No. 10-56529

United States Court of Appeals for the Ninth Circuit

Palomar Medical Center,
Plaintiff/Appellant,

vs.

Kathleen Sebelius, Secretary of
The United States Department of Health and Human Services,
Defendant/Appellee.

On Appeal from the United States District Court
For the Southern District of California

Brief of *Amici Curiae* American Medical Association and California Medical Association Supporting Plaintiff/Appellant and Reversal

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RULE 26.1 CERTIFICATION

In compliance with Fed. R. App. P. 26.1, *amicus* the American Medical Association (AMA) states that it is a nonprofit corporation organized and operating under the laws of the State of Illinois. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

Amicus the California Medical Association (CMA) states that it is a nonprofit corporation organized and operating under the laws of the State of California. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

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INTEREST OF *AMICI CURIAE*

The AMA is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in every medical specialty area and in every state, including California.

The CMA is a professional association of more than 30,000 physicians practicing in the State of California. CMA's membership includes California physicians engaged in the private practice of medicine in all specialties. CMA's primary purposes are ". . . to promote the science and art of medicine, the care and well-being of patients, the protection of public health and the betterment of the medical profession." CMA and its members share the objective of promoting high quality, cost-effective health care for the people of California.

Amici appear herein in their own capacities and as representatives of the Litigation Center of the AMA and the State Medical Societies. The Litigation Center is a coalition of the AMA and state medical societies to

represent the views of organized medicine in the courts, in accordance with AMA policies and objectives.

Amici seek to protect those physicians who participate in the Medicare program from arbitrary and unreasonable efforts to recover payments for services rendered long prior to the initiation of the recovery action. Although the instant case concerns a recovery action against a hospital, *amici* believe this case could set a precedent that would affect the rights of physicians who participate in the Medicare program. Recovery actions are particularly burdensome to solo or small group practices, which may have limited personnel available to address payment documentation issues.

These burdens are not just financial. Recovery audit and collection proceedings divert physician and staff time from patient care. The disruptions to physicians' practices only increase as claims age, records are sent to storage or become otherwise inaccessible, and memories fade. When the burdens of Medicare participation become too onerous, physicians may decline to continue their participation, with potentially drastic consequences to the nation's health.

Pursuant to Fed. R. App. P. 29(c)(4), *amici* state that the source of their authority to file this brief is the consent of the parties.

SUPPLEMENT TO PALOMAR'S STATEMENT OF THE CASE

The rehabilitation services Palomar provided to Mr. Doe were in accordance with a physician's direction and were needed to help Mr. Doe recover from hip replacement surgery. The Department of Health and Human Services (HHS) seeks to justify its recoupment of the money paid to Palomar because the services were purportedly not "medically necessary." What HHS actually means, however, is that the services were not fiscally justified under the Medicare guidelines. According to HHS, Mr. Doe could have received adequate rehabilitative treatment at a skilled nursing facility, in which case the rehabilitation would have justified a lower level of payment.

The medical profession recognizes a different definition of "medical necessity" than does Medicare. Under AMA Policy H-320.953[3], "medical necessity" is defined as follows:

> "Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of

> the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider."

See http://www.ama-assn.org/ama1/pub/upload/mm/363/insurance-conduct.pdf, at pp. 15-16. CMA has its own policy, HODD-2-10, which adopts the AMA definition of "medical necessity" with minor modifications. See http://www.cmanet.org/member/memberdoc.cfm?templateinc=POLICYNEW&docid=28&parent=26&policyid=6984.

Congress gives HHS latitude to determine what health care services it will pay for and in what amounts and even, perhaps, to coin terms of art that may have specialized meanings within the context of the Medicare program. Nevertheless, *amici* emphasize that nothing in the record suggests that the services provided to Mr. Doe were medically unnecessary under the criteria of the medical profession.

