UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GENTIVA HEALTHCARE CORP., d/b/a HERITAGE HOME HEALTH, **Plaintiff,** **v.** **KATHELEEN SEBELIUS, Secretary, U.S. Department of Health and Human Services,** **Defendant.**	**Civil Action No. 11-438 (JEB)**

MEMORANDUM OPINION

Plaintiff Gentiva Healthcare Corporation provides home health services to beneficiaries under the Medicare program, which reimburses providers like Gentiva. Operating under a contract with Defendant Kathleen Sebelius, the Secretary of the U.S. Department of Health and Human Services, a Medicare contractor in 2007 undertook a review of a subset of Gentiva's claims for such reimbursement. Finding a "sustained or high level of payment error" among Gentiva's claims, the contractor proceeded to calculate Medicare's total overpayment to Gentiva by extrapolating from a sample of 30 claims to the universe of 1,951 claims. After determining that 26 of the 30 claims in the sample had been overpaid, the contractor extrapolated that 85.64% error rate across the total number of claims and sought to recoup from Gentiva the sum of $4,242,452.10 in Medicare overpayments.

Gentiva sought administrative review of the overpayment assessment and eventually succeeded in overturning the contractor's overpayment determination with respect to most of the claims in the sample. The total amount Gentiva owed was correspondingly diminished to approximately $850,000. The Secretary, however, upheld the contractor's finding of a

"sustained or high level of payment error" and subsequent use of extrapolation.

In this suit Gentiva claims that the Secretary's decision upholding the contractor's use of extrapolation to calculate its overpayment amount was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the Administrative Procedure Act and the Medicare statute. Specifically, Gentiva argues that the Secretary, not a Medicare contractor, must make the "sustained or high level of payment error" determination before a contractor can use extrapolation to calculate a provider's overpayment amount. In the alternative, Gentiva challenges the merits of the contractor's determination that a "sustained or high level of payment error" was present.

Both parties now seek summary judgment. Because the Medicare statute contains a broad authorization for the Secretary to delegate her responsibilities to contractors and in light of the deference to which agencies' interpretations of their own statutes are entitled, the Court finds that the Secretary's determination that a contractor may make the "sustained or high level of payment error" determination was neither arbitrary and capricious nor contrary to law. Furthermore, because Congress expressly precluded judicial review of "sustained or high level of payment error" determinations, the Court lacks jurisdiction to consider Gentiva's challenge to the contractor's finding that such a level of payment error existed here. The Court will thus grant Defendant's Motion for Summary Judgment and deny Plaintiff's.

I. Background

A. Regulatory Framework

Established in 1965 by Title XVIII of the Social Security Act, the Medicare program provides federally subsidized health insurance for elderly and disabled individuals. See 42 U.S.C. § 1395 *et seq.* The program reimburses participating providers of medical services,

including home health services, for the reasonable, actual costs of services rendered to Medicare beneficiaries. See id. § 1395f(b)(1). The Centers for Medicare & Medicaid Services (CMS), a component of HHS, is charged with administering the Medicare program on the Secretary's behalf.

Private entities have long played a role in the administration of Medicare. See, e.g., id. § 1395h(a) (authorizing Medicare contractors, referred to as "intermediaries," to perform processing and payment functions for Part A); id., § 1395u(a) (authorizing contractors, referred to as "carriers," to perform processing and payment functions for Part B); see also 42 C.F.R. 421 *et seq*. Indeed, Congress has provided the Secretary with the broad authority to "perform any of [her] functions under [the Medicare statute] directly, or by contract . . . as [she] may deem necessary." 42 U.S.C. § 1395kk(a); see also Nat'l Ass'n of Home Health Agencies v. Schweiker, 690 F.2d 932, 943 (D.C. Cir. 1982) (interpreting § 1395kk(a) as "authoriz[ing] the Secretary to perform any of his Medicare functions, including his reimbursement functions, either directly or indirectly").

In 1996 Congress created the Medicare Integrity Program (MIP), pursuant to which the Secretary was required to "promote the integrity of the Medicare program" by engaging contractors to perform a variety of activities aimed at reducing overpayment and fraud. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, §§ 201-02, 110 Stat. 1936, 1994-96 (Aug. 21, 1996), codified at 42 U.S.C. §§ 1395i(k)(4), 1395ddd. Congress expanded and amended the MIP when it passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub L. No. 108-173, §§ 911, 935, 117 Stat. 2066, 2409 (Dec. 8, 2003), codified at 42 U.S.C §§ 1395kk-1, 1395ddd(f). Consistent with this initiative, Medicare contractors are empowered to identify instances in which the program

overpaid a provider and to recoup any such overpayments on the Secretary's behalf. See generally 42 U.S.C. § 1395ddd.

