

931 F.2d 914  
289 U.S.App.D.C. 276, 33 Soc.Sec.Rep.Ser. 302,  
Medicare&Medicaid Gu 39,181

DM.D., Secretary, Department of Health and  
Human Services.

*No. 90-5100.*

**United States Court of Appeals,  
District of Columbia Circuit.**

*Argued Jan. 22, 1991.  
Decided April 26, 1991.*

Appeal from the United States District Court for the District of Columbia.

James C. Pyles, with whom Barbara S. Woodall was on the brief, Washington, D.C., for appellants.

Robert M. Loeb, Atty., Dept. of Justice, with whom Stuart M. Gerson, Asst. Atty. Gen., Jay B. Stephens, U.S. Atty., Barbara C. Biddle, Atty., Dept. of Justice, and Henry R. Goldberg, Counsel, Dept. of Health and Human Services, were on the brief, for appellee. John C. Hoyle, Atty., Dept. of Justice, Washington, D.C., also entered an appearance for appellee.

Before MIKVA, Chief Judge, SENTELLE, and HENDERSON, Circuit Judges.

Opinion for the Court filed by Chief Judge MIKVA.

MIKVA, Chief Judge:

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Several home health care providers appeal from a district court decision rejecting their challenges to procedures adopted by the Department of Health and Human Services ("HHS") for the recoupment of Medicare overpayments. Appellants contend that the Secretary of HHS improperly suspended the existing individual claims adjudication process under Part A of the Medicare Act and replaced it with a scheme based on statistical sampling to calculate amounts of overpayment. In granting summary judgment to HHS, the district court held that the statistical method violated neither the terms of the Act nor procedural due process, and that the Health Care Financing Administration ("HCFA") Ruling 86-1 (which purported to explain the Department's legal authority for engaging in sample adjudication) was neither retroactively applied nor subject to notice and comment rulemaking. See *Chaves County Home Health Services, Inc. v. Sullivan*, 732 F.Supp. 188 (D.D.C.1990). We affirm the district court's decision.

I. BACKGROUND

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Appellants are health care providers who receive Medicare payments from HHS for home health services they provide to eligible individuals. The Medicare program is divided into two main parts, one providing insurance for hospital and related post-hospital services (known as "Part A," see 42 U.S.C. Secs. 1395c-1395i (1988 & 1990 Supp.)), and the other providing additional insurance for supplementary medical services ("Part B," see Secs. 1395j-1395w). ("Part C," Secs. 1395x-1395ccc, contains general provisions applicable to both Parts A and B.) The present dispute arises under Part A, which can be further divided into "coverage" determinations and "reasonable cost" determinations. See *Mount Sinai Hospital v. Weinberger*, 517 F.2d 329, modified, 522 F.2d 179 (5th Cir.1975), cert.

denied, 425 U.S. 935, 96 S.Ct. 1665, 48 L.Ed.2d 176 (1976). Coverage determinations involve decisions about whether specific items or services are covered by Part A; reasonable cost determinations yield periodic interim payments to providers based on estimated costs incurred and subject to a year-end reconciliation. See *id.* at 335-36.

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The present appeals concern only coverage determinations. The payment claims submitted by providers are initially processed by private entities under contract with the Department (called "fiscal intermediaries") on a case-by-case basis to determine (1) whether the amounts are for covered items or services provided to an eligible beneficiary, see Sec. 1395y(a)(1), and (2) whether, in case a service is not covered, HHS should waive this requirement. Waiver is routine so long as neither the beneficiary nor the provider knew or should have known that the items were not covered. See Sec. 1395pp(a). For purposes of the waiver determination, the Department presumes good faith by the beneficiary so long as he or she has not previously been notified that a service was not covered, see Sec. 1395pp(a)(2), and by the provider so long as fewer than 2.5% of its claims were disallowed in the previous quarter. See Sec. 1395pp(f)(1) & (4) (codifying the regulations in effect at the times relevant to these claims).

