Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Puerto Rico Department of Health
Docket No. A-10-54
Decision No. 2385
June 9, 2011

DECISION

The Puerto Rico Department of Health (PRDH) appealed the determination of the Health Resources and Services Administration (HRSA) disallowing $24,340,789 in federal reimbursement paid to PRDH under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (the Ryan White CARE Act or Act). The Act funds a range of programs for people with Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS). At issue here is reimbursement under the Act's "AIDS Drug Assistance Program" or ADAP. ADAP funds medications for low-income people with HIV/AIDS where payments for such medications cannot "reasonably be expected to be made . . . under any State compensation program, under an insurance policy, or under any Federal or State health benefits program." 42 U.S.C. § 300ff-27(b)(7)(F)(i).

We uphold the disallowance in full on the ground that PRDH has failed to show that it used this ADAP reimbursement to make payments for medications that could not reasonably be expected to be made under other federal or state programs or private insurance policies. In summary, we conclude that HRSA, based on a review of randomly selected ADAP prescriptions, reasonably relied on statistical sampling in calculating this disallowance; PRDH failed to show that the statistical methodology on which HRSA relied was unsound or prejudicial; PRDH failed to show that any of the disallowed sampled prescriptions were eligible for funding under ADAP; and PRDH's other arguments are without merit.

Applicable laws and authority

HRSA made the grants at issue under Part B (formerly Title II) of the Ryan White CARE Act, Pub. L. 101-381, 104 Stat. 576 (1990), as reauthorized most recently by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Pub. L. 111-87, 123 Stat. 2885. Part B is codified at 42 U.S.C. §§ 300ff-21 et seq. and authorizes grants to states and territories (hereinafter "states") for a range of HIV/AIDS programs. Section 300ff-22(b)(1) requires states to use a percentage of the Part B grant for "core medical services," which, under section 300ff-22(b)(3)(B), includes funding "AIDS Drug Assistance Program [or ADAP] treatments in accordance with section 300ff-26 of this title." Under ADAP, a state can pay for "therapeutics to treat HIV/AIDS or prevent the

serious deterioration of health arising from HIV/AIDS in eligible individuals . . . ." 42 U.S.C. § 300ff-26(a).

Section 300ff-26(b) defines an eligible individual as follows:

> ELIGIBLE INDIVIDUAL.-To be eligible to receive assistance from a State under this section an individual shall-
> (1) have a medical diagnosis of HIV disease; and
> (2) be a low-income individual, as defined by the State.

Section 300ff-27(b)(7) requires states to make specific assurances in their applications for Part B funds. Section 300ff-27(b)(7)(F) requires that --

> the State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service --
>
> (i) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or
>
> (ii) by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Service).

(Emphasis added.)[1] Section 300ff-27(b)(7)(F) is known as the payer of last resort requirement. PRDH Appeal Br., Att. 1, Office of Inspector General (OIG) Audit at 1 (Audit).

Based on grants administration requirements, the Board has long held that a grantee has the burden of documenting the allowability of its claims for federal funds. *See Massachusetts Executive Office of Health and Human Services*, DAB No. 2218, at 11 (2008), *aff'd Commonwealth of Massachusetts v. Sebelius*, 701 F.Supp.2d 182 (D. Mass. 2010); *Maryland Dept. of Health and Mental Hygiene*, DAB No. 2090, at 4 (2007); *New York State Dept. of Health*, DAB No. 1827, at 10 (2002); *New York State Dept. of Social Services*, DAB No. 433, at 9 (1983).

Background

In March 2002, 2003, and 2004, HRSA issued Notices of Grant Award (Notices) for Grant No. X07HA00046 awarding PRDH funds for an ADAP program under Part B

[1] During the audit period, this provision was codified at 42 U.S.C. § 300ff-27(b)(6)(F). It was redesignated section 300ff-27(b)(7)(F) by the Ryan White HIV/AIDS Treatment Modernization Act of 2006, Pub. L. No. 109-415, which also amended subsection (ii) by adding the parenthetical reference to the Indian Health Service.

(then Title II) of the Act. HRSA Ex. 1. The annual budget years for the grant began April 1 of those years. *Id.* PRDH administered the Part B grant, including ADAP. Audit at 1.

The Notices stated that the awards were subject to the terms and conditions of the grant award, the grant program legislation, and federal regulations at 45 C.F.R. Part 92. *Id.* In its grant application for these funds, PRDH made the payer of last resort assurance required by 42 U.S.C. § 300ff-27(b)(7)(F). *See, e.g.*, HRSA Ex. 8, at unnumbered 5-6.

In 2006, the Office of Audit Services of the Department of Health and Human Services Office of the OIG audited PRDH's ADAP expenditures for compliance with the payer of last resort requirement. The audit covered the period April 1, 2002 through March 31, 2005. Audit at 2. During this period, PRDH claimed "ADAP expenditures totaling $73,561,082 for HIV/AIDS drugs dispensed at eight outpatient clinics." *Id.* PRDH identified these clinics as the "PRDOH Regional Immunology Clinics (RICs)." HRSA Ex. 5, at 4.

After concluding the audit, the OIG estimated that PRDH was overpaid $24,340,789 in ADAP funds. As for the cause of that overpayment, the OIG determined that –

> [t]he Health Department claimed unallowable expenditures because it had not developed procedures to bill HIV/AIDS drugs to other insurance plans that would have covered the drugs. Although the Health Department had contracted with a billing agent to bill [Part B] medical visits and laboratory tests to plans with primary payment responsibility, the contract did not apply to billing for HIV/AIDS drugs.

Audit at 4.

In conducting this audit, the auditors used the OIG Office of Audit Services' statistical sampling software, which is named RAT-STATS. *Id.* at 1. The auditors used RAT-STATS as the "random number generator" to generate a simple random sample of ADAP-funded prescriptions and, after identifying ineligible prescriptions in the sample, to estimate the total unallowable ADAP reimbursement. *Id.* The OIG "considered a sample item improper if the patient had other Federal, State, or private health insurance that covered the dispensed drugs. The amount of the improper payment was the amount that the other health plan would have paid." *Id.*, App. A, at 1.

The OIG described the methodology it used in this audit as follows:

- identified a sampling frame of 105,440 HIV/AIDS prescriptions for which [ADAP] claims totaled $73,561,082;

- [using RAT-STATS] selected a simple random sample of 100 prescriptions from the sampling frame of 105,440 prescriptions and, for the sample prescriptions:
    - used a [PRDH] database to identify patients enrolled in the Puerto Rico Government Health Insurance Plan (GHIP), which included Medicaid and the State Children's Health Insurance Program,
    - used [PRDH] clinic files to identify patients enrolled in private health insurance plans,
    - confirmed HIV/AID drug coverage and the amount of that coverage with officials of the GHIP and private health insurance plans, and
    - identified from [PRDH] payment invoices the costs of drugs dispensed; and
- [using RAT-STATS] estimated, based on the sample results, the total unallowable Federal funding claimed.

Id. at 3.

After considering PRDH's arguments and evidence challenging specific disallowed sample prescriptions, the OIG concluded that 57 of the 100 prescriptions were "incorrectly claimed to [ADAP] for patients who had other health insurance that would have covered the drugs." *Id.* at 4.

The OIG found that the federal funding for these 57 disallowed prescriptions totaled $28,560. *Id.*, App. B. "Using its statistical program, RAT-STATS, the OIG extrapolated [or projected] the sample results to the universe and calculated the unallowable cost" paid to PRDH under ADAP. PRDH Appeal Br., Att. 1, Disallowance letter dated March 15, 2010, at 2. Relying on a 90% confidence interval, the OIG estimated the point estimate of the unallowable payments as $30,113,864, the upper limit of the unallowable payments as $35,886,939 and the lower limit as $24,340,789. Audit, App. B. The OIG recommended to HRSA that it disallow $24,340,789, the lower limit. *Id.* at ii.

On March 15, 2010, HRSA disallowed $24,340,789 in Part B reimbursement. PRDH appealed the disallowance to the Board. Upon the close of the standard briefing process set out at 45 C.F.R. § 16.8, the Board issued an Order to Develop the Record (Order) requesting further submissions from the parties "to assist in its decision making." Order dated January 18, 2011. The parties filed simultaneous submissions. Although they were entitled to file replies to one another's submission, neither party filed a reply.

Analysis

PRDH challenges the disallowance on the following grounds. PRDH argues statistical sampling and extrapolation should not have been used to calculate the disallowance and attacks aspects of the OIG's statistical sampling methodology. PRDH challenges HRSA's error findings in 19 of the sampled prescriptions. PRDH raises a number of equitable arguments related to the impact of "barriers" in its Medicaid program, the alleged failure of federal officials to provide guidance for administering ADAP, and its good faith and the hardship this disallowance will cause for its HIV/AIDS population. Below we explain why none of the arguments provide a basis for reversing or modifying this disallowance.

