishing standards such as those involved here."

Catholic Health and the hospitals brought this action in the district court after the Secretary's delegate – the Administrator of the Centers for Medicare and Medicaid Services – declined to review the Board's decision. *See* 42 U.S.C. § 1395*oo*(f); 42 C.F.R. § 405.1877. The district court viewed the issue as "whether the Board's ruling – which found the reimbursement standard expressed in the PRM to be consistent with both the Medicare statute and the Medicare regulations – was lawful, not whether the PRM provision itself was lawful." *Catholic Health Initiatives v. Sebelius*, No. 07-555, slip op. at 7, 2009 WL 3112575 (D.D.C. Sept. 30, 2009). Granting summary judgment in favor of the Secretary, the court found that the Board's adherence to the Manual's interpretation was "not plainly erroneous or inconsistent with the statute or the regulation . . .." *Id.* at 15.

The Secretary defends the Manual's investment limitations on the ground that the limitations comprise an "interpretative" rule. *See* 5 U.S.C. § 553(b)(A); *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993). As the Secretary puts it, "the cost of insurance premiums that

Medicare is asked to reimburse can be considered 'reasonable' only if those premiums actually purchase reliable coverage." Reliability depends on "the financial soundness of the insurer," Br. of Appellee at 15, which depends on the competence of the insurer's regulator and the pervasiveness of its regulations, *id.* at 29-31.[2] The rule, the Secretary contends, is consistent with the statute and regulations, supported by substantial evidence, and not arbitrary or capricious. *Id.* at 14-17, 28.

The hospitals dispute each of these assertions. They claim that the rule regulates insurance investment decisions and therefore lies outside the scope of the Secretary's "reasonable cost" authority under the Medicare Act. In addition, the hospitals believe that an important premise of the rule is wrong. The Board majority believed that offshore captives "are not subject to the same level of industry regulations applied to onshore agencies by State insurance companies." Board Decision at 6. But the evidence submitted at the hearing before the Board showed "that the level of state regulation of equity investments by domestically domiciled captives is essentially zero." Br. of Appellants at 39. In fact, "only a minority of states – twenty-three – regulate captive insurers at all." *Id.* at 40. The hospitals argue that to the extent that the Manual's limitations were intended to promote the financial strength and solvency of the offshore insurer, the limitations are arbitrary because they are both overbroad and underinclusive. The limitations are overbroad, for instance, because they permit equity investments only in securities that pay dividends. Yet the hospitals point out that many companies that appear to be financially sound – such as Microsoft during the years at issue

---

[2] The Secretary's argument assumes that the less heavily regulated an insurance company is, the more likely it will fail. There may be reason to doubt the assumption at least as applied to captive insurers, but we will make nothing of this.

and Google – do not pay dividends. The Manual's investment limitations are underinclusive, the hospitals claim, because there is no requirement that a captive diversify its investments. Although no one equity investment may make up more than ten percent of a captive's equity holdings (and thus one percent of its total assets), nothing in the Manual prevents a captive from having all of its assets in, for instance, one corporation's bonds. *See* PRM § 2162.2.A.4.

We do not decide whether the Medicare Act's reasonable cost provision would authorize the ten percent rule, or whether the reasoning and evidence in support of the Board's decision enforcing the Manual provision are sufficient. There is an antecedent question, discussed by the dissenting Board members and raised – although without much elaboration – by the hospitals. The question is whether the Manual's investment limitations for offshore captives is, as the Secretary contends, an "interpretive rule."

To fall within the category of interpretive, the rule must "derive a proposition from an existing document whose meaning compels or logically justifies the proposition. The substance of the derived proposition must flow fairly from the substance of the existing document." Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules, and "Spurious" Rules: Lifting the Smog*, 8 ADMIN. L. J. AM. U. 1, 6 n.21 (1994). If the rule cannot fairly be seen as interpreting a statute or a regulation, and if (as here) it is enforced, "the rule is not an interpretive rule exempt

from notice-and-comment rulemaking."[3] *Central Tex. Tel. Coop. v. FCC*, 402 F.3d 205, 212 (D.C. Cir. 2005) (citing *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. 1997)); *United States v. Picciotto*, 875 F.2d 345, 347-49 (D.C. Cir. 1989); *Hoctor v. USDA*, 82 F.3d 165, 170 (7th Cir. 1996).[4]

Although § 2162.2.A.4 of the Manual does not identify what it is purporting to interpret, the Manual's Foreword claims that every Manual provision rests on the "reasonable cost" language in the statute and the regulations. But as Professor Anthony has written, if the relevant statute or regulation "consists of vague or vacuous terms – such as 'fair and equitable,' 'just and reasonable,' 'in the public interest,' and the like – the process of announcing propositions that specify applications of those terms is not ordinarily one of interpretation, because those terms in themselves do not supply substance from which the propositions can be derived." *Lifting the Smog*, 8 ADMIN. L. J. AM. U. at 6 n.21. This court's opinion in *Paralyzed Veterans of America v. D.C. Arena L.P.*, stated much the same.

