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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

GENERAL MEDICINE, P.C.,

Plaintiff-Appellant,

v.

ALEX M. AZAR, II, Secretary of the U.S. Department of Health and Human Services,

Defendant-Appellee.

No. 19-1365

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
No. 2:17-cv-12777—Mark A. Goldsmith, District Judge.

Argued: December 13, 2019

Decided and Filed: June 24, 2020

Before: COLE, Chief Judge; SILER and MURPHY, Circuit Judges.

COUNSEL

ARGUED: Barry M. Rosenbaum, SEYBURN KAHN, P.C., Southfield, Michigan, for Appellant. John B. Meixner, Jr., UNITED STATES ATTORNEY'S OFFICE, Detroit, Michigan, for Appellee. **ON BRIEF:** Barry M. Rosenbaum, SEYBURN KAHN, P.C., Southfield, Michigan, for Appellant. Sarah Karpinen, UNITED STATES ATTORNEY'S OFFICE, Detroit, Michigan, for Appellee. Joanne Geha Swanson, KERR, RUSSELL & WEBER, PLC, Detroit, Michigan, for Amici Curiae.

SILER, J., delivered the opinion of the court in which MURPHY, J., joined, and COLE, C.J., joined in part. MURPHY, J. (pp. 13–14), delivered a separate concurring opinion. COLE, C.J. (pp. 15–16), delivered a separate opinion concurring in part and dissenting in part.

OPINION

SILER, Circuit Judge. General Medicine appeals a post-payment audit that began over fifteen years ago. The audit revealed many of General Medicine's Medicare claims should not have been paid or should not have been paid at the level billed. The auditor requested records from the long-term care facilities where General Medicine provided services but did not request any records from General Medicine. General Medicine did not find out about the audit until it was finished and the overpayment was assessed. General Medicine argues that this assessment should be void or reduced because the auditor failed to give notice of the audit.

Under 42 U.S.C. § 1395ddd(f)(7)(A), Centers for Medicare and Medicaid Services contractors ("CMS contractors") are required to give providers, like General Medicine, notice prior to conducting a post-payment audit. The statute does not provide a remedy if CMS contractors violate this requirement.

The Medicare Appeals Council determined that no remedy should be granted because the lack of notice was inconsequential. The Council explained that failure to provide notice did not prevent General Medicine from ably and thoroughly arguing the principal issues resulting from the audit, the validity of the sampling methodology, and the coverage of the reviewed claims over the course of several years. The Council also noted that the addition of more medical records would not have materially impacted its findings. The district court upheld the Council's conclusion. We find that substantial evidence supports the Council's determination that General Medicine was not prejudiced by the lack of notice. Therefore, we **AFFIRM**.

I. FACTUAL BACKGROUND

General Medicine is a medical services provider whose physicians and nurse practitioners perform services for patients in long-term care facilities. General Medicine bills Medicare for most services. Medicare is a federally subsidized health insurance for the elderly and those with disabilities. 42 U.S.C. § 1395 *et seq.* The Secretary of the U.S. Department of Health and Human Services ("Secretary") acts through the Centers for Medicare and Medicaid Services

("CMS") to administer Medicare. *Id.* § 1395hh(a)(1). CMS contracts with private entities, known as Medicare Administrative Contractors ("CMS contractors"), to help administer the program, including investigating fraud and abuse. *Id.* §§ 1395kk-1, 1395ddd.

CMS contractors may conduct a post-payment audit of providers to ensure that the Medicare services that providers are billing are medically necessary and meet the requirements of the Medicare program. *See id.* § 1395ddd(b). In a post-payment audit CMS contractors review a random sample of a provider's Medicare claims. *See id.* § 1395ddd(f)(4). CMS contractors will review the records and then calculate an error rate based on the review. If there is a sustained or high level of payment error, the CMS contractor will extrapolate that error rate over the provider's total Medicare claims to determine a total amount of overpayment. *See id.* § 1395ddd(f)(3).