Congress, however, imposed a limit on contractors' ability to estimate overpayment amounts by extrapolating from a sample of relevant claims (as opposed to evaluating each and every claim individually). Specifically – and this is the language in dispute here – the statute provides that "[a] medicare contractor may not use extrapolation to determine overpayment amounts . . . unless the Secretary determines that . . . there is a sustained or high level of payment error . . . or . . . documented educational intervention has failed to correct the payment error." Id., § 1395ddd(f)(3). Congress further specified that there would be "no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors" in this context. Id.

The Secretary promulgated regulations implementing this statutory provision, see 42 C.F.R. § 405.926(p), and also addressed it in the Medicare Integrity Program Manual. See Pub. 1008-08, Trans. 114 (June 10, 2005), available at www.cms.hhs.gov/transmittals/downloads/R114PI.pdf. While the regulation merely classifies "[d]eterminations by the Secretary of sustained or high levels of payment errors" as an "[a]ction that [is] not [an] initial determination[ ] and [is] not appealable," 42 C.F.R. § 405.926, in comments made during the notice-and-comment rulemaking process the Secretary stated that "Congress required contractors to identify a likelihood of sustained or high level of payment error." 74 Fed. Reg. 65296, 65303 (emphasis added). The Manual provides contractors with guidance concerning how the "sustained or high level of payment error" determination should be made. See Pub. 1008-08, Trans. 114 (June 10, 2005), Requirement No. 3734.2. Specifically, it provides that a contractor may use a "variety of means" to identify the requisite level of payment error, including, for

example, sample probes, information from law-enforcement investigations, provider history, and allegations of wrongdoing by current or former employees. See id.

B. Factual and Procedural Background

Operating under the name Heritage Home Health, Gentiva provides home health services to Medicare beneficiaries in Salt Lake City, Utah. See Administrative Record (A.R.) at 57, 392. In January 2007, Cahaba Safeguard Administrators, LLC, operating under a contract with the Secretary pursuant to 42 U.S.C. § 1395ddd, initiated an onsite audit of Heritage Home Health. See id. at 5, 681. After reviewing claims for services provided between July 1, 2005, and November 30, 2006, Cahaba determined that 58% of those claims had been overpaid. See id. at 351, 682. Based on this 58% error-rate determination, Cahaba concluded that Gentiva's Salt Lake City location had a "sustained or high level of payment error" such that Cahaba was entitled to use extrapolation to calculate the total amount Gentiva had been over-reimbursed under § 1395ddd(f)(3). See id. at 351, 682.

Cahaba then proceeded to draw a sample of 30 claims from a universe of 1,951 claims for services rendered by Gentiva during a slightly different time period, November 1, 2005, through November 24, 2006. See A.R. at 3, 682. After reviewing these 30 claims individually, Cahaba determined that 26 of them had been overpaid – an error rate of approximately 85.64%. See A.R. at 5435, 681-83. In a letter dated October 23, 2008, Cahaba notified Gentiva that, based on its extrapolation of the results of that initial sample to the 1,951 total claims, it would seek to recoup $4,242,452.10 in Medicare overpayments. See id. at 5, 336, 356, 681-83.

Believing that the overpayment assessment was erroneous, Gentiva then began what was to be an extensive appeals process. Consistent with Medicare regulations governing the appeals process, see 42 C.F.R. §§ 405.920, 405.924(b), 405.940-58, Gentiva first sought a

redetermination from Cahaba and then sought reconsideration by another Medicare contractor. See A.R. at 467-71, 5348-49. As a result of these preliminary appeals, Cahaba's initial overpayment findings with respect to 10 of the allegedly overpaid claims were reversed. See id. at 467-71, 5348-49. With the number of overpaid claims reduced to 16 out of the sample of 30, the overpayment assessment was correspondingly reduced to $2,112,778. See id. at 467-71, 5349.

Gentiva then requested hearings before an administrative law judge on 10 of the remaining 16 claims, declining to pursue further appeals of the other 6 allegedly overpaid claims. See id. at 5, 529, 388-406. The ALJ ultimately issued ten separate but substantively similar decisions that reversed Cahaba's overpayment determination for all 10 claims on the ground that the services for which Medicare had reimbursed Gentiva had in fact been reasonable and necessary. See id. at 3, 55-75. The ALJ, however, upheld Cahaba's use of sampling and extrapolation. See id. at 3, 20-21, 70-71, 74. The effect of the ALJ's decisions, therefore, was to further reduce the number of overpaid claims in the sample of 30 from 16 to 6 – the only remaining overpaid claims being those 6 that Gentiva declined to bring to the ALJ's attention – and, by extrapolation, the amount owed from $2,112,778 to approximately $850,000. See Compl., ¶ 23.