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HCFA Ruling 86-1, *Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers* (Feb. 20, 1986), describes the Department's policy of allowing fiscal intermediaries to conduct post-payment sampling audits to recoup suspected overpayments. The Secretary concluded that sampling provides the only feasible means for protecting the Medicare Trust Fund in situations where a provider is suspected of overbilling and the number of claims involved is large. See *id.* at 10. HCFA Ruling 86-1 details the type of audit that is appropriate in such circumstances: the fiscal intermediary examines a randomly selected and statistically significant number of sample claims along with their supporting documentation to determine whether they involved non-covered services that the provider knew or should have known were not covered. These results are then extrapolated to the entire universe of claims from that provider for a given time period. The full amount of the provider's overpayment liability is calculated from the percentage of claims denied in the sample. See *id.* at 11. The provider is given the same opportunity to challenge the non-coverage and waiver determinations regarding sample claims as that provided on pre-payment review, and, in case of any incorrect determinations, the overcharge projection will be correspondingly reduced. The provider can also challenge the statistical validity of both the sample and the extrapolation.

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In these cases, the Department decided to audit thousands of previously approved payment claims, allegedly after having received a tip that two of the appellants were overbilling, to determine whether there was a pattern of billing Medicare for non-covered services that the providers knew or should have known were not covered. The third appellant was targeted because its claims were so much higher than those of comparable providers. All the claims subject to post-payment review were initially approved, because the services were deemed covered or else waived on the premise that neither the provider nor the beneficiary had reason to know of non-coverage. Claims denied on post-payment review were ones involving non-covered services that HHS decided the provider (but not the beneficiary) had reason to know were not covered.

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The Department engaged in post-payment review of over 1000 claims submitted by and paid to Chaves County Home Health Service, Inc. ("Chaves"), over 2000 claims from Albuquerque Visiting Nurse Services, Inc. ("Albuquerque"), and over 10,000 claims from Bayonne Visiting Nurse Association, Inc. ("Bayonne"). The audit took representative samples of each group of claims (200

each from Chaves and Albuquerque, and 320 from Bayonne), determined that a certain portion of each sample group involved payment for non-covered services that the providers should have known were not covered, and then extrapolated that figure to all claims in assessing repayment liabilities (approximately \$47,000 against Chaves, \$138,000 against Albuquerque, and over \$1.5 million against Bayonne). These figures were reduced after successful appeals regarding denied claims in the sample. The Department withheld payments of subsequent claims to offset the unpaid liabilities. It is about that offset that the providers complain.

## II. ANALYSIS

### A. Statutory Authority

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The primary issue before us is whether Congress has allowed use of a sample auditing procedure for recoupment of overpayments to home health care providers. Nothing in the language or legislative history of the statute specifically authorizes sample audits on post-payment review of coverage determinations, but nothing expressly disallows it either. Appellants primarily rely on the individualized adjudication scheme for initial payment determinations and argue that a sample audit on post-payment review is incompatible with that scheme. By contrast, HHS emphasizes its general power to recoup overpayments and argues that this power authorizes assessments for overpayments based on extrapolations from a sample audit. Although appellants repeatedly emphasize the small sample size used in these cases (averaging less than 10% of all claims), they never took issue with the statistical validity of the procedure in the proceedings below even though an opportunity for such challenge was made available. We accept the Secretary's reading of the statute as permissible.

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According to appellants, nothing in the language of the statute or in its legislative history indicates that Congress authorized HHS to "suspend" individual coverage determinations and rights of appeal when such a procedure is deemed too burdensome. They argue that sample adjudication is incompatible with the statutory scheme requiring case-by-case review of payment claims to decide questions of coverage and waiver. Appellants do not take issue with sample auditing as such, but they assail the extrapolation of those results to the universe of all claims for recoupment purposes (hence the label "sample adjudication"). Appellants emphasize that extrapolation of a sample audit abrogates their right to appeal from specific denials, because they do not know which claims in a group were denied or the exact basis for the denials. The difficulty with their argument is that HHS has not, in fact, suspended individualized determinations and substituted sample adjudication on initial review of payment claims (a decision that would be inconsistent with the statute); instead, the Department has supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review of providers suspected of overbilling. We cannot find a statutory preclusion to such post-payment auditing nor to the method used to accomplish such objective.