If a provider objects to the CMS contractor's overpayment determination, there are four levels of administrative review that the provider can pursue: (1) redetermination by the Medicare Administrative Contractor; (2) reconsideration by a Qualified Independent Contractor; (3) a hearing before an Administrative Law Judge; and (4) review of the Administrative Law Judge's decision by the Medicare Appeals Council. *See id.* § 1395ff; 42 C.F.R. §§ 405.900–405.1140. After exhausting all four levels of administrative review, the provider can seek judicial review in a federal district court. 42 U.S.C. § 1395ff(b)(1)(A).

Beginning in 2002, a CMS contractor, AdvanceMed, initiated a series of audits after the CMS fraud unit received complaints about General Medicine's billing practices. In July 2004 AdvanceMed initiated an audit of all General Medicine physicians without providing any notice to General Medicine. To conduct the audit AdvanceMed sent records requests to twelve facilities where General Medicine's physicians provided services. Specifically, AdvanceMed requested the medical records for 382 claims involving 278 General Medicine patients that received Medicare services between January 1, 2002, and March 24, 2004. Between 2002 and 2004 General Medicine's clinicians kept their medical records in the patient charts at the facilities where they worked but did not maintain offices in the facilities. General Medicine was not notified of these requests, and AdvanceMed did not request any records from General Medicine.

Based on these records AdvanceMed determined that only 35 of the 382 claims were allowed as billed and 33 of the claims were allowed at different levels than billed. The remaining 314 claims were denied: 3 because they did not meet policy guidelines; 73 because there was no documentation to support the services; and 238 were considered medically unnecessary.

General Medicine first learned of this audit when it received a letter with the results in January 2007. The letter indicated that AdvanceMed determined that General Medicine had been overpaid with regard to 337 claims in the amount of $16,778.80. Under 42 U.S.C. § 1395ddd(f)(3), the overpayment was extrapolated to a universe of 41,818 claims and the total amount of overpayment assessed and demanded was $1,836,646.56.

II. PROCEDURAL HISTORY

General Medicine filed for a redetermination of the overpayment assessment and engaged in the administrative review process for several years. At each level of the process General Medicine contested individual overpayments and was able to obtain significant reductions in the overpayment assessment. At one point the total extrapolated overpayment was reduced to $1,073,183.00. The Medicare Appeals Council further reduced the amount of overpaid claims and ordered CMS to recalculate the overpayment to conform with its decision.

In addition to challenging individual overpayments, General Medicine sought to invalidate the entire overpayment assessment due to lack of notice. In the alternative, General Medicine sought to reduce the assessment to the actual amount of overpayments as opposed to the extrapolated amount. The Medicare Appeals Council rejected General Medicine's notice argument as inconsequential because: (1) the statute does not provide a consequence for the failure to provide notice; and (2) failure to provide notice did not prevent General Medicine from "over these many years, ably and thoroughly argu[ing] the principal issues resulting from the audit, the validity of the sampling methodology, and the coverage of the reviewed claims."

After completing the four-level administrative review process General Medicine sought judicial review in federal court. The district court denied General Medicine's motion for

summary judgment and entered judgment in favor of the government, concluding that General Medicine did not demonstrate it suffered any prejudice as a result of the lack of notice.

III. STANDARD OF REVIEW

Our review "is limited to determining whether the district court erred in finding that the [administrative] ruling was supported by substantial evidence" and whether proper legal standards were employed. *Heston v. Comm'r of Soc. Sec.*, 245 F.3d 528, 534 (6th Cir. 2001); *see also Cutlip v. Sec'y of Health & Human Servs.*, 25 F.3d 284, 286 (6th Cir. 1994); 42 C.F.R. § 405.1136(f).

"Substantial evidence is more than a scintilla of evidence but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Cutlip*, 25 F.3d at 286. If there is substantial evidence to support the decision, "it must be affirmed even if the reviewing court would decide the matter differently . . . and even if substantial evidence also supports the opposite conclusion." *Id.* (internal citation omitted). Whether the Medicare Appeals Council made an error of law in applying a statute, however, is reviewed de novo. *See Perkins v. Chater*, 107 F.3d 1290, 1294 (7th Cir. 1997).

IV. DISCUSSION

A. Whether an overpayment assessment should be invalidated when the government fails to provide notice of a post-payment audit under 42 U.S.C. § 1395ddd(f)(7)(A)

It is an issue of first impression whether an overpayment assessment should be invalidated when the government fails to provide notice of a post-payment audit under 42 U.S.C. § 1395ddd(f)(7)(A). Our analysis must "start, as always, with the language of the statute." *Williams v. Taylor*, 529 U.S. 420, 431 (2000).