---

[3]The Medicare Act, 42 U.S.C. § 1395x(v)(1)(A), requires "reasonable cost" to "be determined in accordance with regulations establishing the method or methods to be used, and the items to be included . . .." This necessarily allows the Secretary to construe her regulations, but it does not appear to allow "reasonable cost" to be based on a rule that is neither part of a regulation nor an interpretation of a regulation.

[4]In *Central Texas*, 402 F.3d at 212, we acknowledged that the "APA's definition of 'rule' contemplates that . . . [both] legislative and interpretive [rules] may interpret 'law.' The EPA regulations at issue in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), for instance, interpreted the term 'stationary source' in the Clean Air Act (and did a good deal more). Nor may one say there is a clear 'line between interpretation and policymaking.' John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 924 (2004)."

117 F.3d 579, 588 (D.C. 1997). In support, *Paralyzed Veterans* cited *United States v. Picciotto*, a case in which the Park Service issued a detailed rule specifying types of property that "may not be stored" in Lafayette Park. 875 F.2d at 346. The rule supposedly interpreted a regulation allowing "additional reasonable conditions" to be added to demonstration permits. The court held that the rule did not interpret this "open-ended" regulation and therefore could not be enforced because it was not issued after notice and comment. *Id.* at 346, 349.

Another general principle cuts against the Secretary. Among other things, § 2162.2.A.4 of the Manual provides that an offshore captive insurer's "investments may include dividend paying equity securities listed on a United States stock exchange provided that the investment in equity securities does not exceed 10 percent of the company's admitted assets, with the investment in any specific equity issue further limited to 10 percent of the total equity security investment." Judge Friendly wrote that when an agency wants to state a principle "in numerical terms," terms that cannot be derived from a particular record, the agency is legislating and should act through rulemaking. HENRY J. FRIENDLY, *Watchman, What of the Night?*, *in* BENCHMARKS 144-45 (1967). We too have recognized that "numerical limits cannot readily be derived by judicial reasoning," although courts occasionally draw such limits.[5] *Missouri Pub. Serv. Comm'n v. FERC*, 215 F.3d 1, 4 (D.C. Cir. 2000). Our statement in *Missouri Public Service* relied on *Hoctor v. USDA*, 82 F.3d 165,

---

[5]*See, e.g.*, *United States v. Thirty-Seven Photographs*, 402 U.S. 363 (1971), which construed a federal statute authorizing the seizure and forfeiture of imported obscene materials to mean that judicial forfeiture proceedings had to be instituted within 14 days and completed within 60 days. The Court held that reading these time limits into the statute was necessary to save it from being declared unconstitutional in violation of the First Amendment.

170 (7th Cir. 1996). *Hoctor* held that an agency performs a legislative function when it makes "reasonable but arbitrary (not in the 'arbitrary or capricious' sense) rules that are consistent with the statute or regulation under which the rules are promulgated but not derived from it, because they represent an arbitrary choice among methods of implementation. A rule that turns on a number is likely to be arbitrary in this sense." *Hoctor* cautioned that the court did not mean "that an interpretive rule can never have a numerical component." 82 F.3d at 171. Examples in this circuit include *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993), and *Chippewa Dialysis Services v. Leavitt*, 511 F.3d 172, 176-77 (D.C. Cir. 2007) (dicta). "Especially in scientific and other technical areas, where quantitative criteria are common, a rule that translates a general norm into a number may be justifiable as interpretation." *Hoctor*, 82 F.3d at 171.

The *Hoctor* court concluded that "[w]hen agencies base rules on arbitrary choices they are legislating, and so these rules are legislative or substantive and require notice and comment rulemaking." *Id.* at 170-71. Section 2162.2.A.4 falls within that category. With respect to the ten percent limits "it is impossible to give a reasoned distinction between numbers just a hair on the OK side of the line and ones just a hair on the not-OK side." *Missouri Pub. Serv. Comm'n*, 215 F.3d at 4. Here the Secretary has not even made the attempt.