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In deciding the statutory question, we are of course guided by the principles set out in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). "If the intent of Congress is clear, that is the end of the matter, ... [but] if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843-44, 104 S.Ct. at 2781-82; see also *Sullivan v. Everhart*, 494 U.S. 83, 110 S.Ct. 960, 964-66, 108 L.Ed.2d 72 (1990) (upholding as permissible the Secretary's construction of provisions of the Social Security Act as allowing a net calculation of over- and under-payments of benefits). Although at times appellants seem to be arguing that this is a "Chevron step one" case, they are hard pressed to show that Congress spoke to the specific question at issue here;

both the statute and legislative history fail to say anything explicit for or against sample adjudication. Appellants ultimately must contend that the Department's interpretation of its authority is unreasonable and not entitled to deference under Chevron 's second step.

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Appellants claim that there is no statutory basis for the Secretary's asserted authority and that, even if there is, other provisions in the Act render unreasonable the Secretary's interpretation of the statute as allowing post-payment sampling audits. We address each contention in turn.

1. Source of the Secretary's Authority

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The Department does not contend that its sample adjudication scheme for post-payment review of coverage determinations is based on explicit statutory authorization; it relies instead on its **general** (and uncontested) **authority to recoup overpayments from providers**. For example, **Sec. 1395gg(b)(1) explicitly contemplates recoupment of overpayments to providers, declaring that where "more than the correct amount is paid under this subchapter to a provider of services ... and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider," an adjustment shall be made "by decreasing subsequent payments" to the beneficiary. See also 42 C.F.R. Sec. 405.370.** Appellants contend that this case is not about whether HHS can recoup overpayments, but rather about how it decides that such overpayments have been made.

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As discussed more fully below, sample adjudication has been used in previous instances involving post-payment review of "coverage determinations" under Part A. In HCFA Ruling 86-1, the agency simply reiterated its belief that it had the latitude to employ sample audits on post-payment review to efficiently recoup overpayments for non-covered services.

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Two courts reviewing post-payment sample adjudications of Part A coverage determinations failed to find any fundamental infirmity in the procedure. For example, in *Mount Sinai Hospital*, the court recounted that

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[a]llegations of wrongdoing by **Mount Sinai** in operation of the Medicare program were made in 1972. HEW subjected to review by a peer review committee of doctors a sample consisting of 710 patients from a single year. The statistical results of the committee's determinations of medically unnecessary hospital stays and ancillary services drawn from this sample were then applied to all years in question, producing a calculated, as opposed to actual, overpayment figure of \$6.3 million.

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517 F.2d at 333. Although it did not address the permissibility of sampling as such, the court held that the predecessor of HHS had a common law right of recoupment for overpayments involving services not covered under Part A. See *id.* at 343 ("Under these circumstances and in light of the construction we put on Sec. 1395gg(b) ..., we think it clear that recoupment has always been available to HEW under facts like those of the instant case."). See also *Daytona Beach General Hosp. v. Weinberger*, 435 F.Supp. 891, 892-93 (M.D.Fla.1977). More recently, in *Mile High Therapy Centers*,

Inc. v. Bowen, 735 F.Supp. 984 (D.Colo.1988), the court approved sample adjudication under Part B of Medicare.