In 2003 Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("Medicare Act"). Pub. L. 108-173, 117 Stat. 2066. This Act allows CMS to recover overpayments to providers and permits the use of extrapolation in cases of sustained or high level of payment error. *See* 42 U.S.C. § 1395ddd(b),(f)(3). The Act permits the use of post-payment audits as a tool to recover overpayments, but it requires CMS contractors to give a

provider written notice "of the intent to conduct [a post-payment] audit." *Id.* § 1395ddd(f)(7)(A). The statute states in relevant part:

> (A) Written notice for post-payment audits. Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this subchapter, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

Id. The statute provides one exception to the notice requirement: Notice is not required if it would "compromise pending law enforcement activities . . . or reveal findings of law enforcement-related audits." *Id.* § 1395ddd(f)(7)(C).

Relatedly, subparagraph (B) requires CMS contractors to give a provider the opportunity to submit additional information on a timely basis and to take that information into account. *Id.* § 1395ddd(f)(7)(B). This provision states in relevant part:

> (B) Explanation of findings for all audits. Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this subchapter, the contractor shall—
>
> …
>
> (iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and
>
> (iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

Id. The statute, however, does not state what, if any, consequence should be imposed if a CMS contractor fails to give the provider notice of the audit.

"It is well established that 'when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.'" *Lamie v. United States Tr.*, 540 U.S. 526, 534 (2004) (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000)). "A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . ." *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (quoting 2A N. Singer, Statutes and Statutory Construction § 46.06, pp 181–86 (rev. 6th ed. 2000)); *see also United States v. Bedford*, 914 F.3d 422, 427 (6th Cir. 2019). The presumption against surplusage

"is strongest when an interpretation would render superfluous another part of the same statutory scheme." *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386 (2013) ("[W]e are hesitant to adopt an interpretation of a congressional enactment which renders superfluous another portion of that same law." (quoting *United States v. Jicarilla Apache Nation*, 564 U.S. 162, 185 (2011))). Although courts should not read statutory language as surplusage, courts also should not add language that Congress has not included. However, "[a]n inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." *Burns v. United States*, 501 U.S. 129, 136 (1991).

Here, the statute is silent as to what, if any, consequence should result from violating the statute's notice requirement. An inference could be drawn from the statute's silence that Congress did not intend any consequence. However, the language of the statute, which states "the contactor *shall* provide the provider of services or supplier with written notice," suggests otherwise. 42 U.S.C. § 1395ddd(f)(7)(A) (emphasis added). The use of the term "shall" indicates that Congress intended nondiscretionary compliance with the notice requirement. *See Cook v. United States*, 104 F.3d 886, 889 (6th Cir. 1997) ("The word 'shall' is 'the language of command' which usually, although not always, signifies that Congress intended strict and nondiscretionary application of the statute.").

If there is no consequence for failing to provide notice of an "intent to conduct" an audit, not only would the notice section of the statute, subparagraph A, be read as "inoperative or superfluous," but other parts of the statute would be as well. For example, subparagraph B requires a CMS contractor to give the provider an opportunity to submit additional information to the contractor. *See* 42 U.S.C. § 1395ddd(f)(7)(B)(iii). A provider can only have the opportunity to submit additional information if it has notice of the audit. Therefore, if there is no consequence for failing to give a provider notice, subparagraph B can be read as "inoperative or superfluous" as well. Thus, despite the statute's silence as to the consequence for failure to provide notice, it would be contrary to "textual and contextual evidence of congressional intent" to find that Congress's silence means that a court cannot issue a remedy when a CMS contractor violates the statute's notice requirement. *Burns*, 501 U.S. at 136. This reading is further supported by the purpose of the statute.