The short of the matter is that there is no way an interpretation of "reasonable costs" can produce the sort of detailed – and rigid – investment code set forth in § 2162.2.A.4.[6] This is

---

[6]It might have been a closer case if the Secretary's Manual had indicated that premiums paid to financially unstable captive offshore (or domestic) insurance companies do not represent "reasonable costs." But § 2162.2.A.4 of the Manual embodies a "flat" rule, and

essentially the point of the dissenting Board members. The statute gives the Secretary authority to promulgate regulations defining "the method or methods to be used, and the items to be included, in determining" what constitutes a provider's "reasonable costs." 42 U.S.C. § 1395x(v)(1)(A). We may assume, without deciding, that the Manual's investment limitations are an "extension" of the reasonable cost provisions in this section and the corresponding regulation, as the Board majority thought, and we may assume that the limitations are "consistent" with those provisions, as the Secretary has argued. But neither assumption leads to the conclusion that the Manual's limitations represent an interpretation of the Medicare Act or of the regulations. *See Hoctor*, 82 F.3d at 170.[7] Consistency with the statute may be enough to sustain a rule duly promulgated after notice and comment, just as consistency with the Commerce Clause, Art. I, § 8, cl. 3, may be enough to sustain the constitutionality of a statute. But no one would say, for instance, that the detailed provisions of the Clean Air Act were interpretations of the language of the Constitution. The same is true here. The connection between § 2162.2.A.4 of the Manual and "reasonable

---

the "'flatter' a rule is, the harder it is to conceive of it as merely spelling out what is in some sense latent in a statute or regulation . . . ." *Hoctor*, 82 F.3d at 171.

[7] *Hoctor* analyzed whether a U.S. Department of Agriculture rule requiring a fence of at least eight feet to enclose lions, tigers, and leopards was an interpretation of a regulation providing that the enclosure had to be of "such material and of such strength as appropriate for the animals involved." 82 F.3d at 167-68. Writing for the court, Judge Posner held that "[e]ven if . . . the eight-foot rule is consistent with, even in some sense authorized by, the structural-strength regulation, it would not necessarily follow that it is an interpretive rule. It is that only if it can be derived from the regulation by a process reasonably described as interpretation." *Id.* at 170.

costs" is simply too attenuated to represent an interpretation of those terms as used in the statute and the regulations.

Our concurring colleague agrees with us that § 2162.2.A.4 of the Manual cannot be sustained as a valid interpretation of "reasonable cost."[8] Based on her reading of *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995), our colleague does not put her conclusion in those terms and then criticizes us for determining that the Manual provision is not a proper interpretive rule. Our colleague's approach rests on what we perceive as a misreading of *Guernsey*. At no point did the Supreme Court suggest that interpretive rules do not have to interpret. The issue was not presented. *Guernsey* simply recognized that a particular provision in the Manual constituted "a prototypical example of an interpretive rule," *id.* at 99, something that cannot be said about the provision we have in front of us.

For the reasons given, the judgment of the district court is reversed. We remand the case to the district court with instructions to set aside the decision of the Provider Reimbursement Review Board and for such other relief as the district court deems appropriate in view of this decision.

So Ordered.

---

[8]Thus we are told that the "investment restrictions in the Manual are clearly outside [the] scope" of the Secretary's authority "to define the 'reasonable cost'," Concurring Op. at 10; that there is no "nexus" between the Manual provision and "reasonable cost," *id.*; that the "rigid" rule in the Manual lacks "any rational connection" to the statute's "'reasonable cost' principle," *id.* at 4-5; and so forth.

BROWN, *Circuit Judge*, concurring in the judgment: The court holds section 2162.2.A.4 of the Secretary's Provider Reimbursement Manual is invalid because the Secretary failed to promulgate it by notice-and-comment rulemaking. The court thus leaves the door open for the Secretary to promulgate an identical provision restricting the investment decisions of a provider's offshore captive insurance company as a full-fledged rule. But a deeper flaw runs through the Manual provision that cannot be cured by more procedure: it exceeds the Secretary's authority under the Medicare statute to determine the "reasonable cost" for which providers are reimbursed. Accordingly, I would close the door left enticingly ajar by the court and hold the Manual provision invalid as beyond the Secretary's authority.