Gentiva appealed each of the ALJ's ten decisions to the Medicare Appeals Council (MAC) of the Departmental Appeals Board. See A.R. at 49-51, 4-5. As the ALJ had found in its favor with respect to each of the overpayment determinations at issue, Gentiva challenged only the portion of her decisions that upheld Cahaba's use of sampling and extrapolation. See id. at 4-5, 21, 24-27, 49-51. Relying on 42 U.S.C. § 1395ddd(f)(3), Gentiva argued that the Secretary – not Cahaba, a contractor – was required to identify a "sustained or high level of payment error"

before Cahaba was entitled to proceed by extrapolation. See id. at 24-27; 42 U.S.C. § 1395 ddd(f)(3) ("A Medicare contractor may not use extrapolation . . . unless the Secretary determines that . . . there is a sustained or high level of payment error . . . .").

On January 27, 2011, the MAC issued its decision, concluding that Medicare contractors are permitted to make the predicate "sustained or high level of payment error" determination under 42 U.S.C. § 1395ddd(f)(3). See A.R. at 7-8. Cahaba, accordingly, had been entitled to determine Gentiva's overpayment amount by extrapolating from a sample of claims after it had determined that a high level of payment error existed. See id. The MAC's opinion constituted the "final decision" of the Secretary. See 42 C.F.R. § 405.1130.

Seeking review of the MAC's judgment, Gentiva filed a Complaint initiating the instant suit on February 25, 2011. Gentiva first contends that the MAC's decision that Medicare contractors like Cahaba may make the "sustained or high level of payment error" determination is arbitrary and capricious and contrary to 42 U.S.C. § 1395ddd(f)(3). See Compl., ¶¶ 27-28. In the alternative, Gentiva maintains that the MAC acted arbitrarily, capriciously, and without substantial evidentiary support by upholding Cahaba's determination that Gentiva had exhibited a sustained or high level of payment error despite the fact that only 6 of the 30 claims in the sample were ultimately found to have been overpaid. See id., ¶¶ 29-30. In addition, Gentiva seeks a writ of mandamus "requiring the Secretary to order her contractors to make a corrected overpayment determination based solely on the unfavorable determinations in the six claims in the 30-claim sample, without any extrapolation." Id., ¶ 32. Parties have now filed Cross-Motions for Summary Judgment.

II. Legal Standard

Summary judgment may be granted if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986); Holcomb v. Powell, 433 F.3d 889, 895 (D.C. Cir. 2006). A fact is "material" if it is capable of affecting the substantive outcome of the litigation. Holcomb, 433 F.3d at 895; Liberty Lobby, Inc., 477 U.S. at 248. A dispute is "genuine" if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. See Scott v. Harris, 550 U.S. 372, 380 (2007); Liberty Lobby, Inc., 477 U.S. at 248; Holcomb, 433 F.3d at 895.

Although styled Motions for Summary Judgment, the pleadings in this case more accurately seek the Court's review of an administrative decision. The standard set forth in Rule 56(c), therefore, does not apply because of the limited role of a court in reviewing the administrative record. See Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89-90 (D.D.C. 2006) (citing National Wilderness Inst. v. United States Army Corps of Eng'rs, 2005 WL 691775, at *7 (D.D.C. 2005); Fund for Animals v. Babbitt, 903 F. Supp. 96, 105 (D.D.C. 1995), amended on other grounds, 967 F. Supp. 6 (D.D.C. 1997)). "[T]he function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." Id. (internal citations omitted). Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review. See Richards v. INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977), cited in Bloch v. Powell, 227 F. Supp. 2d 25, 31 (D.D.C. 2002), aff'd, 348 F.3d 1060 (D.C. Cir. 2003).

The Administrative Procedure Act "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." FCC v. Fox Television Stations,

Inc., 129 S. Ct. 1800, 1810 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This is a "narrow" standard of review as courts defer to the agency's expertise. Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). An agency is required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Id. (internal quotation omitted). The reviewing court "is not to substitute its judgment for that of the agency," id., and thus "may not supply a reasoned basis for the agency's action that the agency itself has not given." Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 285-86 (1974) (internal quotation omitted). Nevertheless, a decision that is not fully explained may be upheld "if the agency's path may reasonably be discerned." Id. at 286.

III. Analysis

Gentiva advances two primary arguments in support of its contention that the Secretary's decision upholding Cahaba's use of extrapolation was arbitrary, capricious, or otherwise contrary to law. First, it maintains that 24 U.S.C. § 1395ddd(f)(3) requires that the Secretary (or her subordinates), not a Medicare contractor, make a determination that a provider's claims exhibit a "sustained or high level of payment error" before the contractor is authorized to use extrapolation. Second, even if Cahaba was permitted to make the "sustained or high level of payment error" determination itself, Gentiva contends that no such level of payment error was present here. The Court will address each argument in turn.