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Although HCFA Ruling 86-1 and the district court both cite Medicare sections that contemplate post-payment adjustments, these provisions deal with "reasonable cost" rather than "coverage" determinations. See 42 U.S.C. Sec. 1395g(a) (authorizing "necessary adjustments on account of previously made overpayments or underpayments"), 1395u(a) (authorizing "such audits of the records of providers of services as may be necessary to assure that proper payments are made under" Part B), 1395x(v)(1)(A)(ii) (dictating that reasonable cost regulations shall "provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive"). Because they govern reasonable cost determinations, we do not read these provisions as explicit statutory authorization for sample adjudication on post-payment review of coverage determinations.

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These provisions do, however, demonstrate that the Secretary generally has the duty and power to protect against overpayments to providers. We are not persuaded by appellants' suggestion that congressional silence in Part A should be construed as an intent to restrict post-payment audit procedures. As the court explained in *Mount Sinai Hospital*, "the specific authority for after-the-fact adjustments for payments subsequently found to be erroneous under HEW's reasonable cost regulations does not suggest that other after-the-fact repayments or adjustments were not contemplated." 517 F.2d at 345 (reversing district court's holding that the right to recoup coverage overpayments was abrogated by the comprehensive statutory scheme of the Medicare Act). In fact, a 1981 amendment to the Act added a provision directing the Secretary to establish utilization guidelines concerning coverage of home health services and "provide for the implementation of such guidelines through a process of selective postpayment coverage review...." 42 U.S.C. Sec. 1395y(f).

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In this case, the district court adopted the holding of another court that had upheld sample adjudication on the basis of these same provisions in the context of Medicare Part B. See *Mile High Therapy Centers*, 735 F.Supp. at 986 ("The above statutory citations give the Secretary considerable discretion and authority to maintain the integrity of the Medicare payment system."); see also *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 109 S.Ct. 468, 472, 102 L.Ed.2d 493 (1988) (construing Sec. 1395x(v)(1)(A)(ii), a subsection governing reasonable cost determinations (quoted above)); *Wilson Clinic & Hosp., Inc. v. Blue Cross of South Carolina*, 494 F.2d 50, 52 (4th Cir.1974) ("Reopenings are contemplated generally by the Act ... [which] impliedly, if not expressly, envisages the canvassing of all payments to a provider."). The court in *Mile High* concluded that "[t]he statistical sample method is one way of exercising this power" to preserve the integrity of the Medicare trust fund and did not exceed HCFA's statutory authority. See 735 F.Supp. at 986. Although Part B is somewhat different from Part A, there is no essential difference in their recoupment powers for coverage overpayments. See *Szekely v. Florida Medical Ass'n*, 517 F.2d 345, 348-49 (5th Cir.1975), cert. denied, 425 U.S. 960, 96 S.Ct. 1742, 48 L.Ed.2d 205 (1976). Furthermore, amendments added in 1986 extended Part A claims adjudication procedures to Part B claims as well. See Sec. 1395ff (amended by Pub.L. 99-509, Sec. 9341, 100 Stat. 2037 (1986)). (Consequently, a contrary holding on the statutory question in this case could imperil sample adjudication under Part B.)

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The logic of sample adjudication, accepted by courts that have approved the technique in other contexts, is that any minor errors will tend to balance out in the end. As the district court correctly observed:

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The clear majority of those few courts having confronted statistical sampling in analogous contexts, while acknowledging its potential for unfairness in the abstract in particular cases, have nevertheless approved its use, primarily as a logistical imperative but also upon the hypothesis that any arbitrariness evens out in the long run.

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Chaves, 732 F.Supp. at 189-90 (footnote omitted). Appellants point to decisions rejecting the Department's use of presumptions to make various determinations under the Social Security Act because these presumptions fail to satisfy the clear requirement for individualized determinations in certain provisions. But presumptions are not the functional equivalent of statistically derived patterns of over-billing by a particular provider. In other contexts and under other statutes, courts have routinely permitted the use of statistical sampling to determine whether there has been a pattern of overpayments spanning a large number of claims where case-by-case review would be too costly. See, e.g., *Illinois Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir.1982) (Medicaid); *Michigan Dep't of Edu. v. United States Dep't of Edu.*, 875 F.2d 1196, 1204-06 (6th Cir.1989) (vocational rehabilitation programs).