I

Catholic Health Initiatives and its affiliated hospitals (the hospitals) challenge the Manual provision as exceeding the Secretary's authority under the Medicare statute. It is a cardinal principle of administrative law that an agency may act only pursuant to authority delegated to it by Congress. *See Lyng v. Payne*, 476 U.S. 926, 937 (1986) ("[A]n agency's power is no greater than that delegated to it by Congress."); *Transohio Sav. Bank v. Dir., Office of Thrift Supervision*, 967 F.2d 598, 621 (D.C. Cir. 1992) ("It is central to the real meaning of the rule of law . . . that a federal agency does not have the power to act unless Congress, by statute, has empowered it to do so."). When an agency has acted beyond its delegated authority, a reviewing court will hold such action *ultra vires*, *Transohio*, 967 F.2d at 621, or a violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(C) (directing courts to "hold unlawful and set aside agency action . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right").

Congress delegates authority to agencies through legislation, and we therefore look to the agency's enabling statute to determine whether it has acted within the bounds of its authority or overstepped them. *See Univ. of the D.C. Faculty Ass'n/NEA v. D.C. Fin. Responsibility & Mgmt. Assistance Auth.*, 163 F.3d 616, 620 (D.C. Cir. 1998) (explaining *ultra vires* claim requires the court to review statutory language to determine whether "Congress intended the [agency] to have the power that it exercised when it [acted]"). The Secretary defends the Manual provision as within her authority under 42 U.S.C. § 1395x(v)(1)(A), which provides:

> The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services . . . .

The Secretary argues, and the hospitals agree, that she has considerable discretion under this section to define what "reasonable cost" means. *See Richey Manor, Inc. v. Schweiker*, 684 F.2d 130, 134 (D.C. Cir. 1982) ("It is well established that Congress granted the Secretary broad discretion to develop the 'reasonable cost' concept, subject, of course, to the general standard enunciated in 42 U.S.C. § 1395x(v)(1)(A)."). However, the Secretary and the hospitals disagree over whether the Manual provision is a permissible exercise of that discretion.

The Manual provision, which the court quotes in full, places three specific investment restrictions on "offshore

captives": (1) an offshore captive seeking to invest its assets must invest 90% or more of them in "low risk investments," defined to include certain categories of government bonds, debt securities, and bank deposits; (2) an offshore captive may invest 10% or less of its assets in "dividend paying equity securities listed on a United States stock exchange"; and (3) an offshore captive must limit its investment in any one equity issue to 10% of the captive's total equity security investment. Manual ch.21 § 2162.2.A.4. The Secretary will consider the insurance premiums a provider pays its offshore captive insurance company to be "reasonable costs" reimbursable under the Medicare program only if the captive satisfies all three investment restrictions. But, as the hospitals argue persuasively, none of the restrictions fits comfortably, or even plausibly, within the plain meaning of "reasonable cost."

II

First, the investment restrictions exceed the Secretary's "reasonable cost" authority because they cause a blanket disallowance of reimbursement of a provider's insurance premiums, even though liability insurance coverage generally is an allowable cost of the provider's Medicare program. The Secretary freely admits "[t]here is no dispute that the costs of purchasing malpractice and workers' compensation insurance are, as a general matter, necessary and proper costs of furnishing health services to Medicare beneficiaries." Appellee's Br. at 23. Nevertheless, if a provider's offshore captive fails to observe just one of the three investment restrictions, the Secretary disallows 100% of the provider's premiums.

The absurd results arising from the investment restrictions' blanket disallowance rule are easy to grasp. For example, if a provider's offshore captive insurer invested in

ten dividend-paying equity securities listed on a United States stock exchange, placing 1% of its assets in each security, the Secretary would reimburse the provider for all premiums paid to the captive. But if the captive insurer invested 1% in *eleven* divided paying U.S. equity securities, the Secretary would refuse to reimburse the provider for a single penny of its premiums. Likewise, if the captive invested 98% of its assets in what the Manual defines as "low risk investments" but placed 2% of its assets in a single U.S.-listed equity security, the Secretary would deny any reimbursement. And in both of these illustrations, the Secretary's reimbursement decision would not change even if the captive remained solvent and paid substantial claims on behalf of the provider.