There is no legislative history available to help explain why Congress enacted the mandatory notice requirement. However, CMS's Medicare Program Integrity Manual ("CMS Manual") suggests that the intention was to give providers an opportunity to gather and review their medical records, wherever they may be located, and present their best case to the auditors before an audit is completed. CMS's Manual "is the Secretary's interpretation of Congress's statutory language." *Southern Rehab. Grp., P.L.L.C. v. Sec'y of HHS*, 732 F.3d 670, 685 (6th Cir. 2013). In 2004, the year the audit was initiated in this case, CMS's Manual outlined its policy for both the content and timing of the notice. Under Section 3.10.6.1.1 CMS contractors:

> shall include at least the following in the notification of review:
>
> - an explanation of why the review is being conducted (i.e., why the provider or supplier was selected),
> - the time period under review,
> - a list of claims that require medical records or other supporting documentation,
> - a statement of where the review will take place (provider/supplier office or contractor/PSC site),
> - information on appeal rights,
> - an explanation of how results will be projected to the universe if claims are denied upon review and an overpayment is determined to exist, and
> - an explanation of the possible methods of monetary recovery if an overpayment is determined to exist.

CMS, Medicare Program Integrity Manual (Internet-Only Manual, Pub. 100-08), ch. 3, § 3.10.6.1.1 (Rev. 71, 04-09-04), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R71PI1.pdf.

As to the timing of the notice, in 2004 CMS's Manual stated "[w]hen advance notification is given, providers and suppliers have 30 calendar days to submit . . . or make available . . . the requested documentation" and "[w]hen advance notification is ***not*** given" CMS contractors must "give the provider or supplier the written notification of review when [they] arrive at their site." *Id.* The Manual also required CMS contractors to get approval from the Government Task Leader when not giving advance notice to a provider. *Id.* at § 3.10.6.1.

In 2004 the CMS Manual likewise prohibited contractors from soliciting additional documentation requests from a third party unless the contractor first or simultaneously solicits the same information from the billing provider. *Id.* at § 3.4.1.2. It is undisputed that the CMS contractor in this case, AdvanceMed, violated all of these provisions.

Like the statute, the CMS Manual does not list any sanction for these violations. Although there is no legislative history available, General Medicine is correct that there does not need to be a statement in the Congressional committee reports to understand that a purpose of the notice requirement was to give the provider an opportunity to gather and review its records in order to present its best case to the auditor before the audit begins. The mandatory language of the notice requirement, coupled with CMS's Manual, indicates that Congress intended for there to be a consequence if the government fails to give a provider notice and the lack of notice substantially prejudices the provider. *Cf. United States v. Montalvo-Murillo*, 495 U.S. 711, 722 (1990) ("[N]onconstitutional error will be harmless unless the court concludes from the record as a whole that the error may have had a 'substantial influence' on the outcome of the proceeding. In this case, it is clear that the noncompliance with the timing requirement had no substantial influence on the outcome of the proceeding."); *French v. Edwards*, 80 U.S. 506, 511 (1871) ("[W]hen the requisitions prescribed are intended for the protection of the citizen, and to prevent a sacrifice of his property, and by a disregard of which his rights might be and generally would be injuriously affected, they are not directory but mandatory."). Therefore, we hold that a court may excuse a CMS contractor's failure to give notice of an audit under 42 U.S.C. § 1395ddd(f)(7)(A) if, and only if, the provider is not substantially prejudiced by the lack of notice.

This conclusion is in line with our decision in *Cook v. United States*. 104 F.3d at 887–89.[1] In *Cook*, we considered a tax statute that requires advance notice when the IRS requests records from a third party. *Id.* at 887. Specifically, 26 U.S.C. § 7609(a) requires notice of a summons to be given within three days of service of the summons and not later than 23 days

[1]General Medicine and the Amici Curiae cite other analogous advance notice cases, but these cases are from outside this circuit. *See, e.g., J.B. v. United States*, 916 F.3d 1161 (9th Cir. 2019); *Jewell v. United States*, 749 F.3d 1295 (10th Cir. 2014); *N. Metro. Residential Healthcare Facility v. Novello*, 777 N.Y.S.2d 277 (N.Y. Sup. Ct. 2004).