A. Authority of Contractor to Make Determination

In full, 42 U.S.C. § 1395ddd(f)(3) provides:

> (3) Limitation on use of extrapolation
>
> A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that –
>
> (A) there is a sustained or high level of payment error; or
>
> (B) documented educational intervention has failed to correct the payment error.
>
> There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

Relying on this provision, Gentiva argues that the statute plainly requires the Secretary, not a contractor, to determine that a "sustained or high level of payment error" is present before a contractor can use extrapolation.

Complicating matters for Gentiva, however, is 42 U.S.C. § 1395kk(a). Section 1395kk(a) states that "[t]he Secretary may perform any of his functions under this subchapter directly, or by contract . . . as the Secretary may deem necessary." In light of the Secretary's broad authority to subdelegate her responsibilities in the administration of the Medicare program to contractors, what Gentiva presents as a simple question of statutory interpretation – "Secretary," it reasonably argues, means Secretary – becomes a more nuanced inquiry into whether 42 U.S.C. § 1395ddd(f)(3) bars the Secretary's subdelegation of the "sustained or high level of payment error" inquiry to Medicare contractors like Cahaba.

Emphasizing Congress's preclusion of judicial review and the plain language of § 1395ddd(f)(3), Gentiva argues that the statue should be read to prohibit subdelegation to contractors. And even if the Secretary could lawfully make this subdelegation, Gentiva further contends, she could only do so via notice-and-comment rulemaking. Highlighting § 1395kk(a)'s

seemingly unbounded subdelegation authorization and the practical necessity of the delegation, the Secretary maintains she lawfully delegated the "sustained or high level of payment error" determination to Medicare contractors. Notice-and-comment rulemaking, she insists, was not required.

The Court perceives these as two distinct questions, and it will consider them separately. First, it will determine whether the Secretary is empowered to subdelegate the § 1395ddd(f)(3) "sustained or high level of payment error" inquiry to contractors. Finding that she is, it then addresses whether that delegation must be made in the form of a notice-and-comment rulemaking. Ultimately, it concludes that the Secretary's subdelegation was lawful, and, accordingly, Cahaba was entitled to make the "sustained or high level of payment error" determination.

1. *Secretary's Power to Subdelegate*

In adjudicating this challenge to the Secretary's interpretation of the Medicare statute, the Court must begin with the standard set forth in (no, not Chevron) U.S. Telecom Ass'n v. FCC, 359 F.3d 554 (D.C. Cir. 2004). In U.S. Telecom, the D.C. Circuit resolved a dispute about whether a statute should be read to permit an agency to subdelegate its authority to an outside entity. See id. at 565-68. Because "the general conferral of regulatory authority does not empower an agency to subdelegate to outside parties," the court eschewed the deference it would normally lend to an agency's interpretation of a statute it administers in favor of a higher bar when dealing with such a subdelegation. Id. at 568. Specifically, it held that "federal agency officials . . . may not subdelegate to outside entities – private or sovereign – absent affirmative evidence of authority to do so." Id. at 566 (emphasis added).

Because this case similarly concerns the Secretary's ability to subdelegate to an outside entity – namely, contractor Cahaba – the Secretary accordingly must identify "affirmative evidence" of her authority to do so. Section 1395kk(a), which grants the Secretary the power to "perform any of [her] functions under this subchapter directly, or by contract . . . , as [she] may deem necessary," id. (emphasis added), however, is just such evidence. As our Circuit has acknowledged, "[T]he clear and reasonable language of the [Medicare] Act, reinforced by statements from its legislative history, appears to give the Secretary the authority to designate intermediaries," now referred to as "Medicare contractors," "to perform [her] reimbursement functions." Schweiker, 690 F.2d at 943 (citing § 1395kk). In light of this strong "affirmative evidence" of subdelegation authority, the Secretary's interpretation of § 1395ddd(f)(3) clears the U.S. Telecom hurdle.

That cannot, however, be the whole story. In finding that § 1395kk constitutes affirmative evidence of the Secretary's power to subdelegate her Medicare functions to private contractors, the Court acknowledges the possibility that Congress might nevertheless have prohibited particular subdelegations. That it has done just that with respect to the "sustained or high level of payment error" determination is Gentiva's position in this litigation. The remaining interpretive question, therefore, is whether § 1395ddd(f)(3) should be read to bar a subdelegation that would otherwise be authorized under § 1395kk(a).

a. Chevron Step One

In addressing this question, we now get to Chevron's familiar framework. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984); see also, e.g., Shays v. Federal Election Comm'n, 414 F.3d 76, 96 (D.C. Cir. 2005); Republican Nat'l Comm. v. FEC, 76 F.3d 400, 404 (D.C. Cir. 1996). "First, always, is the question whether Congress has

directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, 467 U.S. at 842-43. This inquiry is commonly referred to as "Chevron step one." See, e.g., Intermountain Ins. Serv. of Vail v. CIR, 650 F.3d 691 (D.C. Cir. 2011). "'Although Chevron step one analysis begins with the statute's text,' the court must examine the meaning of certain words or phrases in context and also 'exhaust the traditional tools of statutory construction . . . .'" Sierra Club v. EPA, 551 F.3d 1019, 1027 (D.C. Cir. 2008) (quoting Am. Bankers Ass'n v. Nat'l Credit Union Admin., 271 F.3d 262, 267 (D.C. Cir. 2001)).