1. PRDH failed to show that the OIG's use of the sampling methodology at issue did not result in a reliable calculation of the amount of unallowable costs or violated PRDH's right to due process.

As PRDH recognizes, courts and the Board have repeatedly upheld the use of statistical sampling in calculating disallowances of public funds. PRDH Reply Br. at ¶ 6 (acknowledging "the longstanding and judicially approved use of statistical sampling").[2] PRDH states that it does not contest "the established policies regarding statistical sampling audits" but does contest the appropriateness of the use of statistical sampling here and "the methodology used with our particular factual background." *Id.* at ¶ 6; *see also id.* at ¶ 8; PRDH Response to Order at ¶¶ 11, 12, 15. PRDH also argues that the sample process here violated its right to due process. PRDH Appeal Br. at ¶ 12.

Where a grantee challenges the use of statistical sampling, the Board looks to whether the agency has shown that sampling is appropriate in the context of the particular disallowance and whether the sampling and extrapolation methodology used to calculate that disallowance is scientifically valid. *Mid-Kansas Community Action Program, Inc.*, DAB No. 2257, at 4 (2009).

a. Appropriateness

Statistical sampling was appropriate in this case because the large number of claims at issue (105,440) made individual review impractical. *See, e.g., New York State Dept. of Social Services*, DAB No. 1394, at 22 (1993) ("Typically sampling is used when a claim for federal funds is based on the sum of numerous cost items (each subject to proof of

[2] *See, e.g., United States v. Freitag*, 230 F. 3d 1019, at 1025 (7th Cir. 2000) (audit of Medicare payments); *Yorktown Medical Lab, Inc. v. Perales*, 948 F.2d 84, at 90 (2d Cir. 1991) (audit of Medicaid payments); *Chaves County Home Health Serv. v. Sullivan*, 931 F.2d 923 (1991); *Georgia v. Califano*, 446 F. Supp. 404 (N.D. Ga. 1977) (audit of Medicaid payments); *Mich. Dep't of Educ. v. U.S. Dep't of Educ.*, 875 F.2d 1196, at 1205-06 (6th Cir. 1989) (audit of payments under the Rehabilitation Act of 1973); *Illinois Dept. of Children and Family Services*, DAB No. 1564 (1996) (audit of title IV-E payments).

allowability), because it is impossible, or at least costly and impractical, to examine each item"). In such situations, the Board has relied on an extrapolated finding because "[i]f done in accordance with accepted rules . . . [it] has a high degree of probability of being close to the finding which would have resulted from consideration of all the cost items." *New York State Dept. of Social Services*, DAB No. 1235, at 9 (1991).
Despite the large number of claims, PRDH argues that the following factors make sampling and extrapolation inappropriate in this case.

- PRDH asserts that, because it is a "public agency," it is "bound by legal, ethical and public policy dispositions in managing public funds, thus the danger of mismanagement of public funds is absent in [this] case." PRDH Reply Br. at ¶ 20.

- PRDH asserts that the decisions HRSA cited in support of sampling involved "overpayment for services and in one case fraud." *Id.* at ¶ 8. It concludes that benefits consisting of "services and/or economic support" are "susceptible to overpayments and fraud." *Id*. In contrast, PRDH asserts that "the services provided [here] were not susceptible to fraud since the antiretroviral [ARV] medication was dispensed to the population for which the grant was created, because this type of medication can only be used by this particular population." PRDH Response to Order at ¶ 11, *see also* PRDH Reply Br. at ¶ 8.

- PRDH asserts that the decisions cited by HRSA involved programs where services received pre- and post-payment reviews and where there was more frequent auditing by the federal government. PRDH Reply Br. at ¶¶ 8, 9. PRDH also asserts that the audit periods for those cases were for "approximately one (1) year." *Id.* at ¶ 9. PRDH concludes that these factors prevented such large disallowances and, consequently, those audits resulted in a "less burdensome economic result." *Id.*

Leaving aside the question of whether all of PRDH's assertions are accurate, we conclude none of them make the sampling in this audit inappropriate. First, the decisions cited by the parties involved the administration of federal funds by state agencies, all of which expect to and are required to properly administer federal programs. As we see here however, the fact federal funds are administered by a public agency does not guarantee that that agency will comply with all federal requirements. Second, medical programs, including prescription drug programs, are vulnerable to a range of types of fraud. However, actual fraud or a potential for fraud are not the only reasons to rely on statistical sampling. As recognized in our decisions, the federal government may elect to use sampling to simply test a grantee's compliance with program requirements, as it did here. Like fraud, noncompliance with program requirements can have significant detrimental consequences. Indeed, the OIG indicated that its reviews of the Ryan White CARE Act requirements were "initially requested by the Senate Committee on Finance," which indicates that a congressional committee was concerned that states' noncompliance could be having a negative impact on the Act's programs. HRSA Ex. 2, at 1. Finally,

while we are not unsympathetic to the problems that this large disallowance will cause PRDH, PRDH identifies no basis to find statistical sampling inappropriate merely because a large disallowance occurred in the absence of more frequent payment reviews. Program offices regularly disallow large amounts of federal reimbursement if they determine that that a state has failed to comply with federal requirements. *See, e.g., Louisiana Dept. of Health and Hospitals*, DAB No. 2350 (2010) (sustaining a Medicaid disallowance of $239,270,483); *New York State Dept. of Health*, DAB No. 1867 (2003) (sustaining a Medicaid disallowance of $301,685,1987); *California Dept. of Finance*, DAB No. 1592 (1996), *aff'd Brown v. HHS*, NO. S-96-1712 FCD/GGH (E.D. Cal. June 16, 1999) (sustaining disallowance of $19,158,773 in contributions to the state pension fund).

b. Scientific validity of sample/extrapolation methodology

As to the soundness of the sampling/extrapolation methodology used here, the OIG described in the audit how it calculated the disallowance. That method involved establishing a sampling frame of all ADAP-funded prescriptions for the three years in question; selecting a simple random sample from that frame by using the RAT-STATS software; reviewing the prescriptions in the sample for erroneous ADAP payments; reviewing PRDH's subsequent challenges to specific error findings (which resulted in reclassifying four prescriptions as correctly paid); and calculating, using the RAT-STATS software and the sample results, a point estimate and the upper and lower limits of a two-sided 90% confidence interval**.** The auditors stated, and PRDH did not dispute:

> We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Audit at 3-4. Also, HRSA represents in its brief (and PRDH does not question) that the auditors followed the Comptroller General's *Government Auditing Standards* (HRSA Response at 10) and that the Board has previously approved the RAT-STATS software as a reliable generator of random numbers for a sample (*id.* at 12-13, citing *California Dept. of Social Services*, DAB No. 816 (1986)). *See also, New York State Dept. of Social Services*, DAB No. 1531 (1995) and *Maryland*, DAB No. 2090, at 62 (upholding OIG's reliance on RAT-STATS).

After reviewing the audit, the Board sought clarification as to whether the sampling frame against which the errors were ultimately projected included, in addition to ADAP funded prescriptions, prescriptions containing drugs listed only in the state-funded formulary and paid for with state-only funds. The Board sought this clarification in its

Order. In response, HRSA explained that, "in Puerto Rico, a prescription could list one or more drugs," and asserted that –

> [o]nly individual prescriptions which received Federal funding, either in full or partially, were numbered and considered part of the sampling frame. Any prescription that had state funding only was eliminated from the sampling frame and the errors were not projected against these prescriptions. The population consisted of all Federally-funded prescriptions for [ADAP] drugs dispensed to HIV/AIDS patients from April 1, 2002 through March 31, 2005. Mixed prescriptions were numbered and valued only for those Federally-funded ADAP drugs listed.

HRSA Response to Order at 2. HRSA also clarified that "Drugs purchased with State funds that appeared on a mixed prescription were not counted as error." *Id.* Therefore, HRSA satisfactorily addressed the only methodological question that was, in the Board's reading of the audit, presented by the OIG's description of the audit methodology.

PRDH never claimed that the error findings were projected against state-only prescriptions and does not dispute HRSA's clarification of the OIG's methodology pursuant to the Order. Moreover, PRDH does not question the integrity of or the OIG's application of the RAT-STATS software. Rather, PRDH challenges the audit methodology by arguing that the sample should have been larger, that the sample was not representative, and that the OIG should have used a stratified rather than a simple sample. PRDH states:

> We also conten[d] that the sample used was not representative of the universe that was being audited. According to standard statistical practices the random sample of 100 prescriptions have a margin of error larger than 9.80% compared to a sample calculation of 660 prescriptions with a margin of error lower than 1%. The random sample should also be stratified to include prescriptions of all three years to be an accurate representation. The target population in the sample should include all clinics and should also include an equal representation by sex, age, time since diagnosis, co-morbidity and doses as the estimated value of the prescription can be accurate if these variables are included in the sample selection.