before the day that the summons indicates the records are to be examined. *Id.* at 888. In *Cook*, the IRS issued a summons for bank records in furtherance of an investigation of a married couple's tax returns. *Id.* at 887. The individuals argued that the summons should be quashed because the summons was served one day late. *Id.* We reasoned that on the one hand, the use of the word "shall" indicated that "Congress intended strict and nondiscretionary application of the statute," but on the other hand "Congress has *not* evidenced an intention to render *void* every third party summons which does not comply with every technical stricture" of the statute. *Id.* at 889. We concluded that "[g]iven the public interest at stake in effective and efficient enforcement of the national revenue laws, this court will not impute such an intention to Congress in the absence of a clear legislative statement." *Id.* We determined that "[a] more equitable resolution would confer discretion upon the trial courts to excuse the Service's technical notification default *if, and only if,* the party (or parties) entitled to statutory notification was (or were) not substantially prejudiced by the violation – that is, if the error was harmless." *Id.*

Here, as in *Cook*, the statute's use of the word "shall" indicates that on the one hand Congress intended for strict application of the notice requirement, but on the other hand the statute does not indicate that Congress intended for every noncompliance with the requirement to render the audit void. Also, like the public interest in the national revenue laws in *Cook*, there is significant public interest in the effective administration of Medicare. *See Palm Valley Health Care*, Inc. v. Azar, 947 F.3d 321, 324 (5th Cir. 2020) ("With annual spending topping half a trillion dollars, Medicare is the largest recipient of federal funds after Social Security and defense."). Therefore, we conclude as the court did in *Cook* that courts can excuse the government's noncompliance with 42 U.S.C. § 1395ddd(f)(7)(A) only if the provider was not substantially prejudiced by the lack of notice. *Cook*, 104 F.3d at 889; *see also Montalvo-Murillo*, 495 U.S. at 722; *Hicks v. Comm'r of Soc. Sec.*, 909 F.3d 786, 812 (6th Cir. 2018).

B. Whether substantial evidence supports the lack of substantial prejudice

Applying this holding we next consider whether the district court erred in finding that substantial evidence supported the Medicare Appeals Council's conclusion that General Medicine was not prejudiced by the lack of notice. *See Heston*, 245 F.3d at 534.

General Medicine argues that the lack of notice prejudiced its ability to document its billings. It contends that if it was provided the proper notice it would have had 30 days to retrieve its records from its custodians at the 12 facilities. General Medicine had access to those records in 2004 when the audit began, but did not have access in 2007, when General Medicine first received notice of the audit. General Medicine's physicians would have had the opportunity to make certain that their own notes and records were both complete and legible. In other words, General Medicine would have had 30 days to present its best case to CMS by making sure that all of its services were properly documented and placed into context before the audit.

The Medicare Appeals Council, however, concluded that having additional medical records would not have made a material difference in the adjudication of the claims. The Council explained that it looked only at the medical notes for the service dates at issue in determining medical reasonableness, necessity, and reimbursement level, because the "treatment or assessment note for each date of service should be expected to stand alone and support coverage for that date of service." The Medicare Appeals Council did not deny or downcode any claims based on the frequency of visits or the condition of any beneficiary that may have been addressed in other medical records. The Medicare Appeals Council also concluded that General Medicine was not prejudiced because it had presented its arguments throughout the years of appeals by "ably and thoroughly argu[ing] the principal issues resulting from the audit, the validity of the sampling methodology, and the coverage of the reviewed claims."

Although the Medicare Appeals Council certainly could have provided a more detailed explanation of its determination that General Medicine was not prejudiced by the lack of notice, we find that this conclusion is nevertheless supported by substantial evidence in the record. Even if we would have decided the matter differently in the first instance, the Medicare Appeals Council's conclusion as to prejudice must be upheld if "a reasonable mind might accept [such evidence] as adequate to support a conclusion." *Cutlip*, 25 F.3d at 286. We conclude that a reasonable mind could accept the Medicare Appeals Council's conclusion that General Medicine was not prejudiced based on the Council's reasoning that General Medicine was able to thoroughly argue the principal issues resulting from the audit over the course of several years and based on the Council's finding that additional medical records would not have made a

material difference in the adjudication of the claims because the CMS contractor had the medical notes for the service dates, which are to stand alone and support coverage.[2] Therefore, even if General Medicine had advance notice of the audit and could have gathered additional documents to support its claims, it would not have changed the overpayment determination because the medical notes for the service dates that the long-term care facilities held and gave to AdvanceMed should have been sufficient on their own.