When the Secretary has established rigid all-or-nothing approaches to reimbursement under section 1395x(v)(1)(A), this court and others have rejected them as lacking any rational connection to "reasonableness." *See, e.g.*, *St. Mary of Nazareth Hosp. Ctr. v. Schweiker*, 718 F.2d 459, 467 (D.C. Cir. 1983) (rejecting Manual section 2345 because "for all practical purposes [it] would mean that hospitals would not be reimbursed at all for the costs of rendering care to Medicare patients in special care units. This result is ridiculous, contrary to the letter of 42 U.S.C. § 1395x(v)(1)(A) . . . ."); *County of L.A. v. Sullivan*, 969 F.2d 735, 741 (9th Cir. 1992) (explaining that "because the 100% limitation unnecessarily restricts reimbursement for ancillary services provided to Medicare patients, we hold that it contravenes the statutory requirements that the Secretary reimburse the hospitals for their reasonable costs and not shift Medicare patients' costs to non-Medicare patients or the hospitals themselves"); *Nw. Hosp., Inc. v. Hosp. Serv. Corp.*, 687 F.2d 985, 992 (7th Cir. 1982) (holding a "blanket disallowance of related-party interest expense . . . is broader than either the language or the purpose of the Medicare statute can be construed to authorize

[where] the government concede[d] interest expense is generally considered to be part of the 'reasonable cost' of providing Medicare services"); *see also Samaritan Health Serv. v. Bowen*, 811 F.2d 1524, 1531 (D.C. Cir. 1987) (noting that "[u]nder § 1395x(v)(1)(A), the sanction for [a provider's request for reimbursement of] 'high costs' would be nonreimbursement for the unduly high portion, not denial for the whole fee"). The investment restrictions in section 2162.2.A.4 of the Manual are no less harsh than the blanket disallowances struck down in prior decisions as exceeding the Secretary's "reasonable cost" authority under section 1395x(v)(1)(A).

The Manual itself reveals that the Secretary appreciates the stark difference between a blanket disallowance and application of section 1395x(v)(1)(A)'s "reasonable cost" principle. For instance, in disallowing reimbursement of luxury items or services, the Manual instructs that once the intermediary has concluded a luxury item or service was furnished to a patient, the "allowable costs must be reduced by the difference between the costs of luxury items or services actually furnished and the reasonable costs of the usual less expensive items or services furnished by a provider to the majority of its patients." Manual ch.21 § 2104.3.C. The Secretary has no credible explanation why reimbursement of insurance premiums should be treated any differently.

The investment restrictions also do not accurately reflect the "cost actually incurred" by a provider at the time it submits the insurance premiums to its offshore captive. Section 1395x(v)(1)(A) states "[t]he reasonable cost of any services *shall* be the cost *actually incurred*." 42 U.S.C. § 1395x(v)(1)(A) (emphasis added). A provider incurs the cost of obtaining liability insurance coverage when it submits the premiums to the offshore captive. Regardless of whether or

how the offshore captive subsequently invests the premiums and regardless of whether the captive ever pays a claim, the provider has "actually incurred" a cost of providing services to Medicare patients at the moment it pays the premiums. The Secretary's reimbursement for the "reasonable cost" of the provider's liability insurance therefore should be a function of the *premiums* paid, not of the coverage that the offshore captive may eventually provide. The Secretary's investment restrictions thus are an inaccurate measure of the provider's cost "actually incurred" in obtaining insurance coverage from its offshore captive and exceed her authority under section 1395x(v)(1)(A).

This principle was explored extensively by a number of courts after the Secretary, in 1979, promulgated a new regulation for calculating reimbursement of providers' malpractice insurance premiums (the Malpractice Rule). *See Menorah Med. Ctr. v. Heckler*, 768 F.2d 292, 293 (8th Cir. 1985). Providers successfully challenged the Malpractice Rule before many courts as exceeding the Secretary's authority under section 1395x(v)(1)(A). *See, e.g.*, *id.* at 296 (noting Secretary could not prove "a system of reimbursing malpractice premiums based solely on the proportion of malpractice losses will accurately reflect premium costs"); *Bedford County Mem'l Hosp. v. Health & Human Servs.*, 769 F.2d 1017, 1023–24 (4th Cir. 1985) (holding the Malpractice Rule contrary to section 1395x(v)(1)(A) because "[b]y basing reimbursement of malpractice costs solely on loss history, the Secretary has failed to take account of administrative expenses, a disproportionate share of which will be borne by non-Medicare patients under the Secretary's system").