PRDH Appeal Br. at ¶ 13. PRDH annotated the second sentence in this quote with a footnote that states: "Using Ransoft-Simple size calculator with 600 samples with a degree of confiability [sic] of 99%." *Id.* at 6, n.1.

In its reply to HRSA's brief, PRDH also states that "the sample size and lack of stratification were not in accordance with accepted rules as pertaining to the facts in our case rendering the audit scientifically invalid" and that the methodology used here "could not create real values in order to extrapolate findings." PRDH Reply Br. at ¶¶ 10, 12.

We reject PRDH's argument for the following reasons.

Unlike other parties who have challenged statistical sampling methodologies in Board cases, PRDH did not support its assertions with expert testimony or with citations to sampling literature or audit standards. Moreover, as discussed below, PRDH's unsupported assertions demonstrate a lack of understanding of statistical sampling principles and of the Board's prior decisions discussing the use of statistical sampling to produce reliable evidence of unallowable costs.

In reviewing disallowances based on statistical sampling, the Board looks to whether the sampling methodology resulted in reliable evidence of the amount of unallowable costs charged to federal funds. *New York State Dept. of Social Services*, DAB No. 1358 (1992). Where the Board has determined that the methodology resulted in reliable evidence, the Board has upheld the disallowance. *Id.* As relevant here, the Board has repeatedly concluded that a result, determined through use of a valid statistical sampling methodology, that is based on the lower limit of a two-sided 90% confidence interval has a 95% probability of being correct and is reliable evidence of the amount of unallowable costs and an appropriate basis for disallowing those funds. *See, e.g., Pennsylvania Dept. of Public Welfare*, DAB No. 1508 (1995); *Oklahoma Dept. of Human Services*, DAB No. 1436 (1993); *New York*, DAB No. 1358; *Pennsylvania Dept. of Public Welfare*, DAB No. 1278 (1991), *aff'd Pennsylvania v. HHS*, No. 92-337 (W.D. Pa. July 15, 1993); *California Dept. of Social Services*, DAB No. 816 (1986). In *Oklahoma*, the Board explained its reasoning, as follows:

> A 90% confidence interval means that there is a 10% probability that the true value of the error rate falls outside the confidence interval; or a 5% probability that the true value is greater than the upper limit or bound of the confidence interval, and a 5% probability that it is below the lower limit. Thus, since the disallowance was based on the lower limit of the confidence interval, and not the point estimate, there was a 95% probability that the true value was above the lower limit. [In other words,] the state was protected with a 95% degree of confidence from having to pay an amount greater than the true value of erroneous payments.

Oklahoma, DAB No. 1436, at 6. Thus, the Board concluded that that the use of the lower bound of confidence resulted in reliable evidence of the amount of unallowable costs charged to federal funds. *Id.* at 8.

The disallowance here, as in the cited cases, was based on the lower confidence limit of a two-sided 90% confidence interval. Citing those cases in its Order, the Board questioned Puerto Rico on the use of a two-sided 90% confidence interval. The Board asked PRDH:

> Does Puerto Rico agree that the use of the lower limit of the 90% confidence interval means that there is a 95% probability that the true value of the erroneous

> payments is greater than the disallowed amount? If not, on what basis does Puerto Rico disagree?

Order at 2.

In its response to the Board's inquiry, PRDH does not directly disagree with or address the reasoning in the Board's prior holdings. *See* PRDH Response to Order at 9. Rather PRDH continues to argue that the OIG should have used a 600 (or 660) prescription sample because that larger sample would have led to a more precise result and a higher degree of confidence (99%) that the point estimate was correct. This assertion is not a basis for reversing this disallowance for the following reasons.

Whether or not PRDH's assertion about a 600 unit sample and 99% degree of confidence is correct, PRDH failed to explain why it believes that it was prejudiced by the use of the 100 prescription sample or what benefit it would be likely to derive (such as smaller disallowance) from the use of a larger sample. As we observed previously when a party argued for a larger sample, such a failure is –

> not surprising since sample size affects the precision of sample results in estimating the most likely true value, and a smaller sample size generates a wider confidence interval. Since [the agency] disallowed only the amount established by the lower limit of the confidence interval, the State potentially benefited from the use of a [smaller sample size].

New York, DAB No. 1358, at 48; *see also Oklahoma*, DAB No. 1436, at 8 (holding that the calculation of the disallowance using the lower bound of the confidence interval as the error rate gave Oklahoma "the benefit of any doubt raised by use of the smaller sample").

Moreover, as the Board has observed previously, "the purpose of using sampling is to get a reliable result while keeping the burden on the auditors and the entity being audited to a minimum." *Alabama Dept. of Human Resources*, DAB No. 1989, at 38 (2005); *Alabama Dep't of Human Resources v. U.S. Dep't of Health & Human Servs.*, 478 F.Supp.2d 85 (D.D.C. 2007). While a larger sample may have resulted in a higher confidence interval, PRDH provides no reason to believe that the benefit to PRDH (or HRSA) would have justified the additional costs of conducting a 600 sample prescription audit.

Finally, PRDH's assertion about the size of the sample does not address the relevant question here. That question is whether the OIG's methodology, including its use of the lower limit of a two-sided 90% confidence interval, resulted in reliable evidence of the amount of unallowable costs PRDH charged to ADAP. PRDH has offered no basis for concluding that the OIG's sample size of 100 (or methodology) does not reliably support the OIG's conclusions as to the point estimate ($30,113,864), confidence interval (90%), and the value of lower limit of that confidence interval ($24,340,789), and the finding

that there is a 95% probability that PRDH claimed at least $24,340,789 in violation of the ADAP payer of last resort requirement.

PRDH also challenges the audit on the grounds that "the sample used was not representative of the universe that was being audited" and that the "target population in the sample" should have included "all clinics" and "equal representation" of such characteristics as sex, age, time since diagnosis, etc. PRDH Appeal Br. at ¶ 13. We reject these arguments for the following reasons.

PRDH's statement implies that the sampling frame from which the sample was drawn was somehow deficient. However, the audit states that the sampling frame included all prescriptions from all clinics for which PRDH claimed ADAP funds during these three years. Audit at 2, 3. Thus, the prescriptions in the sampling frame did include all years, clinics, and characteristics of recipients. The random sample of 100 prescriptions should, therefore, have been representative of these years, clinics, and characteristics. Indeed, the record contains a spreadsheet of the prescriptions in the random sample that were found to be paid in error. PRDH Appeal Br, Att. 8. The entries on that sheet show prescriptions from all three years, prescriptions for men and women, prescriptions with a range of costs, and prescriptions for different ARV medications. Therefore, we conclude that PRDH has failed to show that the sampling frame was deficient or the sample was not representative of the universe. *See New York*, DAB No. 1531, at 9-10 (holding that the state failed to meet its burden to support its allegation that the sample was not representative of the universe of foster care cases).

Moreover, PRDH's assertion that there should have been "equal representation" of characteristics such as sex, age, etc., in the sample is simply incorrect. Characteristics in a sampling frame should be reflected in the sample in proportion to their presence in the sampling frame – that is the expected effect of a random sample, unless otherwise shown. PRDH provides no evidence here that would indicate that any percentages of sample items with these characteristics were significantly different from the percentages of the total prescriptions in the universe with these characteristics.

Finally, PRDH argues the sample should have been stratified. PRDH Appeal Br. at ¶ 13. In a stratified sample, the sample is separated into groups sharing some particular variable relevant to the purpose of the sampling.[3] As the Board has found, "as a matter of statistical theory, a stratified random sample will generally provide more precise estimates than a simple random sample where stratification is based on a variable that

[3] Both parties cite *Ratanasen v. State of California*, 11 F.3d 1467 (9th Cir. 1993), a case upholding the use of statistical sampling to calculate a Medicaid overpayment. In that case, the doctor also attacked the state's reliance on a simple random sample rather than a stratified random sample. The court upheld the use of a simple random sample after hearing expert testimony from both parties. The court explained that stratified random samples are used to adjust for heterogeneous populations. As explained above, PRDH presented no expert testimony and offered no basis for concluding that any particular characteristic(s) made the population in this sampling frame so heterogeneous as to call for stratification.

may affect the outcome of the sample." *Pennsylvania*, DAB No. 1278, at 7 (emphasis added).