Accordingly, we affirm the district court's finding that the Medicare Appeals Council's decision was supported by substantial evidence.[3]

CONCLUSION

In sum, a provider may be entitled to a remedy if a CMS contractor fails to give the provider notice in violation of 42 U.S.C. § 1395ddd(f)(7)(A) *and* the provider is substantially prejudiced by the lack of notice. Here, the district court correctly concluded that substantial evidence supports the Medicare Appeals Council's conclusion that General Medicine was not prejudiced by the lack of notice. Accordingly, we **AFFIRM**.

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[2]The dissent is correct that the Council's conclusion that additional medical records would not have made a material difference in the adjudication of the claims is from the section of the Council's opinion that discusses a subpoena issue not the notice issue. Although this analysis does not occur in the notice section of the Council's decision it is part of the record as a whole and relevant to the overall conclusion that General Medicine was not prejudiced by the lack of notice because it indicates that if General Medicine had received proper notice and been able to gather additional medical records it would not have materially impacted the assessment. *See Fluor Daniel, Inc. v. NLRB*, 332 F.3d 961, 967 (6th Cir. 2003) ("We review factual findings of the [agency] to determine if they are 'supported by substantial evidence *on the record considered as a whole*.' 'Substantial evidence' is 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" (emphasis added)).

[3]General Medicine also individually challenged twelve of the overpayment claims. However, it did not raise this argument before the district court. Any argument that is "not raised before the district court is waived on appeal to this Court." *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 948 (6th Cir. 2018) (quoting *Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 552 (6th Cir. 2008)); *see also Thompson v. Parker*, 867 F.3d 641, 652 (6th Cir. 2017) (declining to address two arguments not raised below because "[t]he clear rule is that appellate courts do not consider issues not presented to the district court."). Therefore, we conclude that General Medicine waived this argument.

CONCURRENCE

MURPHY, Circuit Judge, concurring. I concur in the majority opinion and write to highlight one issue that neither party addresses, but that may be worth considering in future cases.

If a federal statute imposes a duty (here, a notice requirement) but does not identify the consequence of a party's noncompliance, what happens if the party fails to live up to the duty? May federal courts impose the implied remedy of their choosing? General Medicine thinks so. It asks us to invalidate the overpayment assessment issued against it because of its lack of notice of the underlying audit. In my view, the court properly rejects General Medicine's requested remedy. The argument that courts have the power to impose implied remedies if a statutory command would be rendered ineffective without them shares much in common with the outdated regime of implying causes of action to enforce statutes that do not expressly contain them. After all, one argument supporting implied causes of action was the need to make the statutory command more "effective." *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001) (quoting *J.I. Case Co. v. Borak*, 377 U.S. 426, 433 (1964)). "Having sworn off the habit of venturing beyond Congress's intent" in that context, *id.*, we should not pick up the habit in this one. The Supreme Court has, in fact, told us not to. It has held, for example, "that if a statute does not specify a consequence for noncompliance with statutory timing provisions, the federal courts will not in the ordinary course impose their own coercive sanction." *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 63 (1993) (citing *United States v. Montalvo-Murillo*, 495 U.S. 711, 717–21 (1990)).

Yet General Medicine and the Secretary have both briefed this appeal on the assumption that courts *may* invalidate the assessment when a party shows substantial prejudice from the lack of the statutorily required notice. If, however, courts do not have the power to impose an implied *automatic-invalidation* remedy, it is not obvious to me why we have the power to impose an implied *invalidation-if-prejudice* remedy. In other cases in which the Supreme Court has suggested that courts have the power to craft remedies, it has pointed to some source of authority