In striking down the Malpractice Rule, one court perceptively explained why the Secretary's approach to reimbursement was inconsistent with insurance cost

principles: "[T]he Malpractice Rule violates the Medicare Act [by] fail[ing] to recognize that malpractice insurance protects against the risk of future loss. Even if a provider has never incurred any actual malpractice losses, for example, it must still purchase malpractice insurance because of the risk that losses will be incurred in the future." *St. James Hosp. v. Heckler*, 760 F.2d 1460, 1472 (7th Cir. 1985). The court noted that "[t]he carrying of malpractice insurance must be deemed a reasonable cost, and thus reimbursable by Medicare, regardless of whether a hospital has paid one dollar or one million dollars in malpractice claims over the relevant five-year period." *Id.* Thus, "[t]o the extent that the Malpractice Rule does not reimburse these costs, . . . it violates the Medicare Act's mandate that providers are entitled to government reimbursement for the 'reasonable cost' of the services they provide for Medicare patients." *Id.*

When we considered a challenge to the Malpractice Rule, we were more cautious than many courts. *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 799 (D.C. Cir. 1984). We recognized the Malpractice Rule required the Secretary to reconcile the statutory obligation to reimburse reasonable costs with the related obligation to prevent cross-subsidization between Medicare and non-Medicare patients. *See id.* at 799–800. Recognizing the tension between section 1395x(v)(1)(A)'s reasonable cost and cross-subsidization requirements, we remanded the case to the district court because the agency had failed to consider an alternative to the Malpractice Rule—separate pools of risk for Medicare and non-Medicare patients—that might more accurately reflect the actual Medicare costs incurred by the providers. *Id.* at 802–03. However, we still required the Secretary's approach to be consistent with both the reasonable cost and cross-subsidization requirements, and with the ultimate purpose of fairly reimbursing hospitals for their Medicare-related

insurance premiums. *See id*. at 801 (noting Secretary's interpretation of the Medicare statute to deny hospitals "some of their premium costs" was not arbitrary and capricious because "paying the percentage of premiums reflecting losses from Medicare patients would in the long run fairly compensate the insurance companies for their expenses, and thus would fairly reimburse the hospitals for necessary expenditures").

In contrast to the Malpractice Rule, the investment restrictions here blatantly contravene section 1359x(v)(1)(A) by preventing the hospitals from obtaining *any* reimbursement of their insurance premiums, while at the same time forcing the hospitals' non-Medicare patients to pay *all* of the cost of purchasing liability insurance coverage for Medicare patients, thereby violating section 1395x(v)(1)(A)'s prohibition on cross-subsidization. The courts that found the Malpractice Rule problematic undoubtedly would be even more troubled by section 2162.2.A.4 of the Manual since it makes no attempt to fairly approximate the provider's costs for obtaining insurance coverage if the offshore captive has failed to comply with one or more of the investment restrictions.

Furthermore, the Secretary has utterly failed to explain why it is unreasonable for a provider to purchase insurance coverage from an offshore captive that fails to invest according to the Secretary's mandate. One does not have to be a hedge fund manager to recognize it may be extremely *un*reasonable to invest one's assets as dictated by the Manual provision. A captive insurer, like any other prudent investor, may need to adjust its investment portfolio multiple times in a given year to respond to changing market conditions. What may be a wise investment one year may be foolish the next. If it is often reasonable for an offshore captive to invest its assets contrary to the investment restrictions in the Manual

provision, then it can hardly be unreasonable for a provider to pay premiums to the captive. And as the hospitals note, Medicare does not reimburse providers for malpractice claims, so the providers have every incentive apart from the Secretary's involvement to ensure they receive coverage from their insurers. The close alignment of interests between a provider and its captive insurer only adds to this incentive. The senselessness of punishing a provider for the investment decisions of its offshore captive insurer is underscored by the irrational nature of the investment restrictions themselves.

The Secretary's primary justification for the restrictions is that they are necessary to ensure offshore captives maintain sufficient reserves to pay future claims on behalf of Medicare providers. *See* Appellee's Br. at 23–24. The Secretary argues, "On a very practical level, [insurance premium] costs—even if in line with those paid by other, similarly situated providers—can be considered 'reasonable' only if they actually purchase reliable coverage for the insured providers." *Id*. at 23. Unmasked, however, the Secretary is asserting section 1395x(v)(1)(A) permits her to micromanage the investment decisions of offshore captive insurers, despite her lack of expertise in either investment strategy or insurance. *See St. Mary of Nazareth Hosp. Ctr.*, 718 F.2d at 466 (declining to defer to Secretary's statutory interpretation announced in Manual provision where agency's expertise was not implicated). The Medicare statute grants the Secretary authority to administer a reimbursement program for providers, not authority to establish an investment management program for vendors. It is unsurprising then that the Secretary's interpretation is far afield from Congress' intent for section 1395x(v)(1)(A) to meet providers' actual costs, both direct and indirect, of providing services to Medicare patients. *See* S. Rep. No. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1976 (June 30, 1965) ("The

provision in the bill for payment of the reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another, except where a particular institution's costs are found to be substantially out of line with those of institutions similar in size, scope of services, utilization, and other relevant factors.").