In contending that the statute unambiguously forecloses the Secretary's interpretation – in other words, that it unambiguously prohibits subdelegation of the "sustained or high level of payment error" determination – Gentiva emphasizes Congress' use of the two terms "Medicare contractor" and "Secretary" in the very same sentence. When Congress uses two words in the same provision, Gentiva suggests, it should be assumed that it intended those words to have different meanings. See, e.g., Washington Hosp. Ctr. v. Bowen, 795 F.2d 139, 146 (D.C. Cir. 1986). Indeed, Congress used "Medicare contractor" and "Secretary" throughout § 935 of the MMA in a seemingly purposive manner, distinguishing the contractor's roles from the Secretary's. See generally MMA, Pub. L. No. 108-173, § 935(1)-(8), 117 Stat. 2066, 2408-11 (Dec. 8, 2003), codified at 42 U.S.C. § 1395ddd(f)(1)-(8).

In the case of § 1395ddd(f)(3), moreover, distinguishing between the contractor's role and the Secretary's makes sense. Titled "Limitation on Extrapolation," this provision was seemingly intended to do just that: limit the use of a technique for calculating overpayment that is undoubtedly more convenient, but that has the potential to prejudice providers. See 42 U.S.C.

§ 1395ddd(f)(3). Predicating a contractor's ability to utilize extrapolation on the Secretary's determination that the "sustained or high level of payment error" existed – as opposed to permitting it to make such a determination itself – would impose a more significant barrier to the use of this technique.

Gentiva also points to Congress's having shielded the "sustained or high level of payment error" determination from agency and judicial review, see 42 U.S.C. § 1395ddd(f)(3), as evidence of its intent that the Secretary, and not a contractor, make that finding. Because it would be quite unusual for Congress to have chosen to insulate a contractor's decision from oversight, the argument goes, the statute should be read as requiring the Secretary to perform the "sustained or high level of payment" analysis herself.

All that, however, goes only so far as to show that the statute is ambiguous. Congress expressly granted the Secretary the authority to subdelegate "any of [her] functions under this subchapter," 42 U.S.C. § 1395kk(a), which includes § 1395ddd(f)(3). In the absence of any explicit indication that the § 1395ddd(f)(3) "sustained or high level of payment error" determination was intended as an exception to this broad power, the statute is certainly not unambiguous on this point. The plain language of the statute simply does not address the Secretary's subdelegation authority, let alone clearly abrogate that authority. The Court, accordingly, cannot find that 42 U.S.C. § 1395ddd(f)(3) unambiguously forecloses subdelegation.

b. Chevron Step Two

Because Congress "has not directly addressed the precise question at issue," Chevron, 467 U.S. at 843, the Court turns to Chevron step two. Before doing so, however, it pauses to note that although the interpretation to which the Court affords deference was not promulgated in

a regulation that was the result of a notice-and-comment rulemaking, it nevertheless is entitled to the respect that accompanies analysis under Chevron step two. Indeed, Plaintiff appears to concede that the Court should afford Chevron deference to the Secretary's interpretation, as outlined in the MAC's decision, if it finds the statute ambiguous (though it, of course, maintains that the statute is not ambiguous). See Pl.'s Mot. at 16; Pl.'s Opp. and Reply at 1-2, 10-15. In any event, because the interpretation of the statute announced in the MAC's decision was the result of a relatively formal adjudication, is consistent with the Secretary's comments during notice-and-comment rulemaking and with guidance previously issued in the Medicare Program Integrity Manual (both of which would be entitled to some deference under Skidmore v. Swift & Co., 323 U.S. 134 (1944), even absent the MAC's decision), and carries the force of law, the Court will proceed to Chevron step two. See Menkes v. Dept. of Homeland Sec., 637 F.3d 319, 331-33 (D.C. Cir. 2011) (applying Chevron deference to an interpretation reached in an informal adjudication); Village of Barrington, Ill. v. Surface Transp. Bd., 636 F.3d 650, 659 (D.C. Cir. 2011) (same); see also Tex. Clinical Labs, Inc. v. Sebelius, 612 F.3d 771, 775-76 (5th Cir. 2010) (defering to an interpretation rendered by the MAC). The outcome, moreover, would likely be the same even were the Court only applying the less deferential Skidmore standard. See U.S. v. Mead Corp., 533 U.S. 218, 234-35 (2001); Skidmore, 323 U.S. at 139-40.