We reject PRDH's stratification argument because PRDH fails to identify (or cite authority or produce any expert testimony) identifying any variable here that "may affect the outcome of the sample" (*id.*) or to explain why it believes that a stratified sample was required to "create real values in order to extrapolate findings" (PRDH Response to Order at ¶ 12). Specifically, PRDH fails to explain any basis for concluding that the OIG's use of a simple sample was methodologically unsound; fails to identify which of the overlapping variables that it lists (such as year, clinic, age, sex) should have been used to stratify the sample; and fails to explain how stratification by any particular variable would be relevant to the purpose of the audit, i.e., estimating the value of prescriptions paid in violation of the ADAP payer of last resort requirement. Moreover, as with its contention that the OIG should have used a larger sample, PRDH has offered no basis for concluding that a stratified sample would have resulted in a smaller disallowance. Finally, even if stratification may have resulted in a more precise point estimate and narrower confidence interval, the method for calculating the confidence interval used here effectively takes into account the lack of stratification. As discussed above, the Board has repeatedly determined that use of the lower limit of a two-sided 90% confidence interval (as here) results in reliable evidence of the amount of unallowable costs charged to federal funds.

For the reasons discussed above, we conclude that PRDH has failed to offer any basis on which we could conclude that the OIG's audit methodology was unsound or prejudicial to PRDH and did not result in reliable evidence of the amount of unallowable costs.

c. Whether PRDH's right to due process was violated

The OIG calculated the disallowance by projecting the sample error findings to the universe of ADAP prescriptions. PRDH's due process attack on this projection is based on PRDH's (and HRSA's) assertion that it was made pursuant to an OIG audit "policy." PRDH argues that its right to due process was violated because it did not have timely notice of this "policy."

As described by HRSA, the OIG "policy" provides that "in situations where 100 sample units result in fewer than six errors, OIG policy does not authorize statistical projection." HRSA Response Br. at 11. HRSA submitted no document purporting to memorialize the alleged policy and did not even state whether or where it is memorialized. HRSA does cite (but does not submit) OIG audits in Missouri and in Maryland, both of which can be located on the internet. *Id.* The Missouri audit states that OIG "policy dictates that statistical projections will be made if six or more errors are identified." *Review of Missouri Medicare Part D Contributions to the Centers for Medicare & Medicaid Services for 'Full-Duals,'* A-07-001044, at App. A (available at http:oig.hhs.gov/oas/reports/region7/70701044.pdf). The Maryland audit involved two 100 unit samples.

In the first sample the errors exceeded six and the OIG projected the errors; in the second there were four errors and the OIG did not project the errors, writing "[t]he number of errors in the second stratum was not sufficient to make a statistical projection based on our statistical sampling policies and procedures." *Audit of Payments for Medicaid Services to Deceased Beneficiaries*, A-05-03-00099, at App. A (available at http://oig.hhs.gov/oas/reports/region5/50300099.htm). PRDH submitted a September 2009 OIG audit of Illinois' ADAP program in which the OIG found three prescriptions of 100 to be improperly paid under the payer of last resort requirement. PRDH Appeal Br., Att. 6. Without specifically referring to any OIG policy, the OIG recommended disallowing only the actual costs for the three ineligible prescriptions.

On the basis of this record, we accept that the OIG had, during the relevant time, a practice of not projecting errors in statistical sampling audits where there were fewer than 6 errors in a sample of 100 units. Because the parties have referred to this practice as a "policy," we use that term. Our use of the term here is not meant to indicate that we have concluded that the OIG's projection practice regarding fewer than six errors is a "policy" as that term is used in other authorities, such as the Administrative Procedure Act, 5 U.S.C. § 500, et seq. (APA).[4]

PRDH's due process argument is limited to its alleged lack of timely notice about this policy.[5] PRDH Appeal Br. at ¶ 12; *see also* PRDH Response Br. at ¶¶ 4, 5, 13. PRDH does not assert that it was unaware that federal grants generally, or ADAP funds in particular, could be subject to disallowances based on sampling and extrapolation. *See* PRDH Response Br. at ¶¶ 4-6. Indeed, PRDH says "Nowhere in [our Appeal Brief] have we contested the established policies regarding statistical sample audits or the longstanding and judicially approved use of statistical sampling."[6] *Id.* at ¶ 6.

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[4] PRDH does not cite the APA. We conclude, in any case, that the APA would not protect PRDH here. Courts (and the Board) have rejected the argument that agency audit methodologies are not binding under 5 U.S.C. § 533 unless they are promulgated using notice and comment rulemaking. *See, e.g., Chaves County Home Health Services*, 931 F.2d at 923 (holding that an agency sampling methodology policy was an interpretive rule which confirmed the agency's longstanding practice and, thus, was not subject to notice and comment rulemaking); *see also Pennsylvania Dept. of Public Welfare*, DAB No. 1508 (1995); *Ohio*, DAB No. 1202. Nor does 5 U.S.C. 552(a)(1) help PRDH here. Under that section, agencies are required to publish certain information in the *Federal Register*, including "statements of general policy or interpretations of general applicability formulated and adopted by the agency." That section provides further that "[e]xcept to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be . . . adversely affected by [] a matter required to be published in the Federal Register and not so published." However, even if section 552(a)(1) applies to the cited OIG "policy" (and we are not deciding that it does), this protection would not apply here because (as discussed above), PRDH has not shown that it was adversely affected by the "policy."

[5] PRDH also does not challenge HRSA's authority to take a disallowance based, as here, on the agency's concurrence in an OIG audit determination.

[6] PRDH also does not argue, as grantees have in other cases for other programs, that sampling and extrapolation are contrary to the Ryan White CARE Act. *See, e.g., Illinois,* DAB No. 1564 (rejecting Illinois' argument that statistical sampling was contrary to congressional policies under Title IV-E of the Social Security Act).

We reject PRDH's due process argument for the following reasons.

First, in upholding the use of statistical sampling, the Board has long held that "no prior notice [to a grantee] is required to use an audit technique which produces reliable evidence of the amount of unallowable costs." *Maryland Dept. of Human Services*, DAB No. 1225, at 5 (1991) (upholding the use of statistical sampling and extrapolation), citing *Tennessee Dept. of Health and Environment*, DAB No. 898, at 6-7 (1987); *Louisiana Dept. of Health and Human Resources*, DAB No. 580 (1984). PRDH has failed to identify any contrary authority for the proposition that it had a due process right (or any other right) to prior notice of OIG audit methodologies generally or the OIG's extrapolation standards in particular.

Second, PRDH has not identified any basis for concluding that it was adversely affected or prejudiced by lack of notice about the OIG policy. The policy establishes an exception to the practice, which is standard in audits based on statistical sampling, of projecting error findings. The mere fact that the OIG adopted an audit policy that has the effect of benefiting states that succeed in administering their programs with a high degree of compliance is not grounds for finding prejudice to PRDH. Moreover, PRDH cannot reasonably (or, with its 57 errors, credibly) argue that, if it had only known about the policy, it would have administered its ADAP program with more care so as to comply with requirements with which it was already obligated to comply.

PRDH, as stated earlier, also points to an ADAP audit conducted by the OIG in Illinois in which the OIG did not extrapolate its three error findings to the universe of Illinois' claims. PRDH Appeal Br., Att. 6. PRDH states that –

> [i]t respectfully requested that the Government of Puerto Rico be provided the same treatment as was given to Illinois . . . . In the Illinois audit the results were similar to ours but in terms of the sanction to Illinois were dramatically different. Illinois was required to reimburse only the actual cost of the medications dispensed with discrepancies.

Id. at ¶ 19.

We reject this argument. Illinois had three errors in a sample of 100 cases; PRDH had a 57. PRDH's and Illinois' "audit results" were not, as PRDH claims, "similar."

2. PRDH failed to document that any of the 19 sample prescriptions for which it challenges the OIG's error findings were eligible for ADAP reimbursement.

In the audit, the OIG "considered a sample item improper if the patient had other Federal, State, or private health insurance that covered the dispensed drugs." Audit, App. A at 1.

In its Order, the Board asked PRDH to specifically identify the disallowed sample prescriptions that it contends are eligible for ADAP reimbursement.[7] In its response, PRDH identifies 19 prescriptions. For each, it gives reasons why it believes the prescription was correctly paid under ADAP and attaches a "Statement" by the Executive Director of the Puerto Rico Health Insurance Administration or the ADAP Coordinator about that prescription.

Below we first review the payer of last resort requirement of the Act and HRSA's guidance to grantees for administering that requirement. We then explain why we conclude that PRDH has failed to meet its burden to document that it complied with payer of last resort requirement for any of the challenged prescriptions.

a. The fact that the cost of a prescription for a low-income HIV/AIDS individual is covered by that individual's Federal, State, or private health insurance establishes a rebuttable presumption that that program could reasonably be expected to pay for the prescription and, therefore, ADAP funds are not available under the payer of last resort requirement.