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In *Illinois Physicians Union*, the court upheld the use of sampling audits to recoup Medicaid overpayments from participating physicians, squarely rejecting the contention that "any formula for sampling and extrapolation is improper per se," and holding that "extrapolation based on review of a relatively small sample is a valid audit technique in cases arising under the Social Security Act." 675 F.2d at 155. See also *State of Georgia v. Califano*, 446 F.Supp. 404, 409-10 (N.D.Ga.1977) ("Audit on an individual claim-by-claim basis of the many thousands of claims submitted each month by each state [under Medicaid] would be a practical impossibility as well as unnecessary."). Similarly, in *Michigan Department of Education* the court upheld the government's use of a sample adjudication method to audit over 60,000 individual expenditure authorizations under the Rehabilitation Act. See 875 F.2d at 1205-06 ("[W]hen, as here, the state is given every opportunity to challenge each disallowance as well as the audit technique itself, it appears that the state has been treated as fairly as is practicable under the circumstances.").

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HHS concedes, as it must, that these decisions do not settle the statutory question in this case, but the Department contends that these holdings support the reasonableness of the sampling procedure generally, and there is nothing explicit in this statute that would prohibit such a procedure here. Appellants maintain that even if the absence of explicit authorization in the statute is not fatal to the Secretary's procedure, other provisions in the Act render his interpretation unreasonable. As explained below, we agree with HHS that the statutory scheme of individualized review of claims on pre-payment review can be reconciled with a sample adjudication procedure on post-payment review. Such an interpretation is reasonable given the logistical imperatives recognized by courts in other comparable circumstances.

## 2. Alleged Incompatibility with the Act

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The process of reviewing initial payment claims requires particularized decisions concerning (1) coverage (was an item or service medically necessary for this person?) and, if not covered, (2) waiver (which is unavailable when the parties knew or should have known that something was not covered). The beneficiary has a right of review for payment denials based on either of these questions, and the statute specifies that a provider "shall have the same rights that an individual has" for review of Part A denials. See Sec. 1395pp(d). Much of appellants' statutory argument amounts to a collection of snippets from the Act and its history using the word "individual," though most of the time the term seems to act as a synonym for "person" or "beneficiary" rather than as an antonym for "group" or "class." The real question, however, relates not to the choice of particular words but more generally whether the same rights to individualized factual determinations and an opportunity to challenge specific denials are at stake on post-payment review.

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Some of the provisions in the statute cited by appellants for their incompatibility argument, such as putting beneficiaries on notice that their claims were denied (for purposes of imputing knowledge for future waiver determinations), see Sec. 1395pp, or seeking repayment from a beneficiary when the provider is not available, see Sec. 1395gg, are simply not implicated in this case. Indeed, both of these provisions inure to the Department's benefit and presumably could be waived by HHS. In any event, all that the statute requires is notification in cases where the providers knew or should have known of non-coverage and HHS decides to indemnify the individual beneficiary for any payments they made to the provider. See Sec. 1395pp(b) ("[T]he Secretary shall notify such individual of the conditions under which indemnification is made...."). These appeals do not involve indemnification (providers were paid directly for services they rendered to beneficiaries), and nothing in the Act requires that a provider already deemed to have knowledge of non-coverage be given notice of such a non-coverage determination for purposes of imputing knowledge in the future.

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A subsequent amendment to the Act added Sec. 1395h(j), which provides in pertinent part that, when a claim for home health services is denied, the fiscal intermediary shall "furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial...." Pub.L. 100-203, Sec. 4032, 101 Stat. 1330-76 (1987) (applicable to claims received on or after January 1, 1988). Though apparently broader than the notice requirements of Sec. 1395pp in effect at the time, the new provisions only cover initial claim denials, see Sec. 1395h(j)(1), or reconsiderations of such denials, see Sec. 1395h(j)(2), without ever mentioning reconsiderations of approvals. Furthermore, section 1395pp(a), which required notification of both the provider and beneficiary in cases where non-coverage was waived, only applies when neither party was already on notice and therefore would not be relevant in cases such as these where the provider is later deemed to have had the requisite knowledge of non-coverage.