ARGUMENT

I. The HHS Regulations, as Interpreted by HHS and By the Lower Court, are Arbitrary or Capricious.

The Administrative Procedure Act (APA) provides that a reviewing court shall "hold unlawful and set aside agency action … found to be … arbitrary, capricious, … or otherwise not in compliance with law." 5 USC § 706(2)(A). The Palomar brief argues persuasively that Congress intended that administrative law judges (ALJs) have jurisdiction to review reopening decisions, and any decision, as in this case, premised on the contrary proposition is "not in compliance with law." Furthermore, Palomar demonstrates that HHS has, in practice, frequently allowed administrative appeals of reopening determinations, and for that reason the contrary decision in this case is arbitrary and capricious. *Amici* will not repeat those arguments.

Instead, *amici* point out that if, *arguendo*, this Court were to accept the HHS proposition (as did the court below) that ALJs lack such jurisdiction, the result, both as a general proposition and under the specific facts of this case, would be arbitrary and capricious. Thus, even if this Court were to find that the ALJ decision was made without authority, the result below still should not stand.

In this case, HHS maintains that the ALJ ruling, which found the decision to reopen the Palomar claim improper under the 42 C.F.R. § 405.980(b) criteria, was made without authority. It relies for that proposition on 42 C.F.R. §§ 405.926(l) and 405.980(a)(5). Even if such were the case, though, the decision to reverse the ALJ ruling would be, under the same regulations, itself invalid.

Under the HHS interpretation, 42 C.F.R. § 405.926(l) provides not only that the decision of the contractor to reopen cannot be subject to appeal, but also

> "Actions that … are not appealable under this subpart include …(i) … [an] ALJ's determination or decision to reopen or not to reopen …"

Likewise, 42 C.F.R. § 405.980(a)(5) states

> "The … ALJ's … decision on whether to reopen is binding and not subject to appeal."

So, whether or not ALJs may err in overturning a reopening decision, as is argued to have happened in this case, higher administrative authorities have no right to remedy the putative mistake.

Certainly, the regulations contemplate some role for ALJs in the determination "not to reopen;" else they would not refer to the "ALJ's determination or decision" in connection with that process. It may be that

this role in the reopening process exists "only by the grace of the Secretary." *Your Home Visiting Health Services v. Shalala*, 525 U.S. 449, 454 (1999). Nevertheless, that role is memorialized in the HHS regulations, and HHS is now bound to abide by those regulations.

If there is no right to correct an error in the decisional process when made by a contractor, then there is no right to correct an error when made by an ALJ. In other words, if the regulations require a provider to live with an erroneous result, so must HHS live with the ALJ determination – erroneous or not – under the same regulations.

By any reasonable definitions of the words, these regulations smack of arbitrariness and caprice. For an administrative regulation to be valid, it must mandate a consistent application of the law. *Allentown Mack Sales and Service v. NLRB*, 522 U.S. 359 (1998). Furthermore, a regulation must be internally consistent. *General Chemical Corp. v. United* States, 817 F.2d 844 (D.C. Cir. 1987). To avoid arbitrariness and capriciousness, agencies must "treat like cases alike." *Water Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). And, it is "the essence of arbitrary and capricious action" for an administrative agency to violate its own guidelines. *Squaw Trust Co. v. United States*, 574 F.2d 492, 496 (10th Cir. 1978).

Under the HHS reading of 42 C.F.R. §§ 405.926(l) and 405.980(a)(5), there is no requirement for consistent application of the law or for treating like cases alike. The reopening process is to depend not on the criteria set forth in 42 C.F.R. § 405.980(b) but on who in the administrative food chain may have been the last to weigh in, rightly or wrongly, in the reopening decision. And of course, HHS did not in this case follow its own regulations, because, contrary to those regulations, it overturned the decision of the ALJ not to reopen the payment to Palomar.

HHS, Magistrate Judge Stormer, and District Court Judge Benitez justify the administrative actions in this case on the grounds that agencies enjoy discretion to interpret their own regulations. While administrative agencies are generally accorded such deference, that rule should not apply here. These regulations do not pass the basic standards for consistent application of the law. To drive that point home, HHS exceeded the unambiguous limitations on its own power when the Medicare Appeals Council overturned the supposedly "binding," unappealable decision of the ALJ. It is no wonder, as these regulations invite such inconsistency.

Thus, 42 C.F.R. §§ 405.926(l) and 405.980(a)(5) should be found invalid on their face. If not, the actions of HHS in this specific case should be found arbitrary or capricious.