Part B of the Act requires states to "ensure that grant funds are not to be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service," by other programs or insurance. 42 U.S.C. § 300ff-27(b)(7)(F). HRSA, in the Ryan White CARE Act Title II Manual (June 1, 2000), Section IV, HRSA Division of Service Systems Program Policy Guidance (Program Policy Guidance) No. 2, at 4, expressly informed states that "[a]t the individual client level, [the payer of last resort requirement] means that grantees and/or their subcontractors are expected to make reasonable efforts to secure other funding instead of CARE Act funds whenever possible."[8]

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[7] This action was necessary because PRDH did not identify sample prescriptions by number in its Appeal Brief, and the brief could be read as disputing only five prescriptions. *See* PRDH Appeal Br. at 6 (referring to "five (5) prescriptions for which evidence was provided").

[8] This Manual provision was cited by the OIG in the Audit at page 2, but neither party submitted a copy of it for the record. The Manual is found at ftp://ftp.hrsa.gov/hab/T2M2003.pdf. In Policy Guidance No. 6 of the Manual, when discussing eligibility of individuals under ADAP, HRSA wrote:

> All States should devise, implement and rigorously monitor the use of consistent eligibility standards across all entities involved in certifying and recertifying ADAP eligibility. Such certification is expected to include review and documentation of an applicant's income from all sources and any pharmaceutical benefits derived from private health insurance or other sources.
>
> * * *
>
> Re-certification procedures should include mechanisms to assure that individuals who have become eligible for Medicaid are transferred to the Medicaid program at the earliest possible date.

Program Policy Guidance No. 6, at 15.

From this statutory language and agency guidance, we conclude that the fact that the cost of a prescription for a low-income HIV/AIDS individual is covered by that individual's Federal, State, or private health insurance establishes a rebuttable presumption that another payer could reasonably be expected to pay for the prescription and, therefore, ADAP funds are not available. A state may rebut this presumption by showing that the state has not succeeded in securing payment from such other payers despite reasonable efforts to do so. Since a state has the burden of documenting the allowability of its claims for federal funds, PRDH has the burden of proving that circumstances exist here which justify concluding that it made such "reasonable efforts" to secure such payment for the challenged sample prescriptions. *See New York,* DAB No. 1827, at 10 (reaffirming that "the State carries the burden of proof with respect to documentation of its claims").

b. PRDH's lack of effective administrative capacity to determine which individuals had health insurance and to bill that insurance for ARV drugs is not a basis for reversing this disallowance.

The OIG found that PRDH made these improper ADAP payments as a result of the fact that PRDH "had not developed procedures to bill HIV/AIDS drugs to insurance plans with primary payment responsibility." Audit at i. PRDH confirmed this finding, writing that, during the audit period, it "did not have automated processes for the dispensing of HIV medications, thus making it impossible to keep track and adequately bill the pertinent entities with primary payment responsibility." PRDH Appeal Br. at ¶ 3. PRDH also states that "[i]t was difficult to determine which patients and drugs were covered by the state or private sponsored health insurance without the information technology in place." *Id.* at ¶ 5. Elsewhere PRDH argues that the disallowed payments were made "due to the fact that at the time PRDH could not reasonably have denied medication to the patient because it did not have knowledge that payment . . . could reasonably be expected to be made under" another program. PRDH Response to Order at ¶ 21. PRDH concludes that "[t]he grant award requires the PRDH to fund the purchase of medications through the ADAP for the medically indigent population of Puerto Rico. The PRDH under the circumstances had no options but to cover the population claiming to have no means to obtain medication." *Id.* at ¶ 10.

To the extent that PRDH is arguing that its lack of "automated processes" for determining which individuals had insurance and for billing that insurance is a basis for treating these prescriptions as properly paid under ADAP, we reject that argument. The failure to develop processes adequate to determine insurance coverage and bill the insurers is a failure to make "reasonable efforts to secure other funding instead of CARE Act funds whenever possible." Program Policy Guidance No. 2.

Below we discuss PRDH's challenges to specific prescriptions that are based on what it describes as "special circumstances." PRDH Appeal Br. at ¶ 3. It argues that, under

these circumstances, PRDH's public health insurance program, GHIP, would not have actually paid for the prescriptions that the OIG found were covered under GHIP. As explained below, we find that PRDH has failed to meet its burden to document that any of these circumstances would support the conclusion that PRDH had made "reasonable efforts to secure" GHIP funding for these prescriptions. We therefore conclude that PRDH has failed to rebut the presumption that ADAP funds were not available under the payer of last resort requirement.

c. PRDH's challenges to individual sample prescriptions are without merit.

(1) For Sample Prescriptions Nos. 7, 30, 40, 52, 69, 77 and 94, PRDH failed to document that prescriptions filled prior to July 1, 2003 for individuals who were HIV positive but did not have AIDS were prescriptions for which payment could be not reasonably be expected to be made by GHIP.

In its initial brief, PRDH argues that certain sample prescriptions that predated July 1, 2003 were eligible for ADAP reimbursement because of "confusion" about coverage of ARV medication under PRDH's public health insurance program for HIV positive individuals who did not also have AIDS (referred to hereafter as HIV-only individuals).[9] PRDH Appeal Br. at 2; *see also* PRDH Response to Order at 2-7 (challenging sample prescriptions 7, 30, 40, 52, 69, 77, 94).

The following background information is relevant to understanding PRDH's arguments about these prescriptions.

PRDH's public health insurance program, GHIP, "is a medical and drug assistance program . . . [that] consists of Medicaid, State Children's Health Insurance Program, Commonwealth, and private funding." Audit at 3, n.5. GHIP is administered by the Health Insurance Administration, for which the Spanish acronym is ASES. PRDH Appeal at ¶ 5. Services for recipients of GHIP were delivered through contracts between ASES and managed care organizations (MCOs). *Id.* at ¶¶ 5, 6; Audit at 4, n.6. In order for GHIP recipients with HIV or AIDS to obtain ARV drugs under GHIP, their primary physician had to request "special coverage" certification for them. HRSA Ex. 5, at 6.

[9] HIV, or Human Immunodeficiency Virus, is a virus that can result in AIDS, or Acquired Immunodeficiency Syndrome. Not everyone with HIV has AIDS, but everyone with AIDS has HIV. For purposes of Puerto Rico's public health insurance programs, a person with AIDS was defined as a "person who is HIV positive, confirmed with Western Blot test with levels of CD-4 < 200 and/or with [certain] opportunistic conditions . . . ." PRDH Appeal Br., Att. 2. The individuals to whom these prescriptions were provided had CD-4 levels greater than 200, and we see no evidence that they had one of the identified opportunistic conditions. PRDH Appeal Br., Att. 8.

PRDH does not dispute that the individuals to whom these prescriptions were provided were GHIP recipients with special coverage certification. It asserts, however, that because these individuals did not meet ASES's AIDS definition, the MCOs did or would have treated them as ineligible for ARV drugs under GHIP. For each of the sample prescriptions in this group, PRDH states:

> According to the records, at the time the prescription was dispensed there was a discrepancy with the requirements for special coverage for antiretroviral medication, in terms of the HIV positive/AIDS definition before July 1st, 2003 as per Normative Letter No. 03-0829. Thus, this [HIV-only] patient had no special coverage for [ARV] medication and had to rely on the Immunological Clinics to fill his prescriptions . . . .

PRDH Response to Order at 2, 3, 4, 5, 6, 7.[10]

As to HIV-only GHIP recipients, PRDH represents as follows in its Appeal Brief:

> Inconsistency with policies and regulations enacted by the ASES related to the access for HIV medications emerged during 2002. An official letter from the ASES, dated September 17, 2002 . . . tried to explain to the [MCOs] contracted by the ASES what was the procedure to service AIDS patients. This letter established a definition for AIDS, which excluded HIV positive only patients. . . . This caused a general misunderstanding that required the ASES to clarify it in another official letter [Normative Letter No. 02-12] dated March 3, 2003 . . . due to the fact that confirmed HIV [only] patients were having access problems for the special coverage therefore, not receiving specialized clinical services including anti-retroviral ("ARV") medication, thus obligating the PRDH to provide the same through [ADAP]. In August 29, 2003, another circular was published to clarify earlier communications stating that MCOs had to provide . . . medications . . . required for both HIV positive only and AIDS patients . . . .
>
> * * *
>
> The resulting confusion regarding the AIDS definition, established by ASES and its special coverage, was in place for the first fifteen (15) months (from April 1st,

[10] We do not see a copy of Normative Letter No. 03-0829 in the record. For each sample case in this group, PRDH also attached a "Statement" from the Executive Director of ASES "certify[ing]" that:

> According to the records, at the time the prescription was dispensed there was a widespread misinterpretation in terms of the requirements for the inclusion in the special coverage for antiretroviral medication, in terms of the HIV positive/AIDS definition before July 1st, 2003 as per Normative Letter No. 03-0829.