for the judicial power. In *State Farm Fire & Casualty Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436 (2016), for example, the Court identified the judiciary's "inherent power" to impose sanctions for "violations of court orders." *Id.* at 444. Here, the parties have not identified a similar source of authority to craft remedies. The Administrative Procedure Act might provide one. *See* 5 U.S.C. § 706. Some decisions have cited § 706's standards in suits like this one challenging agency action under 42 U.S.C. § 1395ff(b)(1)(A). *See, e.g.*, *Nader v. Hargan*, 721 F. App'x 287, 287–88 (4th Cir. 2018) (per curiam); *John Balko & Assocs., Inc. v. Sec'y U.S. Dep't of Health and Human Servs.*, 555 F. App'x 188, 191 (3d Cir. 2014). Section 706 allows courts to "set aside agency action" "not in accordance with law," 5 U.S.C. § 706(2)(A), but also makes clear that "due account shall be taken of the rule of prejudicial error," *id.* § 706. It thus might authorize courts to set aside assessments made in violation of the statutory notice provision when the violation of that provision prejudices a party. *Cf. Shinseki v. Sanders*, 556 U.S. 396, 406–07 (2009). If applicable, it could provide further textual support for the approach the court suggests today. Since neither party raised the Administrative Procedure Act, I merely flag it for future consideration.

CONCURRING IN PART AND DISSENTING IN PART

COLE, Chief Judge, concurring in part and dissenting in part. I concur in Part IV.A of the majority opinion, which explains that "courts can excuse the government's noncompliance with 42 U.S.C. § 1395ddd(f)(7)(A) only if the provider was not substantially prejudiced by the lack of notice." (Maj. Op. 10.) Where I depart is in the application of this standard to the facts of this particular case.

Substantial evidence does not support the Medicare Appeals Council's conclusion that General Medicine was not prejudiced by the lack of notice. An agency's conclusory statements are not sufficient to support a finding of substantial evidence. *See Dir., Office of Workers' Comp. Programs, U.S. Dep't of Labor v. Congleton*, 743 F.2d 428, 430 (6th Cir. 1984) ("[W]e remain steadfast in our conviction that an [ALJ's] conclusory opinion, which does not encompass a discussion of the evidence contrary to his findings, does not warrant affirmance . . . even in applying the deferential standard of "substantial evidence[.]"); *see also, e.g.*, *Elec. Consumers Res. Council v. F.E.R.C.*, 747 F.2d 1511, 1515 (D.C. Cir. 1984) (per curiam) (finding a lack of substantial evidence where the agency's "stated reasons . . . . [were] almost wholly conclusory").

On the specific issue of prejudice, the Medicare Appeals Council made the following cursory findings: 1) "Having examined the record as a whole, we do not see that the appellant was irreparably harmed by the lack of formal notice of the pending audit"; and 2) "[T]he appellant has, over these many years, ably and thoroughly argued the principal issues resulting from the audit, the validity of the sampling methodology, and the coverage of the reviewed claims. We see no area where the form of notice which the appellant received compromised its ability to present its case." (MAC Decision, R. 1-4, PageID 42–43.) This explanation is inadequate, "necessitat[ing] a remand with directions for more specific findings of fact." *See Congleton*, 743 F.2d at 430.

The majority opinion relies on another section of the Medicare Appeals Council's decision to find substantial evidence. Specifically, it points to a section of the Council's opinion that determined the Administrative Law Judge had not erred by failing to issue subpoenas to third-party facilities for "the complete medical records for each beneficiary that was part of the sample," as the entire medical records for each beneficiary would not have made "a material difference in the claims' adjudication here." (MAC Decision, R. 1-4, PageID 37, 40.) The Council explained that it only looked to the "medical notes for the date(s) of service at issue in determining medical reasonableness and necessity and reimbursement level," and "[t]he treatment or assessment note for each date of service should be expected to stand alone and support coverage for that date[.]" (*Id.* at PageID 40–41.) Thus, the Council concluded that there was no need to subpoena third parties for the beneficiaries' complete medical records. General Medicine does not challenge this determination on appeal.

General Medicine's lack-of-notice argument is distinct from its now-abandoned subpoena claim. General Medicine argues that if it had received notice of the audit, its physicians could have ensured that their medical notes and records for the relevant dates of service were complete, legible, and properly documented before the audit began. The fact that the Council concluded it did not need to receive additional medical records from other dates of service for the same Medicare beneficiaries via subpoenas to third parties does not speak to General Medicine's argument that it could have ensured it had proper, complete records for the relevant dates of service that were audited if it had been given notice. The Council's findings on the subpoena claim thus do not provide substantial evidence for the Council's separate finding of no prejudice on the notice issue.

I would therefore reverse and remand for the Medicare Appeals Council to reassess and explain whether General Medicine was substantially prejudiced by the lack of notice.