In sum, although the Secretary has broad authority under section 1395x(v)(1)(A) to define the "reasonable cost," this authority is not unlimited, and the investment restrictions in the Manual provision are clearly outside its scope. This case does not require us to determine what may be the outer limits of the Secretary's authority. Because the Manual provision has no discernible nexus with the Secretary's authority to determine reimbursement of "reasonable costs" under section 1395x(v)(1)(A), it is invalid.

III

The court's opinion raises several issues warranting a response. First, because the Manual provision exceeds the Secretary's authority, we need not and, indeed, should not address whether the provision should have been passed through notice-and-comment rulemaking. The court describes the notice-and-comment issue as "antecedent" to the question of the Secretary's statutory authority, Maj. Op. at 8. Not so. Where the agency has acted outside its statutory authority, notice and comment is no cure for the disease. *See Lyng*, 476 U.S. at 937; *Transohio*, 967 F.2d at 621. In contrast, a holding that the agency has exceeded its statutory authority negates any need to delve into the notice-and-comment issue. *See Am. Bus Ass'n v. Slater*, 231 F.3d 1, 7–8 (D.C. Cir. 2000) ("Because we hold [the agency] had no authority to promulgate that rule in the first instance, the Court finds it unnecessary to take up [appellant's] notice-and-

comment claim. The agency has exceeded the scope of the authority delegated to it by Congress, and it matters not that they adhered to the APA's procedural requirements in doing so."). Thus it was pointless for the hospitals to argue the Manual provision should have been passed by notice-and-comment rulemaking when it plainly exceeded the Secretary's authority. This explains why the hospitals raised the notice-and-comment issue in a single footnote of their opening brief, *see* Appellants' Br. at 32 n.13, or as the court describes it, "without much elaboration," Maj. Op. at 8, while devoting the lion's share of their briefs to challenging the Secretary's statutory authority. And counsel for the hospitals confirmed this was their position at oral argument:

> The Court: So your position is that if [the Secretary] had gone through a notice-and-comment rulemaking and received whatever substantial evidence support what appears in the Manual, that even then [she] couldn't promulgate this rule?
>
> Counsel: . . . That is both our position and, obviously, the logical import of our position.

Oral Arg. Recording at 11:21–40.

The hospitals paid the insurance premiums for which they seek reimbursement during the period from 1997 to 2002. The Board conducted a hearing on the hospitals' appeal from the intermediary's denial of reimbursement in 2004 but did not issue its decision until 2007. The district court issued its decision in 2009. It is time for this dispute to end. Fortunately for the hospitals, the court's opinion should allow for quick resolution of their reimbursement claims,

since, even if the investment restrictions are passed through notice-and-comment procedures, the Secretary will be unable to apply them retroactively to the hospitals. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208–213 (1988) (holding Secretary lacks authority under section 1395x(v)(1)(A) to promulgate cost-limit rules with retroactive effect). Nevertheless, there is no good reason for the court to give the Secretary the opportunity to prospectively promulgate a rule implementing precisely the same restrictions when she has offered no basis to believe her statutory authority reaches that far in the first place. *See PIA-Asheville, Inc. v. Bowen*, 850 F.2d 739, 740–41 (D.C. Cir. 1988) (noting "the Secretary offers no new substantive justification for his erstwhile policy, but instead claims that the existence of the new regulation incorporating that policy should change our view" and rejecting this argument where court had held in prior decision that the policy violated the statutory requirement to reimburse reasonable costs). Instead, we should do as courts ordinarily do and answer the question the parties have put before us—particularly since that answer would resolve this dispute for good.

Second, the court's opinion may cause unintended and unwelcome consequences by calling into question the procedural legitimacy of many other provisions in the Manual. In *Shalala v. Guernsey Memorial Hospital*, the Supreme Court affirmed the Secretary's use of the Manual to provide guidance to providers and intermediaries, describing its interpretive rules as part of "a sensible structure for the complex Medicare reimbursement process," 514 U.S. 87, 101 (1995). As we have noted, the Court in *Guernsey* explained the Secretary "does not have a statutory duty to promulgate regulations that 'address every conceivable question in the process of determining equitable reimbursement.' Rather, for 'particular reimbursement details not addressed by'

regulations, [the Secretary] properly 'relies upon an elaborate adjudicative structure which includes the right to review by the [Board].'" *Tenet HealthSystems HealthCorp. v. Thompson*, 254 F.3d 238, 248 (D.C. Cir. 2001) (quoting *Guernsey*, 514 U.S. at 96).

