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MEDICARE LITIGATION: EXPERIENCES WITH COURTS PAST AND PRESENT

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I. CASES ADDRESSING DEFICIENCIES IN NOTICES TO BENEFICIARIES

Gray Panthers v. Schweiker, 466 F.Supp. 1317 (D.D.C. 1979), rev'd, 652 F.2d 146 (D.C.Cir. 1980), appeal after remand, 716 F.2d 23 (1983).

Nationwide class action brought by Medicare beneficiaries denied a hearing by statute that required at least $100 in controversy. Held: due process requires that plaintiffs receive an adequate notice of the reasons for denial, and an opportunity to present evidence either telephonically or in person, depending on circumstances of the case.

Martinez v. Richardson, 472 F.2d 1121 (10th Cir. 1973).

Court held that due process entitles home health beneficiaries to a hearing prior to termination of their benefits. Exhaustion of administrative remedies was not required because of hardship to beneficiaries, and there was mandamus jurisdiction.

Grijalva v. Shalala, 946 F.Supp. 747 (D.Ariz. 1996), aff'd 152 F.3d 1115 (9th Cir. 1998), vacated and remanded, 526 U.S. 1096 (1999), on remand, 185 F.3d 1075 (9th Cir. 1999), on remand, Civ. 93-711 TUC ACM (Dec. 5, 2000 Order Approving Settlement Agreement).

Both the district court and the court of appeals held that due process applies to entitle Medicare beneficiaries in managed care plans to adequate notice of adverse action and timely or expedited hearings. After remand from the Supreme Court for consideration of the state action issue, the nationwide class action was settled with significant liberalization of managed care appeal procedures. Plaintiffs' claims concerning inadequate enforcement of Medicare coverage rules by the Secretary were dismissed without prejudice.

Lutwin v. Thompson, 361 F.3d 146 (2nd Cir. 2004), aff'g in part, rev'g in part *sub nom. Healey v. Thompson*, 186 F.Supp.2d 105 (D.Conn. 2001).

This nationwide class action successfully challenged the Secretary's failure to provide home health beneficiaries with written notice of reduction or termination of home health services. The Second Circuit held that the notice required by statute was not limited to curtailment of services based on adverse Medicare coverage determinations, but it upheld the district court's rejection of plaintiffs' claim for a pre-deprivation review procedure for decisions made by a home health agency.

Weichardt v. Leavitt, C-03-5490 VRW (N.D.Cal. Order of Dismissal Oct. 25, 2005).

Plaintiffs challenged the regulations establishing notice and appeal procedures upon discharge of Medicare patients from hospital on due process and APA grounds. The case was settled, with CMS agreeing to publish a Notice of Proposed Rulemaking with the following terms: 1) a standardized discharge notice given to the patient on the day before discharge; 2) the standardized notice informs the patient of her right to request a detailed notice of the reasons for discharge; and 3) the notice further informs her of the right to request an immediate appeal to the Quality Improvement Organization and remain in the hospital until the day after the appeal decision without charge. The final regulations deviated from the proposed regulations required by the settlement agreement. See 71 F.R. 68708 (Nov. 27, 2006).

Connecticut State Department of Social Services v. Leavitt, 242 F.Supp.2d 127 (D.Conn. 2003), rev'd, 428 F.3d 138 (2d Cir. 2005).

A Connecticut class of beneficiaries eligible for both Medicaid and Medicare ("dual eligibles") and a state agency sued the U.S. Dept. of Health and Human Services alleging that the failure of a fiscal intermediary to provide written initial determinations and timely decisions concerning home health care for dual eligibles violates the Medicare statute and due process. After a ruling in favor of plaintiffs in the district court, the court of appeals reversed, holding that Medicare fiscal intermediaries are not required to issue initial determination notices when the provider has not filed a claim; that statutory or regulatory citations are not required in notices; and that notices need not be sent to beneficiary representatives.

II. MEDICARE LITIGATION CONCERNING CLAIMS PROCESSING ISSUES

Schweiker v. McClure, 456 U.S. 188 (1982).

The Supreme Court reversed a district court decision holding that the appointment of Part B hearing officers by the private carriers that denied beneficiaries' claims initially does not violate due process.

Sarrassat v Sullivan, Medicare & Medicaid Guide (CCH) ¶ 38,504, 1989 WL 208444, Civ. Act. No. 88-20161 RPA (N.D.Cal. Order Approving Settlement Agreement May 17, 1989).