Atts. 1, 4, 7, 10, 15, 16, 18.

> 2002 through June 30th, 2003) of the OIG auditing time period. As a result of this ASES policy, HIV patients who did not meet with the AIDS definition criteria did not have access to [GHIP] AIDS special health insurance coverage with ARV medications. The PRDH had the obligation to provide HIV medications to all [GHIP] positive patients who did not comply with the ASES's AIDS patient definition.

PRDH Appeal Br. at ¶¶ 6, 8.

In its Order, the Board sought to clarify (1) whether PRDH was asserting that these prescriptions were eligible for ADAP funding because prior to July 1, 2003 HIV-only GHIP recipients were ineligible for ARV medications under the GHIP programs or under some reasonable interpretation by ASES of GHIP requirements or (2) whether PRDH was asserting that these prescriptions were eligible for ADAP funding because "confusion" created by the ASES letter caused MCOs to improperly deny ARV drug coverage to HIV-only GHIP recipients.

In response, PRDH does not explicitly state that these prescriptions were ineligible for reimbursement under GHIP. Rather, it asserts (contradicting its prior assertions about the March 2003 letter) that "it was not until August 29, 2003, that [ASES] clarified the limitation and conditions of the prescription services for Medicaid beneficiaries . . . ." PRDH Response to Order at 10. It states (without further explanation) that this "clarification was brought about by the Puerto Rico Medicaid State Plan approved on March 5, 2003 with an effective date of August 13, 2003." *Id.* PRDH attaches two pages of its State plan. An entry at the bottom of each page indicates that unidentified language on these pages was adopted in "TN No. 03-001A" and that TN No. 03-001A had an effective date of August 13, 2003 and "supersede[d]" TN No. 84-3. PRDH does not use the term State plan "amendment," but we assume that TN No. 03-001A identifies a Medicaid State plan amendment.

PRDH quotes the following provision from one of the pages:

> Limitations and conditions of the prescriptions services
>
> * * *
>
> b. Drugs required for the . . . treatment of diagnosed beneficiaries with AIDS or with an HIV positive factor are covered under the special coverage to include antiretrovirals but excluding Protease inhibitors.

PRDH Response to Order at 10, Att. 20 (state plan excerpt).

For the following reasons, we determine that PRDH has not documented that the September 17, 2002 letter or any State plan provision or other authority provides a basis

for concluding that any of the sample prescriptions listed above were ineligible for GHIP funding and, therefore, eligible for ADAP funding.

- The quoted excerpt from its State plan indicates coverage for HIV-only patients as well as HIV patients with AIDS. PRDH never asserts (and we see no basis to conclude) that its Medicaid State plan in effect prior to August 13, 2003 (the effective date of TN No. 03-001A) did not authorize coverage of ARV drugs for HIV-only recipients and, as discussed below, PRDH has submitted no evidence that would support such a conclusion. Nor has PRDH argued that, in the September 17, 2002 letter, ASES reasonably interpreted the Medicaid State plan as not providing coverage for ARV drugs for HIV-only individuals.

- The auditors specifically determined that HIV-only individuals were eligible for Medicaid under the State plan and that the Medicaid contractors were obligated to provide special coverage for ARV drugs to them during the entire audit period. *See* Audit at 4 n.6; HRSA Ex. 6 (OIG email of February 24, 2009; OIG email of March 13, 2009). Indeed the auditors appear to have relied on the excerpt quoted by PRDH, writing that "[p]ursuant to a Puerto Rico Medicaid State plan amendment and contracts between the Health Department and insurance companies that pay for services rendered to GHIP patients, the GHIP covers all drugs required for the treatment of HIV/AIDS patients except for seven protease inhibitors." *Id.*, n.6. If PRDH is now arguing that the auditors incorrectly construed its State plan generally or the effect of this provision specifically, PRDH was on notice that it needed to provide evidence about the pre-August 2003 terms of its State plan, which it failed to do.[11] Nor did PRDH contest HRSA's statement in HRSA's response to the Board's Order that PRDH "has not indicated in its approved State plan any limitation on AIDS prescription drug coverage." HRSA Response to Order at 4.

- Finally, we note both the ASES March and August 2003 letters claim to be clarifying existing coverage rather than implementing a change and neither letter mentions any amendment to the State plan.

Therefore, PRDH has failed to document that the sample prescriptions 7**,** 30, 40, 52, 69, 77, and 94 were ineligible for GHIP funding.

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[11] Indeed, the disallowance letter stated:

> The OIG has also advised HRSA that based on the GHIP and contractor policies, all antiretroviral drugs (excluding protease inhibitors) were included as part of the GHIP special coverage regardless of whether the patient had been registered as an AIDS patient or had been diagnosed as HIV positive.

PRDH Appeal Br., Att. 1, at 2.

We also reject PRDH's argument that, because of the alleged "misunderstanding" or "confusion" between ASES and the MCOs that allegedly caused MCOs to deny ARV drugs to HIV-only GHIP recipients with special coverage, it "had the obligation to provide HIV medications under [ADAP]" to these individuals. PRDH Appeal Br. at ¶ 8. To the extent that ASES's September 17, 2002 correspondence resulted in the MCOs' improperly excluding HIV-only recipients from receiving HIV drugs under GHIP, PRDH has failed to show that this confusion was not caused by ASES's misadministration of GHIP, which would not be a basis for shifting these costs to ADAP. Specifically, PRDH has not shown that it worked with ASES to address ASES's apparent failure to supervise the MCOs so that they administered the GHIP program in accordance with the Medicaid state plan or the other GHIP program requirements. PRDH has therefore has not shown that there was not a failure "to make reasonable efforts to secure other funding instead of CARE Act funds whenever possible" as instructed by Program Policy Guidance No. 2. Under such circumstances, the payments for these prescriptions are payments that could be fairly regarded as ones that could "reasonably be expected to be made . . ." by sources other than ADAP. 42 U.S.C. § 300ff-27(b)(7)(F).

(2) As to Sample Prescriptions Nos. 21, 31, 39, 58, 59, and 67, PRDH failed to document that prescriptions for HIV/AIDS recipients who were certified for basic but not special coverage under GHIP were prescriptions for which payment could not reasonably be expected to be made by GHIP.

According to PRDH, these sample prescriptions share the characteristic that they were provided to GHIP recipients with basic coverage who, as HIV/AIDs patients, should have also been certified for special coverage. Because they had not been so certified, the individuals could not obtain ARV drugs under GHIP. For each of these prescriptions, PRDH stated in its Response to the Order:

> According to the records, at the time the prescription was dispensed this patient had basic coverage and thus could not obtain [ARV] medication through the government health insurance plan.

PRDH Response to Order at 3, 4, 5, 6. PRDH also attached a "Statement" from the Executive Director of ASES "certify[ing]" that the above statement was true for each of these prescriptions. *Id.* at Atts. 3, 5, 6, 11, 12, 14.

As to special coverage, PRDH said elsewhere in the record:

> [I]t was always a requirement that for a patient to receive medications for the treatment and management of HIV/AIDS conditions that the primary physician requests a special coverage certification for each patient. Without the official certification, community pharmacies could not dispense HIV medications to patients. Furthermore, some of the beneficiaries of the government health

> insurance treated at the Regional Immunologic Clinics were not registered with special coverage for HIV medications, making them eligible for ADAP.

PRDH Appeal Br. at ¶ 7; *see also* HRSA Ex. 5, at 6.

The fact that these recipients, who PRDH does not deny were eligible for special coverage under GHIP, had not been certified in the GHIP system for that coverage is not, in itself, a basis for treating these prescriptions as eligible for ADAP. Since PRDH does not explain why these recipients were not properly certified, the reasonable inference is that the lack of certification was the result of some administrative problem in ASES's operation of the GHIP program. PRDH does not assert that it took any steps (1) to address ASES's apparent failure to supervise the MCOs so that they administered the GHIP program in accordance with Puerto Rico's Medicaid state plan and other GHIP standards or (2) to obtain, through its ADAP program or otherwise, the required certification from patient's primary physicians. Therefore, we conclude that PRDH has failed to show why these payments were not ones that "[could] reasonably be expected to be made . . ." by sources other than ADAP, specifically Medicaid or other GHIP programs.