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Nor are the providers' rights to seek reimbursement from beneficiaries implicated in these cases. The legislative history accompanying Sec. 1395pp recognized that in cases where the beneficiary knew or should have known of non-coverage, "liability would remain with the beneficiary and the provider could ... exercise his rights under State law to collect for the services furnished...." S.REP. No. 1230, 92d Cong., 2d Sess. 294 (1972). For purposes of the original claims approvals here, the beneficiaries were deemed to be without knowledge of any non-coverage. The revised waiver determinations on post-payment review only applied to the providers. See HCFA Ruling 86-1, at 8-9. Under these circumstances, a provider would have no right to seek reimbursement for subsequently denied claims from the beneficiary unless the provider could show that the beneficiary (including any outside the sample) was previously informed that he was receiving noncovered services. See *id.* Furthermore, even if the provider could show that the beneficiaries of payment claims denied without review also

had the requisite knowledge (notwithstanding the provider's implicit representation that such knowledge was lacking when the claim was initially submitted), providers are constrained in their ability to charge patients for services subsequently deemed to be non-covered. See Sec. 1395cc(a)(1)(B) (providers must agree not to seek reimbursement from patients for services that HHS decides are not covered more than three years after original notice of payment, and the Secretary may reduce this statute of limitations to one year if circumstances warrant).

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Appellants also contend that sample adjudication vitiates their rights to appeal. Unlike the notice requirements discussed above, the statute makes no apparent distinction between pre-payment and post-payment review when setting out an individual's right to appeal an adverse determination. A beneficiary's right to appeal extends to "any determination" with which an individual is dissatisfied. See 42 U.S.C. Sec. 1395ff(b). As noted previously, Sec. 1395pp(d) accords providers the same rights as individuals. The issue, then, is whether the right to appeal initial claim denials is fully transferable to denials on post-payment review, or whether a right to dispute denials in the sample and challenge the statistical validity of the extrapolation suffices to protect the interests of providers. Appellants fill in this crucial gap in their position by relying on a supposed concession by HHS that, in appellants' words, a provider's "rights are the same whether the claim is being adjudicated at the time it is submitted or upon post-payment review." However, HHS made no such concession, noting only that its sample adjudication procedure afforded providers the same protections and right to challenge denials in the sample group, not that the rights were equally applicable to all post-payment denials. Nothing in the statute appears to require case-by-case review of all claims on post-payment review. At best, congressional intent on the matter is ambiguous.

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The question is what "determination" was made in these cases that could be subject to appeal. As HCFA explained in its ruling, "[s]ampling only creates a **presumption of validity** as to the amount of an overpayment which may be used as the basis for recoupment. **The burden then shifts to the provider** to take the next step." Ruling 86-1, at 11. A provider might first of all object to a coverage or waiver determination as to a claim in the sample, and HCFA's sample adjudication scheme permitted **such challenges**. In fact, the providers in these cases were able to successfully challenge many of the denied sample claims, thereby reducing their projected overpayment liability. Secondly, a provider may also take issue with the statistical validity of an extrapolation from the sample, and this right was also available in the proceedings below. Although they repeatedly emphasize that the sample sizes were too small, appellants failed to make any such objections to the statistical validity of the extrapolation in the proceedings below. Instead, the providers argued that the entire scheme is unauthorized because their right to appeal specific claim denials has been foreclosed.