Action brought by Medicare beneficiaries whose nursing homes refused to submit claims for coverage to Medicare. The case was settled, with HCFA agreeing to adopt procedures requiring participating nursing homes to give beneficiaries notice of their right to request that claims ("demand bills") be submitted to Medicare even when the nursing home believed that Medicare would deny coverage. Billing was prohibited unless and until after the Medicare intermediary made an adverse decision on the claim.

Linoz v. Heckler, 800 F.2d 871 (9th Cir. 1986).

The Ninth Circuit overturned a district court decision in action brought by Part B beneficiaries challenging a manual provision denying coverage for ambulance services to transport a beneficiary from one hospital to another with a specialist physician. The court held that the manual provision was a substantive rule (in conflict with the statute) that had not been promulgated pursuant to the Administrative Procedure Act.

Vorster v. Bowen, 709 F.Supp. 934 (C.D.Cal. 1989).

Class action challenged use of frequency of service screens in Part B claims determination. The court held that 1) use of screens does not violate Medicare statute, but 2) notice must be given to beneficiary that a screen was the basis for denial and more information needs to be submitted to show that number of services received were medically necessary.

Zinman v. Shalala, 835 F.Supp. 1163 (N.D.Cal. 1993), aff'd, 67 F.3d 841 (9th Cir. 1995).

A nationwide class of Medicare beneficiaries challenged the Secretary's interpretation of the Medicare Secondary Payer statute to demand recovery of the full amount of its payments for medical services from a personal injury settlement, although the beneficiary did not receive the full amount of her medical bills. The court held that the statute was ambiguous and the Secretary's interpretation was reasonable.

Erringer v. Thompson, 371 F.3d 628 (9th Cir. 2004)

Class action was partially settled at district court level with agreement to include description of use and appealabilty of Local Coverage Determinations ("LCDs") in Medicare denial notices. The Ninth Circuit ruled against plaintiffs on remaining APA claim that criteria for LCDs was substantive rule requiring notice and comment rule-making.

Public Citizen v. U.S. Dept. of HHS, 332 F.3d 654 (D.C.Cir. 2003).

The D.C. Circuit affirmed a holding that D.H.H.S. regulations and manual, which prohibited disclosure of substantive disposition of Peer Review Organization review of the quality of care unless the physician consented, conflicted with the statute and were invalid.

Wallis v. Thompson, No. CIV-02-448-TUC-WDB, 2004 WL 1618894 (D.Ariz. June 10, 2004); *Guzzo v. Thompson*, 393 F.3d 652 (6th Cir. 2004).

These two cases successfully challenged the Medicare policy of denying coverage for a service formerly denied under a national coverage rule even after the agency had found that the particular service was "reasonable and necessary" -- until an effective date for the liberalized policy chosen by the agency.

Gray Panthers Project Fund v. Thompson, 273 F.Supp. 2d 32 (D.D.C. 2002), on motion for fees, 304 F.Supp.2d 36 (D.D.C. 2004).

The court held that the Secretary acted illegally by unilaterally extending a statutory deadline for Medicare+Choice Organizations (MCO) to submit information about coverage options, and by announcing that HHS would not follow a statutory directive requiring it to disseminate comparative plan information by mail. The court later awarded fees on the ground that the Secretary's violations of the statute were so blatant as to amount to bad faith.

III. CURRENT LITIGATION: PITFALLS AND SOLUTIONS.

Webber v. Norwalk, No. CIV 05-4219-PHX-NVW (D.Ariz. Order Feb. 7, 2007).

This case challenged regulations issued by CMS that set up a corps of Medicare Administrative Law Judges (ALJs) that perform most hearings by telephone or videoconferencing. The plaintiffs' cases were dismissed variously on standing and mootness grounds.

Action Alliance v. Leavitt, 456 F.Supp.2d 11 (D.D.C. 2006), vacated, 483 F.3d 852 (D.C.Cir. 2007).

Plaintiffs are Part D enrollees who were asked to return Part D premium amounts mistakenly refunded to them without being informed of their right to request waiver of the erroneous

payment. A district court preliminary injunction order that the Secretary send back the amounts returned to plaintiffs and offer them the right to waiver was vacated by the court of appeals, which held that the district court lacked jurisdiction because plaintiffs had failed to "present" their claims to the Secretary prior to commencing the lawsuit. Plaintiffs have since met the letter of the court of appeals' presentment requirement and may seek to file an amended complaint to "cure" the jurisdictional defect in the district court.

Situ v. Leavitt, 240 F.R.D. 551 (N.D.Cal. 2007) (class certification order) and 2006 WL 3734373 (2006) (ruling on motion to dismiss).