We note the following special circumstances about Prescription No. 59, which was provided to an individual with the initials R.R.M. on March 1, 2004. PRDH Response to the Order at 5; and Att. 12. While PRDH identifies R.R.M. as having basic coverage in its Response to the Order, the record contains conflicting evidence which raises a question as to whether R.R.M. was covered at all by GHIP as of March 1, 2004. PRDH, however, did not rely on this evidence, and we are unable to conclude on the record before us that the prescription was eligible for ADAP reimbursement.

Attached to HRSA Exhibit 5 is a January 22, 2009 letter to HRSA about a person with the initials R.R.M. (and also the same full name as used in the PRDH Response to the Order) from Triple S, Inc., one of ASES's MCOs. The letter refers to two dispense events for R.R.M., on November 24, 2003 and on March 1, 2004 (neither of which, it says, were made "through our health plan"). The letter lists the dates R.R.M. was "insured with [GHIP]." Those dates encompass November 2003 but not March 2004 -- March is the prescription at issue here. This information is consistent with PRDH's entries on the spreadsheet attached to the PRDH Response to the Order where the individual for Prescription No. 59 is listed as being "UNINSURED" and having "NO COVERAGE." It is inconsistent with other entries on that spreadsheet which indicate that R.R.M. was insured with "Triple C," which was an MCO and a subsidiary of Triple S. *See* OIG email dated March 13, 2009 at HRSA Ex. 6 (stating Triple C was subsidiary of Triple S).

We cite here the conflicting evidence regarding Prescription No. 59 so that HRSA may, if it chooses, review this evidence and other documents that it may have to determine

whether they show that this prescription was eligible for ADAP reimbursement, and, if so, may reduce the disallowance accordingly.

(3) PRDH failed to document that Sample Prescription Nos. 10, 41, 45, 62, 95, and 85 were ones for which payment could not reasonably be expected to be made by GHIP.

Sample Prescription No. 10

As to Sample Prescription No. 10 for an individual with the initials "I.M.S.," PRDH says in its Response to the Order:

> According to the records, at the time the prescription was dispensed, this patient had no medical or pharmacy insurance, and was not found in the [Medicaid] System or any insurance company contracted by ASES. For this reason, this patient is identified as uninsured.

See also, Att. 2 to Response to Order (giving the same justification).

We reject PRDH's assertions because they are inconsistent with its prior assertions to HRSA and other evidence in the record that indicate that the individual who received this prescription was covered by GHIP. In an email of February 3, 2009, the ADAP coordinator informed HRSA that "Prescription #10 was insured by Triple S on the date of the services [August 26, 2002], had Medicare Advantage coverage with pharmacy coverage and was registered in the Special Coverage." February 3, 2009 email attached to HRSA Ex. 5. In its submission dated March 5, 2009 to HRSA about this prescription, PRDH again represented to HRSA that this person was insured under "Government Health Insurance," had "Special Coverage" and its "Justification" for claiming under ADAP was "Health Reform – HIV/AIDS Definition before July 1st of 2003." HRSA Ex. 5, at spreadsheet attachment. Finally, a January 29, 2003 letter from Triple-S, Inc., an MCO, stated that this recipient (initials I.M.S., prescription date August 26, 2002) had GHIP special coverage as of August 26, 2002. Letter dated January 23, 2009 attached to HRSA Ex. 5.

Sample Prescription No. 41

In its Response to the Order, PRDH says that this individual with initials J.P.M. "was uninsured because at the time of the service [he had] a private plan without pharmacy coverage making this patient eligible for [ADAP]." Att. 8 to PRDH Response to Order; *see also* PRDH Appeal Br. at Att. 8 (giving the same justification).

We reject PRDH's assertions because they are inconsistent with its prior assertions to HRSA and other evidence in the record that shows the individual receiving this prescription had drug coverage under GHIP. First, while the auditors did not dispute that J.P.M. had private health coverage, they found J.P.M. was also eligible for HIV

supplemental drug coverage under GHIP (Att. 8 to PRDH Appeal Br.), specifically with MCO Triple C, a subsidiary of MCO Triple S (OIG email dated March 13, 2009 at HRSA Ex. 6). This information is consistent with PRDH's entries on the spreadsheet attached to HRSA Exhibit 5, on which it recorded that J.P.M. had "Private - Triple SSS" coverage, but argued that he was qualified for ADAP because of the confusion over GHIP coverage for HIV-only individuals before July 1, 2003, an argument that we have rejected.

Sample Prescription Nos. 62 and 95

For both of these prescriptions, the Executive Director of ASES said: "According to the records, at the time the prescription was dispensed this patient was not active in any insurance companies contracted by ASES." Atts. 13, 19 to PRDH Response to Order. In its response to the Order, for each of these individuals PRDH said: "According to the records, at the time the prescription was dispensed this patient was not certified as Medicaid eligible nor was he active in any of GHIP's [programs]." PRDH Response at 6, 7-8; PRDH Appeal Br., Att. 8 (giving the same justification).

In an email to HRSA, the ADAP Executive Director wrote to HRSA that "[p]rescription #62 was certified by the Medicaid Program but the patient was not active in the health plan at the date of service." February 3, 2009 email attached to HRSA Ex. 5.

According to the information in PRDH's spreadsheets, HRSA found that these people were covered by Triple C, an MCO. Att. 8 to PRDH Appeal Br.

PRDH has failed to explain what was meant by "certified as Medicaid eligible" or "active in any insurance companies contracted by ASES." Elsewhere, PRDH said about a group of unidentified prescriptions it categorized as "Uninsured Findings," that each individual --

> was eligible for the GHIP (Reform) but was inactive at the time. In the norms and procedures of the GHIP (Reform) patients had to comply with certain requirements to be insured. The patients had to be low income, adequately certified to be insured with the GHIP (Reform) and activated in the insurance company delivering the hard copy eligibility approval.

HRSA Ex. 5, at 9.

Based on this explanation, "inactive" and "uncertified" do not appear to mean that the person is ineligible for GHIP. Instead these terms appear to be related to an administrative process of establishing eligibility over which it appears ASES had control. Moreover, PRDH has failed to explain why the fact that a person was not "active" or not "certified" would support a finding that payments for these drugs could not "reasonably be expected to be made . . ." by GHIP. 42 U.S.C. § 300ff-27(b)(7)(F). Thus, PRDH has

failed to document any basis on which we could conclude that it "made reasonable efforts to secure" GHIP funding for these prescriptions. Program Policy Guidance No. 2.

Sample Prescription No. 45

In Sample Prescription No. 45, ADAP paid for a prescription dispensed February 2, 2005. In its Response to the Order, PRDH says that "according to the records, at the time the prescription was dispensed this patient was certified as Medicaid eligible but was not active in ASES." Att. 9 to PRDH Response to Order; PRDH Appeal Br. at Att. 8 (giving the same justification).

We also note the following additional evidence in the record related to this patient.

- In a letter dated January 22, 2009, MCO Triple-S "certif[ied]" to HRSA that this patient "was insured with the Puerto Rico Government Health Insurance Plan for November 4, 1998 through April 1, 2005. She did not have Special Coverage." HRSA Att. 5, Triple S letter of January 22, 2009.

- In an email dated February 3, 2009, a Puerto Rico official wrote to HRSA: "Prescription #45 was evaluated by Medicaid Program and certified as eligible to the Puerto Rico Government Health Insurance Plan. However the patient was insured by MCS Health Plan posterior to the date of service." Email attached to HRSA Ex. 5.

Based on this evidence, we reject PRDH's argument for this prescription. First, documentation submitted to HRSA by the contractor stated that the patient did have GHIP coverage, but no special coverage, as of the date of service. As discussed above, the failure to obtain a special coverage certification for a GHIP recipient does not make the recipient eligible for ADAP. Moreover, as stated earlier, PRDH has failed to explain what it means for a patient to be certified as "Medicaid eligible" but not "active in ASES" and why this would justify payment by ADAP. Finally, we find PRDH's statement in the February 3, 2009 email unpersuasive because it is inconsistent with the January 22, 2009 Triple-S letter and not supported by other evidence in the record.

Sample Prescription No. 85

As to Sample Prescription No. 85, PRDH states: "According to the records, at the time the prescription was dispensed this patient was not certified as Medicaid eligible nor was she active in any of GHIP's [programs]." PRDH Response to Order at 7. In his statement about this prescription, the Executive Director of ASES asserts: "According to the records, at the time the prescription was dispensed this patient was not active in any of the insurance companies contracted by ASES." PRDH Response to Order, Att. 17.