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Sample adjudication is not, however, a determination that some particular, though unidentified claims outside the sample should have been denied; instead, it is a monetized estimate of the scope of a provider's overcharges derived from a sample. To the extent that appellants were dissatisfied with that adverse determination, they were given an ample opportunity to challenge its basis. This is not to say that the providers were prohibited from raising challenges based on particular claims in the non-sample universe. For instance, as explained previously, a provider is permitted to identify individual beneficiaries of claims not in the sample who were on notice that the claims involved non-covered services and to then directly bill those beneficiaries. **Furthermore, in an effort to challenge the accuracy of the extrapolation, a provider could separately present evidence of a different random sample from the universe of claims that yields a lower rate of denials or prove that the projection is not a true estimate of the rate of denials in the non-sample universe. For instance, if a sampling**

projection estimated 100% denials in the non-sample universe, a provider could demonstrate that one or more of those unreviewed claims was proper.

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Even when a provider is not able to invalidate the statistical validity of the sample audit, if the extrapolation has improperly invalidated any number of correct claims, the provider could always appeal the determination by establishing the validity of all or a sufficient number of its actual claims to demonstrate that the HHS projection is factually impossible of correctness. Obviously, where thousands of claims are involved,, this would impose a daunting burden on the provider, but the alternative urged by appellants imposes an equally daunting burden on the agency. It is not apparent to us that the regulatory scheme becomes invalid simply because it requires the protesting provider rather than the agency to bear the burden.

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Appellants also claim that the Department's interpretation of the statute is not entitled to deference because it conflicts with HHS regulations and policy statements. They contend that the regulations implementing Part A, see 42 C.F.R. Secs. 405.701-.750 (1989), clearly require individual factual determinations and administrative review in making coverage denials. When initial determinations of non-coverage and no waiver are made on payment claims, the provider is entitled to written notice "stat[ing] in detail the basis for the determination." 42 C.F.R. Sec. 405.702. At the request of an aggrieved party, initial payment denials can be reconsidered (Sec. 405.710), and providers are entitled to the same procedural rights on reconsideration, including a written statement (Sec. 405.716) and administrative review (Sec. 405.720). Again, to the extent that the regulations and other agency pronouncements reiterate the requirement for case-by-case review at the initial payment stage, they do not address the question of post-payment sample audits for recouping overpayments.

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HHS emphasizes that sample adjudication is a long-standing practice, utilized at least since 1972. Indeed, internal manuals clearly contemplate just such a procedure. For example, the Medicare Intermediaries Manual, brought to the district court's attention by the plaintiffs, provides that

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[t]he decision to conduct a sample study of a provider's claims constitutes a reopening of all determinations.... Send a notice to the provider as soon as possible explaining: the reason for the study (e.g., possible over-utilization of services); the period to which the results will apply; the sampling procedure, including the method used to select the sample and a statement that the sample findings will be projected to the entire population of claims.

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Medicare Intermediaries Manual, Sec. 3799.5. Furthermore, the regulations governing the collection and compromise of claims for over-payments against providers appear to draw a distinction between pre-payment and post-payment review in defining the scope of the right to appeal. See 42 C.F.R. Sec. 405.374(j) ("Any action taken by HCFA under this section regarding the compromise of an overpayment claim ... is not an initial determination for purposes of the appeal procedures" under, inter alia, 42 C.F.R. Secs. 405.702-.730.). Appellants are thus unable to demonstrate that the sample adjudication procedure used in these cases was incompatible with either the statute or Department regulations. Thus, we cannot say that the Secretary's interpretation of his authority under the Act is unreasonable.

## B. Procedural Due Process

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Appellants contend that they enjoy a clear property interest in retaining previously made payments for services rendered and are therefore entitled to the protections of due process. To sustain such a contention they have a very difficult burden of persuasion in light of the three-factor analysis adopted in *Mathews v. Eldridge*, 424 U.S. 319, 335, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). Absent an explicit provision in the statute that requires individualized claims adjudications for overpayment assessments against providers, the private interest at stake is easily outweighed by the government interest in minimizing administrative burdens; in light of the fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates. See *Illinois Physicians Union*, 675 F.2d at 157 ("[I]n view of the enormous logistical problems of Medicaid enforcement, statistical sampling is the only feasible method available."). It should be remembered that appellants failed in these cases to timely and specifically challenge the statistical validity of the sampling procedure as applied to them. HHS emphasizes that providers have no legitimate expectation of retaining payments for services they knew or should have known were not covered, that subjecting the audit to notice and hearing minimizes the risk of error, and that the cost of case-by-case review would exceed the amounts of overpayment. We can find no general constitutional defect with sample adjudication.