A nationwide class of beneficiaries enrolled in Medicare Part D brought this suit seeking to compel the Secretary to correct errors in the administration of the Low Income Subsidy (LIS) portion of the Part D prescription drug program. The motion to dismiss was granted as to several of the plaintiffs but not to most of them. A nationwide class was certified, and both discovery and magistrate-managed settlement discussions are underway.

Machado v. Leavitt, No. 07-30111-MAP (D.Mass. filed June 19, 2007).

This case brings claims under the Medicare statute, the anti-assignment provision of the Social Security Act, and due process, against the Secretary of HHS and the Commissioner of Social Security for continuing to withhold Part D premiums after plaintiffs asked them to stop. Plaintiffs also seek a return of the amounts improperly withheld.

Landers v. Leavitt, 232 F.R.D. 42 (D.Conn. 2005) (class certification) and 2006 WL 2560297 (2006) (merits), appeal pending, No. 06-4921 (2d Cir.).

The Secretary's policy of excluding days spent in a hospital emergency room or in "observation" status from its calculation of the 3-day hospital stay is at issue. The result of the exclusion is that plaintiffs did not qualify for Medicare coverage of their subsequent nursing home care, despite having spent 3 days or more in the hospital. Plaintiffs, on behalf of the nationwide class, are appealing the adverse decision of the district court.

Resident Councils of Washington v. Leavitt, 2005 WL 1027123 (W.D.Wash. 2005), aff'd, --- F.3d ---, 2007 WL 2458535 (9th Cir.).

Plaintiffs challenge regulations issued in 2003 that permit states to allow nursing facilities to use feeding assistants with only eight hours of training. A decision by the district court upholding the regulation was affirmed by the Ninth Circuit.

IV. ANALYSES OF LITIGATION BY TYPES OF ISSUES

a. Jurisdictional Issues

In some cases, the government has not raised the jurisprudential issues that it raises in other cases. Thus, in *Gray Panthers Project Fund, Healey* (aka *Lutwin*), and *Weichardt* the government did not question the standing of the organizational plaintiffs or suggest that the district court lacked jurisdiction under 42 U.S.C. § 405(g). It may be that the HHS Office of

General Counsel and/or the Justice Dept. Civil Division are becoming, or will become, more consistently aggressive on these and other issues, but for now there seems to be little logic as to why some types of challenges are raised and others are not.

In *Webber*, for instance, the Secretary contested the various individual plaintiffs' standing on a number of theories and was largely successful. More distressing, though, was that the government questioned venue, claiming that the venue provision in section 405(g) required that all the named plaintiffs reside in that district. The district court ultimately disagreed with that approach, holding that, like the general venue provision, as long as the district where the suit was filed was the proper venue for one named plaintiff, that would suffice for all the named plaintiffs. But if this issue is raised in future litigation, it may become increasingly difficult to bring class actions that cover more than one district.

A more disturbing development arose in the *Action Alliance* litigation, in which the government strongly disputed the standing of the organizational plaintiffs but raised no other jurisdictional challenges. On the government's appeal of the order granting plaintiffs' motion for preliminary injunction, however, the Court of Appeals *sua sponte* questioned whether the district court could properly exercise jurisdiction over the plaintiffs' claims. After receiving supplemental briefing on the issue, the court held that the plaintiffs had failed to "present" their claims under section 405(g). 483 F.3d 851 (D.C.Cir. 2007). Specifically, although the individual plaintiff had called Social Security and Medicare to complain, there was no allegation that she had specifically asked to have the overpayment waived. More distressing was that although the organizational plaintiffs had written a letter to the Secretary contending that the affected beneficiaries should be able to seek waiver of the overpayment, they had not specifically cited the statutory provision for requesting waiver. This extremely narrow view of what constitutes presentment deviates from Supreme Court authority and could establish a difficult procedural hurdle for plaintiffs to overcome in challenging the Secretary's policies.

In the *Situ* litigation, the government focused primarily on standing and mootness, which was problematic because, as with many cases of this type, the beneficiaries who become the named plaintiffs almost by definition have advocates, and those advocates are able to cut through the bureaucratic red tape and obtain the relief that the individuals need. At that point, the claims are no longer "live" and may be dismissed as moot. To avoid this problem, plaintiffs filed their class motion very soon after the complaint was filed, but the district judge questioned that tactic, contending that they should have waited until they had more information. This contrasted with the *Webber* case, in which the plaintiffs' decision to hold off filing the class motion was criticized by the district court, which contended that they should have filed it sooner to protect the class in the event (as it turned out) that the named plaintiffs' claims became moot.