II. The HHS Regulations, as Interpreted by HHS and By The Lower Court, Violate the "Take Care" Clause of U.S. Const. Art. II, § 3.

Article II, § 3 of the United States Constitution reads, in part, as follows:

"[The President] shall take Care that the Laws be faithfully executed." As HHS and the lower court interpret the powers and responsibilities of HHS under 42 C.F.R. §§ 405.926(l) and 405.980(a)(5), the President is prevented from doing just that.

42 C.F.R. § 405.980(a)(5) states that the decision of "the contractor" on whether to reopen "is binding." HHS has argued and the lower court has held that the binding force of the reopening decision is notwithstanding that the decision may have violated the reopening criteria of 42 C.F.R. § 405.980(b). At p. 15 of its Memorandum of Points and Authorities in Support of Defendant's Motion for Summary Judgment and in Opposition of Plaintiff's Motion for summary Judgment (Doc. 24-1 below), HHS, citing to various authorities that it had promulgated, asserted: "the good cause regulation is meant only to supply a metric for evaluating Medicare contractors without granting any rights to providers." Later on the same page, HHS states:

> "The agency's construction of the good cause standard – as enforceable through the Secretary and CMS's internal performance reviews of contractors only but **not** as creating any enforceable rights for provider – was reiterated throughout the promulgation process for the good cause regulations."

Notably, there is no suggestion that the "binding" decision of an independent, private contractor to reopen would be subject to oversight or reversal by HHS in the context of a specific case or through any mechanism other than an overall, after the fact performance review.

Federal regulations are deemed "laws" of the United States within the contemplation of the Constitution. *City of New York v. FCC*, 486 U.S. 57, 63 (1988) (Supremacy Clause case). Under the "Take Care" Clause, the President is affirmatively required to make sure that the laws are faithfully executed. *United States v. Nixon*, 418 U.S. 683 (1974); *United States v. Cox*, 342 F.2d 167 (5th Cir. 1965), *cert. denied*, 381 U.S. 935 (1965).

The various departments of the United States, here HHS acting through its Secretary, act on behalf of the President. *National Treasury Employees Union v. Nixon*, 492 F.2d 587, 613 (D.C. Cir. 1974). Thus, these departments must take care that the laws they administer are faithfully

executed. At least, they should not erect roadblocks to prevent faithful execution.

General, *post hoc* oversight of an independent contractor's performance is not sufficient to meet the Take Care Clause requirements. While the exact facts of the instant case appear to be *sui generis*, the *National Treasury Employees Union* case, *id.*, is instructive in making this point. There, Congress had enacted a law that required the President to determine, based on comparisons with private sector jobs, how much federal employees should be paid and then to adjust their pay accordingly. President Nixon refused to do this, and the National Treasury Employees Union ("NTEU") sued for a writ of *mandamus*, based on the Take Care Clause. The President raised several defenses, one of which was that the appropriate mechanism for ensuring that he carries out his duties under the law was through impeachment, rather than judicial action. To this the court remarked

> "However, even if such failure to enforce constitutes an impeachable offense under the Constitution, it hardly opens up a meaningful road to effectuate the rights of NTEU's members under [the law mandating a pay adjustment], certainly not on any reasonably timely schedule."

Id., at 615.

Although the analogy between the case at bar and the *NTEU* situation is not exact, it does carry logical force. The reopening guidelines do exist, and on their face they are intended to benefit health care providers, such as Palomar, who may find it difficult to defend against a stale claim. HHS contends – and the lower court found – that providers cannot enforce those guidelines either administratively or through the courts. HHS abjures any right within itself to enforce those guidelines except through internal performance reviews. For those providers, like Palomar, who have already repaid claims, such reviews provide no road, "meaningful" or otherwise, to protect their rights, and there would be no timetable, let alone a reasonable timetable, to ensure that the law was "faithfully executed" as to them. Under the interpretation HHS has given, the President and his agent (HHS) would not be fulfilling their constitutional duty to ensure faithful execution of the law.

Palomar has every right to complain in this Court about the Take Care Clause violation. As a general principle, "where a specific duty is assigned by law, and individual rights depend upon the performance of that duty, it seems … clear that the individual who considers himself injured, has a right to resort to the laws of his country for a remedy. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 166 (1803).