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### C. Irregularities in Adoption of HCFA Ruling 86-1

#### 1. Retroactive effect

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Appellants urge that their challenges before the agency to the sample auditing procedure were rejected on the strength of HCFA Ruling 86-1 even though that ruling was issued after their overpayment assessments were made. If Ruling 86-1 changed HHS procedures, then its use here indeed would be impermissibly retroactive. See *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 109 S.Ct. 468, 471-74, 102 L.Ed.2d 493 (1988). However, the Ruling was not the source of administrative authority in these cases but merely explained and reaffirmed the Department's long-standing and well-established practice of conducting sample audits. While the past frequency of such audits is unclear, the practice appears to have been in use as early as 1972. See *Mount Sinai Hosp.*, 517 F.2d at 333; *Daytona Beach General Hosp.*, 435 F.Supp. at 892-93. The audits at issue in *Mile High Therapy Centers*, 735 F.Supp. at 985, were undertaken in the early 1980s, and the sample audits in the cases before us on appeal also predated HCFA Ruling 86-1. Moreover, sample auditing is referenced in internal agency manuals. See *Medicare Intermediaries Manual*, Sec. 3799.5 (quoted above); *Medicare Carrier's Manual* Sec. 7150 (discussed in *Mile High*, 735 F.Supp. at 985-86). In light of this evidence that sample adjudication represents a long-standing HHS procedure, we reject appellants' retroactivity objection.

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#### 2. Compliance with APA Rulemaking Procedures

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Appellants finally contend that HCFA Ruling 86-1 was adopted without the notice and comment procedures required by the Administrative Procedure Act (APA). See 5 U.S.C. Sec. 553 (1988). The sole question is whether Ruling 86-1 is excepted from the APA requirements as an interpretive rule.

See Sec. 553(b)(A); *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044-47 (D.C.Cir.1987). Appellants argue that HCFA Ruling 86-1 is a legislative rule, and not just an advisory statement, because it is binding both by its own terms and as used by the Department in the proceedings below. The Department responds that it has been performing sample audits for nearly two decades and that HCFA Ruling 86-1 simply states what the agency thinks it can do under the statute and reminds parties of their existing duties. See *Mile High*, 735 F.Supp. at 985-86 (holding that HCFA Ruling 86-1 is an interpretive rule not subject to notice and comment rulemaking requirements); cf. *McCown v. HHS*, 796 F.2d 151, 157 (6th Cir.1986) (policy statement concerning offset policies for social security disability benefits was interpretive), cert. denied, 479 U.S. 1037, 107 S.Ct. 893, 93 L.Ed.2d 845 (1987). The dispute, therefore, boils down to the previously-resolved question of whether sample adjudication for Part A overpayments was a longstanding practice or a brand new scheme ushered in by HCFA Ruling 86-1. As explained above, we agree that it was the former.

### III. CONCLUSION

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Appellants' remaining challenges to the proceedings below are equally without merit. The statutory question is complicated, but this much is clear: neither the plain language nor the legislative history discusses sample adjudication. Appellants' claim that HHS is proposing an unreasonable interpretation of its authority under the statute is close, but not strong enough to trump the deference we must accord agency interpretations of an ambiguous governing statute under *Chevron*. Sample adjudication represents a judicially approved procedure that can be reconciled with existing Medicare requirements for case-by-case consideration on pre-payment review of claims. The district court's order granting summary judgment to the Secretary of HHS is

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Affirmed.