The court's opinion ignores *Guernsey*'s test for whether a Manual provision must be promulgated by notice-and-comment rulemaking. *See Guernsey*, 514 U.S. at 100 (noting "APA rulemaking would still be required if [the Manual provision] adopted a new position inconsistent with any of the Secretary's existing regulations [but the Manual provision] does not . . . effec[t] a substantive change in the regulations") (internal quotation marks omitted). Moreover, the court fails to identify clear limiting principles by which the Secretary and providers can distinguish Manual section 2162.2.A.4 from other Manual provisions. For instance, the court states, "[T]he process of announcing propositions that specify applications of [vague] terms [such as "just and reasonable"] is not ordinarily one of interpretation, because those terms in themselves do not supply substance from which the propositions can be derived." Maj. Op. at 9 (internal quotation marks omitted). But this perspective fails to account for the way complex regulatory regimes such as Medicare really work. The Secretary relies on a hybrid of rulemaking and adjudication—an approach approved by the Court in *Guernsey*. *See* 514 U.S. at 96–97 ("The APA does not require that all the specific applications of a rule evolve by further, more precise rules rather than by adjudication. The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate."). Interpretive rules are the glue that holds this regulatory structure together. The Secretary's administration of the Medicare program frequently calls for specific applications of vague statutory terms, including

"reasonable cost," and, as we have noted, "an agency may use an interpretive rule to transform a vague statutory duty or right into a sharply delineated duty or right." *Cent. Tex. Tel. Co-op, Inc. v. FCC*, 402 F.3d 205, 256 (D.C. Cir. 2005); *see also id.* ("[A]n interpretive rule does not have to parrot statutory or regulatory language but may have the *effect* of creating new duties.").

By ignoring these principles, the court's opinion calls into question many other provisions in the Manual. *See*, *e.g.*, Manual ch.2 § 215.1 ("An exception to this limitation is permitted when the debt cancellation costs are less than 50 percent of the amount of interest cost and amortization expense that would have been allowable in that period had the indebtedness not been cancelled, in which case, the full amount will be allowable in the period incurred."); *id.* ch.21, § 2162.5 (establishing a 10% test for determining when losses relating to insurance deductible are allowable costs); *id.* ch.21, § 2109.2.D ("The allowance for membership in professional associations and continuing medical education is limited to the lesser of actual cost or 5 percent of the applicable [Reasonable Compensation Equivalent] base amount."); *id.* ch.22 § 2208.1.E (establishing the specified percentages for the per diem method of cost apportionment as 93% for short-term hospitals and 98% for long-term hospitals); *id.* ch.22 § 2202.7.II.A.5 ("A minimum nurse-patient ratio of one nurse to two patients per patient day must be maintained . . . .").

As the Secretary's counsel explained during oral argument, "*Guernsey* . . . stands for the proposition that the technical specifics of the application of the broad Medicare standards are appropriately resolved through adjudication by the agency with the Manual guideline as a tool . . . ." Oral Arg. Recording at 21:22–51. In light of *Guernsey*'s

endorsement of the Secretary's "sensible structure" for administering the Medicare program, courts should refrain as much as possible from tinkering with this regulatory framework. *See Nat'l Med. Enters., Inc. v. Shalala*, 43 F.3d 691, 693, 696–97 (D.C. Cir. 1995) (deciding Manual section 2203 which "provide[d] a three-part guide for allocating costs to routine or ancillary centers" was an interpretive rule rather than a substantive rule requiring notice and comment); *Sentara-Hampton Gen. Hosp. v. Sullivan*, 980 F.2d 749, 759–60 (D.C. Cir. 1992) (per curiam) (holding Manual provision not subject to notice-and-comment rulemaking). Invalidating the Manual provision as exceeding the Secretary's authority thus is less intrusive than declaring the provision must be enacted, if at all, by notice-and-comment rulemaking. The first approach affects only the investment restrictions while the second casts doubt upon the procedural legitimacy of the Manual as a whole.

* * *

The investment restrictions in the Manual provision are beyond the Secretary's authority because they have no connection to the "reasonable cost" language in section 1395x(v)(1)(A) of the Medicare statute. I would hold the provision invalid on that basis alone.