The record contains additional evidence about Sample No. 85. In an email to HRSA, the ADAP Executive Director stated that "[t]he prescription #85 was insured by Triple C with a different social security number, it was active at the date of the service and it was registered in the Special Coverage. PRDOH withdraw[s] its claim that prescription #85 was uninsured because of an error in the data." February 3, 2009 email attached to HRSA Ex. 5. This is consistent with PRDH's Attachment 8 to the PRDH Appeal Brief, which reports that the OIG had found this individual was insured by Triple C, an MCO.

We uphold HRSA's finding as to this prescription based on PRDH's statement in the email and the fact that, as discussed above, PRDH has failed to explain what "active" means in relation to whether payment for this prescription could have been reasonably expected to be made under GHIP.

3. PRDH's remaining arguments are without merit.

PRDH makes a number of other arguments. Below we explain why we reject them.

a. The 15-Day Policy

First, PRDH represents that "ASES policies . . . created barriers and limitations for patients to access HIV/AIDS medications." PRDH Appeal Br. at ¶ 9. One such barrier was ASES's policy of approving certain ARV medication prescriptions for only 15 days, which PRDH represents was a cost-containment measure "based on a cap that the federal government has instituted on federal funds to the Puerto Rico Medicaid Program since its inception." *Id*. PRDH asserts that "since patients had to complete their monthly therapy; the PRDH classified them as underinsured because of the access limitations to antiretroviral combination therapies. In those cases, the PRDH provided complete therapies to assure the required and proper treatment." *Id*.

In the Order, we questioned whether this 15-day policy meant that (1) Medicaid recipients using ARV drugs could obtain only 15 days of drugs each month from Medicaid or that (2) these recipients were required to get two 15-day prescriptions to fulfill their monthly needs under Medicaid.

PRDH responded:

> [T]he restriction of 15 days is a consequence of a $500.00 limitation on the coverage of antiretrovirals such as Videx, Combinvir, Trizivir, Sustiva, Epivir and Viramune. Patients that use any of these antiretrovirals as part of their treatment can only obtain a 15-day supply for the prescription, and **then have to go again to obtain the other 15 days filled each month**. **The resulting outcome was that due to the fact that the PRDH did not have a mechanized system and no way of determining insurance coverage, many patients opted to visit our Clinics in order to have the full 30-day prescription filled [by ADAP].**

PRDH Response to Order at 10 (emphasis added).

This 15-day restriction is not grounds for charging any of the disallowed costs to ADAP. In the first place, PRDH has not identified any sample prescriptions that it asserts should be allowed because of the 15-day limit. Furthermore, as PRDH has conceded, while the 15-day limit may have led some Medicaid (or other GHIP) recipients to use ADAP facilities to get a 30-day prescription, the costs for 30 days of medication were eligible for coverage under GHIP. Thus, payment of the costs of these prescriptions "[could] reasonably be expected to be made by sources other than" ADAP, and the costs were properly disallowed. 42 U.S.C. § 300ff-27(b)(7)(F).

Furthermore, PRDH created this logistical hurdle, thereby encouraging or causing some recipients to go to the RICs, while not having "a mechanized system" that would enable it to identify Medicaid recipients if they sought Ryan White services/medications. As HRSA points out, this amounts to a failure by PRDH to "develop . . . procedures to screen and bill HIV/AIDS drugs to the insurance plans with primary payment responsibility." HRSA Response Br. at 5. Such administrative failures are evidence that PRDH did not make "reasonable effort[s] to secure other funding." Program Policy Guidance No. 2.

b. Alleged lack of oversight

PRDH asserts that --

> the alleged noncompliance with regulations during the period of time of the grant was never acted upon by the federal officers in charge of providing technical assistance, guidance and monitoring of the use of the grant award. There is also a lack of questioning of the grant officers. By their omissions, the grant officers should also be held liable for any negligent management of the funds. In our review of the PRDH administrative record, we find no process or progress report in place that could have identified mismanagement of the grant and would have prevented such situation to have happened.

Id. at ¶ 14.

We reject this argument. PRDH has pointed to no authority for the proposition that HRSA had supervisory responsibility during the period in question, which, if not exercised, would preclude a disallowance. In any event, the fact that a federal agency exercises oversight over federal funds or provides technical assistance to a grantee does not relieve the grantee of its obligation to administer its grant in compliance with all federal laws and grant conditions, nor does it make federal grant officers "liable" for what PRDH characterizes here as "any negligent management of the funds."

Moreover, while PRDH alleges that HRSA grant officers did not "question" it sufficiently to "identif[y] mismanagement" and to "prevent[] such situation," the following aspects of the record show that, at the time PRDH expended these funds, PRDH understood both that it was obligated to recover Part B expenditures from primary payers and that it lacked the administrative capacity to do so.[12] First, the fact that PRDH had a "contract with a billing agent to bill [Part B] medical visits and laboratory tests to plans with primary payment responsibility" indicates that it understood that it was responsible for identifying and recovering Part B costs from primary payers. Audit at 4. Second, PRDH represents that the reason that it did not recover ADAP costs from primary payers was because it "did not have automated processes for the dispensing of HIV medications, thus making it impossible to keep track and adequately bill the pertinent entities with primary payment responsibility." PRDH Appeal Br. at ¶ 3. Therefore, PRDH was in no way dependent on HRSA grant officers to identify PRDH's mismanagement of its ADAP grant.

Finally, even where grantees allege that they affirmatively sought and were misled by federal guidance (which PRDH does not allege here), the Board has rejected such estoppel defenses, writing:

> [E]stoppel against the federal government, if available at all, is presumably unavailable absent "affirmative misconduct" by the federal government. *Office of Personnel Manangement v. Richmond*, 496 U.S. 414, at 421 (1990). Certainly estoppel is unavailable where the party fails to show even the traditional elements of estoppel, such as reasonable reliance. *Heckler v. Community Health Services*, 467 U.S. 51, at 60 (1984) (fiscal intermediary gave provider incorrect advice but provider failed to show reasonable reliance).

Family Health Services of Darke County, DAB No. 2269, at 19 (2009). We see nothing in the record indicating that PRDH's errors in the administration of the ADAP grant were based on reasonable reliance on federal guidance or resulted from even the lack of federal guidance. As discussed above, PRDH knew it lacked the administrative capacity to comply with the ADAP payer of last resort requirement and cannot avoid the consequences of that lack by blaming HRSA.

c. **Large amount of the disallowance**

Third, PRDH asserts that disallowing this large amount of money puts it in "more than a precarious position as it has no means to be able to claim or bill any entity which might

[12] HRSA stated that, subsequent to the audit, PRDH "satisfactorily responded to the OIG's recommendation that [PRDH] develop procedures to bill HIV/AIDS drugs to the Federal, State, or private health insurance plans with primary payment responsibility. However, the corrective actions that have been taken relative to this recommendation are subject to review during future periods to determine their adequacy." PRDH Appeal Br., Att. 1. PRDH represents that "[a]fter the new billing system was mechanized in 2008, the PRDH has recovered 31.7 million dollars from January of 2008 through May of 2010 . . . ." PRDA Appeal Br. at ¶ 4.

have had at the time the primary payment responsibility" for paying for these prescriptions. *Id.* at ¶ 15. It asserts further that the disallowance "ultimately frustrates the whole purpose of the Grant by preventing HIV/AIDS patients from access to life saving medication as we cannot sustain a similar program with only State funds." PRDH Reply Br. at ¶ 14. According to PRDH, this disallowance will put a "burdensome load on the Agency" and force it "to put patients with HIV/AIDS medications necessities on waiting lists further jeopardizing the health of this population." PRDH Appeal Br. at ¶¶ 15, 16.

HRSA does not dispute these allegations. However, the Board lacks authority to grant PRDH's request for what is essentially equitable relief. *West Virginia Dept. of Health and Human Resources*, DAB No. 2185, at 20 (2008); *Utah Dept. of Health*, DAB No. 2131, at 23 (2007). We must uphold a disallowance if it is supported by the evidence of record and is consistent with the applicable statutes and regulations. *West Virginia*, DAB No. 2185, at 20, citing 45 C.F.R. §§ 16.14, 16.21. As explained above, we conclude that this disallowance satisfies those criteria.

Finally, to the extent that PRDH is arguing that the disallowance "ultimately frustrates the whole purpose of the Grant," we note that the purpose of ADAP was frustrated here because PRDH did not comply with the payer of last resort requirement. It needlessly spent limited ADAP funds for prescriptions for which payment could reasonably be expected to be made by other payers, principally GHIP.

Conclusion

For the preceding reasons, we uphold this disallowance in full.

_____/s/_____
Judith A. Ballard

_____/s/_____
Leslie A. Sussan

_____/s/_____
Sheila Ann Hegy
Presiding Board Member