"At Chevron step two we ask whether the agency's interpretation of the statute is 'reasonable.'" Northeast Hospital Corp. v. Sebelius, 657 F.3d 1, 23 (D.C Cir. 2011) (citing Abington Crest Nursing & Rehab. Ctr. v. Sebelius, 575 F.3d 717, 719 (D.C. Cir. 2009)); see Chevron, 467 U.S. at 843. At this stage, the Court must uphold the agency's interpretation if it is "based on a permissible construction of the statute." Chevron, 467 U.S. at 843. "The court need not conclude that the agency construction was the only one it permissibly could have adopted to

uphold the construction, or even the reading the court would have reached if the question initially had arisen in the judicial proceeding." Id. at 843 n. 11. Especially in the context of the "'complex and highly technical' statutes governing Medicare," the Secretary's considerable expertise justifies the Court's deference to her interpretation. Cape Cod Hosp. v. Sebelius, 630 F.3d 203, 216 (D.C. Cir. 2011) (quoting Methodist Hosp. v. Shalala, 38 F.3d 1225, 1229 (D.C. Cir. 1994)).

In adjudicating Gentiva's claim, the Secretary interpreted § 1395ddd(f)(3) as permitting – or, at least, as not prohibiting – subdelegation to Medicare contractors of the "sustained or high level of payment error" determination. In so doing, she relied on § 1395kk(a)'s broad grant of subdelegation authority, see A.R. at 7, highlighted other responsibilities that were statutorily assigned to "the Secretary" but that the Secretary has subdelegated to Medicare contractors, see id., and noted that the Eastern District of Arkansas had previously upheld the subdelegation. See id. at 8 (citing John v. Sebelius, No. 09-cv-552, 2010 WL 3951465 (E.D. Ark. 2010)). This interpretation, moreover, was consistent with the Secretary's comments during notice-and-comment rulemaking, see 74 Fed. Reg. 65296, 65303, and with the Medicare Program Integrity Manual. See Pub. 1008-08, Trans. 114 (June 10, 2005), available at www.cms.hhs.gov/transmittals/downloads/R114PI.pdf. Because it concludes that the Secretary's interpretation is a reasonable one, the Court will afford it deference.

First and foremost, Section 1395kk's grant of subdelegation authority, which the D.C. Circuit has previously interpreted as providing "the Secretary the unequivocal right to designate [Medicare contractors] to perform [her] reimbursement functions," Schweiker, 690 F.2d at 943, is not expressly limited or even mentioned by § 1395ddd(f)(3). It is reasonable, therefore, to interpret § 1395ddd(f)(3) to leave the Secretary's power to subdelegate intact.

In addition, the Secretary emphasizes that one would have to read Congress to have imposed a very significant burden on her agency in order to credit Gentiva's interpretation. "Given the size of the Medicare program," she argues, "the Secretary does not have the resources to conduct a review of payment claims for every audited Medicare provider to determine whether any particular provider has a sustained or high level of payment error." Def.'s Mot. & Opp. at 14. It is correct that requiring HHS's intervention at this preliminary stage of an audit would be strikingly inefficient given the volume of reimbursement claims. Reading § 1395ddd(f)(3) to forbid subdelegation, furthermore, would run counter to the Medicare Integrity Program's broader goal of encouraging reliance on Medicare contractors in the audit context.

Indeed, the Secretary has delegated to Medicare contractors essentially all functions related to initial payment determinations, audits, and even the preliminary stages of dispute resolution. See 42 C.F.R. § 421.100; see also Schweiker, 690 F.2d 932, 943 (D.C. Cir. 1982). While contractors have played a larger role in the administration of the Medicare program since the institution of the MIP, private parties have been involved with the Medicare reimbursement process since the program's inception. See, e.g., id. § 1395h(a) (authorizing Medicare contractors, referred to as "intermediaries," to perform processing and payment functions for Part A); id., § 1395u(a) (authorizing contractors, referred to as "carriers," to perform processing and payment functions for Part B). Against this backdrop and in light of § 1395kk, one would certainly have expected Congress to have explicitly prohibited subdelegation had it intended that a particular portion of the audit process be performable only by agency officials.

The only other court to have considered this question, moreover, found that a Medicare contractor may perform the "sustained or high level of payment" determination on the Secretary's behalf. In John v. Sebelius, No. 09-cv-552, 2010 WL 3951465 (E.D. Ark. 2010), the

Eastern District of Arkansas addressed a plaintiff's argument **"**that there is no statutory authority for the Secretary to delegate the function of making a finding of a sustained or high level of payment error for purposes of § 1395ddd(f)(3)." Id. at *3. Although the court resolved the question without a detailed analysis, it, too, concluded that the Secretary had lawfully subdelegated her authority to a Medicare contractor in compliance with § 1395ddd(f). See id. Like the MAC, which cited the decision in John in resolving the instant dispute, see A.R. at 8, this Court can identify no meaningful difference between that case and this one.