The better practice is probably to file the class motion as soon as possible, and to run the risk of a district judge disagreeing with that tactic as opposed to -- as happened in *Webber* -- having the complaint dismissed altogether. In the recently filed *Machado* case, plaintiffs filed the class motion with the complaint.

In *Situ* the government also contended that many of the named plaintiffs had not presented their claims. The district court, however, following the standard practice of interpreting presentment liberally, concluded that calling either CMS, Social Security, or the Part D plan was sufficient to meet presentment. The court did not accept a broader theory, however, that, once eligibility has been established, a potential plaintiff need not specifically raise a particular claim in order to meet presentment. It was necessary, the court held, that the plaintiff take some action to challenge the specific action or inaction of the government at issue.

b. Substantive v. Procedural

The "procedural" cases tend to offer a greater opportunity to succeed or to achieve settlement. Even those cases, however, do have a significant built-in problem, because, whether resolution is by settlement or court order, the Secretary still has considerable discretion as to what steps to take in response. The determination that an existing procedure violates either the Medicare statute or due process does not guarantee that plaintiffs will be able to obtain as relief a procedure that is fully satisfactory.

For instance, in *Weichardt,* although the settlement set out the parameters of the proposed new regulations, the government contended that it could not be bound as to what the final regulations would look like. The consequence was that the final regulations departed significantly from what the parties had envisioned in the settlement documents, but, because of the need to follow the notice-and-comment rules, the settlement was technically not violated. Similarly, in *Healey*, although the courts held that the Secretary's notices to home health beneficiaries were not satisfactory, plaintiffs had relatively little control over how the notices ultimately appeared. Unlike in the eligibility context, procedural problems have numerous possible solutions in the remedy phase of a case, and plaintiff-beneficiaries cannot control the outcome as neatly as they do in substantive cases.

While the substantive cases may lend themselves to more easily definable and obtainable relief, winning them can be particularly difficult. Often, they are the product of regulations, which, except in rare cases, entitle the Secretary to considerable deference. In *Resident Councils of Washington,* in which the plaintiffs challenged the "feeding assistant" regulations as incompatible with the Nursing Home Reform Law, the district court upheld the regulation even though it represented a 180-degree reversal from the previous interpretation of the statute and no explanation was provided as to why that new interpretation was appropriate. (The unstated real reason was that a new Administration had taken over.)

The Ninth Circuit recently affirmed that decision, holding that the Secretary's interpretation was entitled to deference under *Chevron* and was reasonable. In the *Landers* case, which raised a challenge to a reimbursement policy (not a regulation) that limits coverage of follow-up SNF care to Medicare patients who spent three days in the hospital after formal admission (i.e., does not count time spent in the ER or on observation status), the district court, even though it had determined that "*Chevron* deference" of the Secretary's interpretation was not warranted, still deferred sufficiently to uphold the regulation -- despite expressing misgivings about the reasonableness of the policy. The appeal of that decision will be argued in late 2007 or early 2008.

c. "Practice" Cases

Another type of case that can be particularly difficulty to litigate is one in which the Secretary does not have a stated policy of taking or not taking certain action, but, rather, has a practice that results in arguably illegal behavior on a large scale. Such a situation creates particularly difficult problems for plaintiffs because, in addition to everything else, they must prove that the Secretary's actions amount to the violation of a statute or of due process. In *Healey,* this was accomplished by documents and statistics demonstrating that only a very few home health beneficiaries actually received notice of their rights -- even as the Secretary claimed that he had a policy requiring his intermediaries to provide notice. In *Situ*, which challenges the failure of the

Secretary to correctly implement the Low Income Subsidy program of Medicare Part D, the litigation has the potential of producing hundreds of thousands, or even millions, of pages of documents in order to demonstrate the extent of the Secretary's inadequacies. Even so, it is unclear how much evidence of failure is necessary to rise to the level of a de facto policy. And the recently filed *Machado* litigation has some of the same problems, but on a smaller scale, as plaintiffs are attempting to demonstrate that the numerous mistakes made by the Secretary and the Commissioner of Social Security in their premium withholding system are so endemic as to amount to a policy.

In these "practice" cases there is often little dispute that the statute is being violated on an individual basis. The question is whether there are so many individual violations that they rise to the level of a systemic violation. Given these problems, settlement may be the best answer in this kind of litigation

V. CONCLUSION

Since the inception of the Medicare program, successful litigation has tended to focus on procedural deficiencies such as inadequate notices or hearing rights. Now, confronted with legislative initiatives to privatize the program and courts that are tilting strongly to the right, advocates must think carefully about how they should structure future litigation.