More particularly, *American Historical Association v. Peterson*, 876 F.Supp. 1300 (D.D.C. 1995), offers guidance on a private party's right to complain about a Take Care Clause violation by an administrative agency. That case concerned the legality of an agreement between President George H.W. Bush and the National Archivist (the Bush-Wilson agreement) to deem certain electronically stored presidential records as the personal property of President Bush, rather than the property of the United States government. Under the Bush-Wilson Agreement, President Bush was to direct the Archivist in the identification and disposition of the records after he left office. However, the Presidential Records Act (PRA) provided that the United States was to "reserve and retain complete ownership, possession, and control of Presidential records." 44 USC § 2202. In a suit brought by a group of historians, researchers, librarians, and journalists, the court found the Bush-Wilson Agreement in violation of the PRA and also the Take Care Clause. In regard to the Take Care Clause issue, President Bush's successor, President Clinton, was required to direct the actions of the National Archivist, but the Bush-Wilson Agreement purported to give ex-President Bush, now a private citizen, the power to impose his own direction on the National Archivist.

The defendants, the currently acting National Archivist and ex-President Bush, argued that the plaintiffs, being private parties, had no cause of action to raise the Take Care Clause argument. The court, however, found otherwise, stating:

> "The APA, however, explicitly establishes a cause of action for private parties seeking judicial review of agency action, including review of whether such action is 'contrary to constitutional right, power, privilege, or immunity.' 5 USC § 706(2)(B)."

876 F. Supp. at 1321. The court then declared the Bush-Wilson Agreement to be invalid and enjoined the defendants from implementing it.

The Take Care Clause prohibits the Executive Branch from divesting itself of the power to ensure that 42 C.F.R. § 405.980(b) is faithfully executed. The regulations at issue here, 42 C.F.R. §§ 405.926(l) and 405.980(a)(5), as interpreted by HHS and the lower court, create such divestment. They therefore exceed the constitutional power of HHS, and the APA gives Palomar a cause of action to complain of this violation.

III. The HHS Regulations, as Interpreted by HHS and By the Lower Court, Would Preclude Judicial Review, In Violation of 5 USC § 702 and 5 USC § 706(2)(C).

Even if 45 C.F.R. §§ 405.926(l) and 405.980(a)(5) preclude Palomar from contesting the reopening determination at the administrative level, they

do not preclude Palomar from contesting that determination in court. Inasmuch as Palomar already covered this point in its brief, however, *amici* will not repeat the argument.

CONCLUSION

The HHS regulations are arbitrary and capricious on their face and as applied to the specific facts of this case. Further, as interpreted by HHS and the lower court, they violate the Take Care Clause of Article II, § 3 of the Constitution. In addition, as so interpreted they infringe upon the Congressionally created right of judicial review.

For these reasons and for the reasons set forth in the Palomar brief, the judgment of the lower court should be reversed and the case should be remanded. The lower court should be instructed, on remand, to grant Palomar's motion for summary judgment or, in the alternative, to proceed further in accordance with the opinion of this Court.

Respectfully submitted,

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Date: January 26, 2011

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RULE 29(c)(5) STATEMENT

Pursuant to Fed. R. App. P. 29(c)(5), *amici* state:

- No party's counsel authored this brief in whole or in part.
- No party or party's counsel contributed money that was intended to fund preparing or submitting this brief.
- No person other than *amici* contributed money that was intended to fund preparing or submitting this brief.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Circuit Rule 29-2(c)(1), I certify that this brief is proportionately spaced, has a typeface of 14 points or more, and that the body of the brief (excluding the cover page, table of contents, table of authorities, signature block, statement of related cases, certificate of service and this certificate of compliance) contains 2,969 words, as calculated by the word processing system used to prepare the brief.

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PROOF OF SERVICE

I, Long X. Do, certify that on this 26th day of January, 2011, a copy of the foregoing Brief of *Amici Curiae* the American Medical Association and the California Medical Association Supporting Plaintiff/Appellant and Reversal was served on all counsel of record by electronically filing it with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the Appellate ECM/ECF system, which automatically provides electronic notification to the following persons:

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