Although Gentiva makes much of Congress's having foreclosed judicial review of the "sustained or high level of payment error" determination and suggests that the preclusion of judicial review reveals Congress's intent to prohibit subdelegation, barring review of such a finding is less consequential than Gentiva would make out. As the Secretary explained in response to comments received during the notice-and-comment process regarding the regulations she ultimately enacted to implement the MMA:

> [W]hile the determination of whether a provider or supplier has a sustained or high level of payment error is not subject to appeal, the initial or revised determinations made on the underlying claims for items or services would be subject to appeal. . . . Therefore, we do not anticipate any denials of claims solely based on this determination. Rather, the determination of a sustained or high error rate will be used as the basis for a contractor undertaking further review of claims submitted by the provider or supplier.

74 Fed. Reg. at 65303-04. The Secretary further emphasized that the "sustained or high level of payment error" is not a "sanction" and "does not result in an assessment of civil money penalties, or any other administrative action." Id. at 65304. Instead, it has no independent effect on a provider and merely "serves as the basis for a contractor's review of a provider's or supplier's subsequent claim submissions." Id.

As this case demonstrates, an aggrieved provider has a panoply of opportunities for administrative and judicial review of the overpayment assessment that ultimately results from a contractor's use of extrapolation. By pursuing redetermination, reconsideration, a hearing before an ALJ, and review by the MAC, Gentiva succeeded in having every overpayment determination it chose to appeal overturned. Indeed, the remaining $850,000 in overpayments Gentiva owes to the agency may have resulted from Gentiva's own decision not proceed with further administrative appeals of the 6 claims that remain designated as overpaid. Despite the fact that the initial "sustained or high level of payment error" determination lies beyond the reach of reviewing tribunals, therefore, Gentiva had a full opportunity to challenge the overpayment assessment.

Finally, it is worth emphasizing that the Secretary has not simply subdelegated her authority to Medicare contractors without providing them guidance on how that authority should be exercised. Indeed, the Secretary has laid out the procedures contractors should follow in making the "sustained or high level of payment error" determination in the Medicare Program Integrity Manual. See Pub. 1008-08, Trans. 114 (June 10, 2005), available at www.cms.hhs.gov/transmittals/downloads/R114PI.pdf. Specifically, the Manual provides that a contractor may use a "variety of means" to identify the requisite level of payment error, including, for example, sample probes, information from law-enforcement investigations, provider history, and allegations of wrongdoing by current or former employees. See id., Requirement No. 3734.2. In determining whether a particular provider has demonstrated a "sustained or high level of payment error," then, a contractor merely follows the procedures the Secretary has outlined.

In the end, therefore, the Court will defer to the Secretary's reasonable interpretation of an ambiguous statute to permit subdelegation of the "sustained or high level of payment error determination" to Medicare contractors.

2. *Notice-and-Comment Rulemaking*

Gentiva suggests, however, that even if such a subdelegation is permissible, it must be effected through a notice-and-comment rulemaking. As no such rulemaking took place, it argues, the Court must reverse the Secretary's finding that Cahaba properly extrapolated from the sample in arriving at Gentiva's overpayment amount.

The only support Gentiva provides for its contention that the Secretary was required to effect her subdelegation via a formal rulemaking is 42 U.S.C. § 1395hh(a)(2), which states:

> No rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by Secretary by regulation . . . .

Gentiva fails to explain, however, how the Secretary's subdelegation of her authority to make the "sustained or high level of payment error" determination "establishe[d] or change[d] a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities or organizations to furnish or receive services." Id.

It has done no such thing. Indeed, Gentiva cannot point to a substantive legal standard affected by the Secretary's subdelegation of her "sustained or high level of payment error" decisionmaking authority because the subdelegation plainly affects only the identity of the initial decisionmaker, not the standards deployed in making that decision. The subdelegation, accordingly, was not required under § 1395hh(a)(2) to be effected via notice-and-comment rulemaking. Cf. John, 2010 WL 3951465 at *3 (rejecting plaintiff's argument that, even if the

Secretary had the authority to subdelegate to a Medicare contractor, "there is no evidence showing such a delegation actually occurred").

That the Secretary may have memorialized some of her delegations in regulations in some instances, see, e.g., 42 C.F.R. § 405.904(a)(2), moreover, does not entail that she is required to do so in every case. Congress's empowerment of the Secretary to subdelegate to contractors in § 1395kk(a) gives no indication that each subdelegation would have to be effected through notice-and-comment rulemaking. Congress's intention, on the contrary, appears to have been to provide the Secretary with a large amount of flexibility in utilizing the services of private contractors. "The need for such flexibility is obvious when one considers the numerous responsibilities assigned to the Secretary under the Medicare Act." Schweiker, 690 F.2d at 943.

Finally, even if the Secretary's subdelegation is a "rule" under the APA – which Gentiva does not even appear to argue – "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice" are exempt from the notice-and-comment requirements of 5 U.S.C. § 553(b)(A). "The reading of the § 553 exemptions that seems most consonant with Congress' purposes in adopting the APA is to construe them as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake." Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987). Because it does not itself "alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency," Chamber of Commerce of U.S. v. U.S. Dept. of Labor, 174 F.3d 206, 211 (D.C. Cir. 1999) (citation and quotation marks omitted), the subdelegation seems properly classified as an interpretive rule, a rule of procedure, or a rule of agency organization. Again, it has no effect on any substantive legal rights or standards; it is

merely an instance of the Secretary's exercising her statutorily conferred authority to employ Medicare contractors to perform various audit-related responsibilities.

Ultimately, while it may have been preferable for the Secretary to have used notice-and-comment rulemaking to effect her subdelegation, Gentiva cannot demonstrate that she was required to do so.

B. Merits of Contractor's Determination

Having resolved Gentiva's challenge to Cahaba's role as decisionmaker, the Court now turns to its alternative argument concerning the substance of that decision. Gentiva maintains that even if a Medicare contractor like Cahaba can make the "sustained or high level of payment error" determination, no such level of payment error was present here. The Court, however, lacks jurisdiction to consider that argument.

Although there is a "strong presumption that Congress intends judicial review of administrative action," Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667, 670 (1986), that presumption can be overcome by "clear and convincing evidence" that Congress intended to preclude the suit. Abbott Laboratories v. Gardner, 387 U.S. 136, 141 (1967). The language of 42 U.S.C. § 1395ddd(f)(3), which provides that "[t] here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph," is precisely that. Cf. Amgen, Inc. v. Smith, 357 F.3d 103, 112 (D.C. Cir. 2007) ("That Congress intended to preclude judicial review is . . . 'clear and convincing' from the plain text of [the statute] alone."). Indeed, it is difficult to think of anything "Congress could have said to make the plain and unambiguous language of the statute, and its corresponding intent more clear." Painter v. Shalala, 97 F.3d 1351, 1356 (10th Cir. 1996). It is unsurprising, therefore, that

courts evaluating parallel language in other provisions of the Medicare statute have found Congress to have precluded judicial review. See, e.g. Amgen, Inc., 357 F.3d at 112 (construing 42 U.S.C. § 1395l(t)(12)(E)); Am Soc'y of Dermatology v. Shalala, 962 F. Supp. 141, 146 (D.D.C. 1996) (construing 42 U.S.C. § 1395w-4(i)(1)), aff'd, 116 F.3d 941 (D.C. Cir. 1997); Tex. Alliance for Home Care Servs. v. Sebelius, 811 F. Supp. 2d 76, 91 (D.D.C. 2011) (construing 42 U.S.C. § 1395w-3(b)(11)).

That Congress would have insulated the "sustained or high level of payment error" determination from judicial review, moreover, makes sense. This determination, as the Secretary has explained and the Court has discussed in detail in Part III.A.1.i, *supra*, is not an initial determination of an overpayment assessment; rather, it merely "serves as the basis for a contractor's review of a provider's or supplier's subsequent claim submissions." 74 Fed. Reg. at 65303-04. No sanction attaches to this initial determination; it merely permits a contractor to use a particular method of calculation in determining an overpayment amount. See id. And perhaps most importantly, an aggrieved provider has myriad opportunities to appeal the overpayment assessment that ultimately results from that calculation.

Gentiva's only response is to resort to its argument that the Secretary, not the contractor, is supposed to determine when a "sustained or high level of payment error" exists. "[T]he bar on administrative and judicial review," it argues, "applies only where the Secretary (and not a Medicare contractor) makes such a determination." Pl.'s Opp. & Reply at 16. Because the Court has already found that the responsibility for making the "sustained or high level of payment error" determination is properly subdelegable to Medicare contractors, however, this argument is unavailing. As Gentiva itself emphasized in arguing against the Secretary's authority to subdelegate, Congress has plainly precluded judicial review of the "sustained or high level of

payment error" determination. That the Secretary has exercised her authority to subdelegate that determination to a contractor does not make an unreviewable determination reviewable.

IV. Conclusion

For the foregoing reasons, the Court will grant Defendant's Motion for Summary Judgment and deny Plaintiff's. A separate Order consistent with the Opinion will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: April 6, 2012