CASE NO. 19-1365

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

GENERAL MEDICINE, P.C.
Plaintiff-Appellant,

v.

ALEX M. AZAR, II, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendant-Appellee.

On Appeal from the United States District Court
Eastern District of Michigan, Southern Division

Hon. Mark A. Goldsmith
Case No. 2:17-cv-12777

BRIEF OF AMICI CURIAE MICHIGAN STATE MEDICAL SOCIETY AND THE AMERICAN MEDICAL ASSOCIATION IN SUPPORT OF PLAINTIFF-APPELLANT GENERAL MEDICINE AND REVERSAL

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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 19-1365 Case Name: General Medicine, P.C. v Alex M. Azar

Name of counsel: Joanne Geha Swanson

Pursuant to 6th Cir. R. 26.1, Michigan State Medical Society
Name of Party
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No.

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No.

CERTIFICATE OF SERVICE

I certify that on June 7, 2019 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record.

s/ Joanne Geha Swanson

This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 19-1365 Case Name: General Medicine, P.C. v Alex M. Azar

Name of counsel: Joanne Geha Swanson

Pursuant to 6th Cir. R. 26.1, The American Medical Association
Name of Party
makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

No.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? If yes, list the identity of such corporation and the nature of the financial interest:

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s/ Joanne Geha Swanson

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CONCISE STATEMENT OF INTEREST OF AMICI CURIAE MICHIGAN STATE MEDICAL SOCIETY AND THE AMERICAN MEDICAL ASSOCIATION

Amicus Curiae Michigan State Medical Society ("MSMS") is a professional association which represents the interests of over 14,000 physicians in the State of Michigan. Organized to promote and protect the public health and to preserve the interests of its members, MSMS is frequently called upon to express its views with respect to legal issues of significance to the medical profession.

Amicus Curiae American Medical Association ("AMA") is the largest professional association of physicians, residents and medical students in the United States. Through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents and medical students in the United States are represented in the AMA's policy-making process. AMA members practice and reside in all states, including Michigan. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health.

MSMS and the AMA join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

In the pending appeal, this Court is being asked to decide whether the assessment of an overpayment is invalidated by the failure of the U.S. Department of Health and Human Services ("Secretary") to provide statutory notice of its intent to conduct a post-payment audit of Medicare claims, as required by 42 U.S.C. §1395ddd(f)(7)(A). General Medicine, a provider of medical services to Medicare patients residing in long-term care facilities, was the subject of a post-payment review conducted by a contractor for the Centers for Medicare and Medicaid Services ("CMS"), which determined that many of the claims should not have been paid or should not have been paid at the level billed. Through an extrapolation of a random sample review, the CMS assessed an overpayment of over $1.8 million.

General Medicine appealed through various layers of administrative review, then filed an action in the United States District Court seeking to vacate and/or reverse the overpayment decision based in part upon the failure to give the required notice.[1] As to the notice issue, the District Court observed that "the statute, despite creating a right to notice, does not prescribe a remedy when that right is violated." *Gen. Med., P.C. v. Azar*, No. 17-CV-12777, 2019 WL 1207588, at *3 (E.D. Mich. Mar. 14, 2019). The District Court continued:

[1] General Medicine also argued that remand to the Qualified Independent Contractor was required to obtain missing medical records that had been ordered by the Administrative Law Judge. General Medicine argued that the records were essential to the issues on appeal.

> General Medicine requests a reversal of the Council decision, which ultimately amounts to dismissal, regardless of any showing of prejudice by the lack of notice. Dismissal is, of course, "an extraordinary remedy," *Moon v. Newsome*, 863 F.2d 835, 837 (11th Cir. 2009), and the Court will not presume that it is the intended remedy for a technical statutory violation without clear guidance from Congress. Cf. *Passarell v. Glickman*, No. 95-2122, 1997 WL 118407 at *3 (D.D.C. Mar. 6, 1997) (finding that, despite a statutory right to a decision on disaster benefits within thirty business days, the failure to get such a decision did not entitle the plaintiffs to automatically receive those benefits). General Medicine has cited no case supporting its contention that it is entitled to dismissal. Given the lack of guidance from Congress, the Court will not take action that is tantamount to dismissal. [*Id*. at *3].

The District Court further noted that General Medicine would have a stronger argument for dismissal if it were able to show that it had been prejudiced by the lack of notice, a showing, the Court opined, that had not been made. [*Id*.].

The notice issue raises a matter of concern to MSMS and the AMA, whose members treat Medicare and Medicaid patients, have been subject to audits, and rely upon the procedural protections afforded by the governing statute and related regulations. Thus, MSMS and AMA have an active interest in the issue before this Court and appreciate the opportunity to share their views.

STATEMENT REGARDING PREPARATION OF THE BRIEF

Pursuant to Fed. R. App. P. 29(a)(4)(E), neither party's counsel authored this brief in whole or in part, nor contributed money that was intended to fund preparing or submitting this brief. Further, no person, other than the amici curiae, have contributed money to fund the preparation or submission of this brief.

STATEMENT OF THE ISSUE FOR REVIEW

The issue addressed by Amici Curiae is whether the extrapolated overpayment assessment is invalidated by the failure of the medicare contractor, acting on behalf of the Secretary of the U.S. Department of Health and Human Services, to provide statutory notice of its intent to conduct a post-payment audit of the Medicare claims submitted by General Medicine, as required by 42 U.S.C. §1395ddd(f)(7)(A).

ARGUMENT

I. The Prejudice Standards for Failure to Give Notice, as Articulated by the ALJ, MAC, and District Court, Are Inconsistent and Unsupported by the Statutory Language But General Medicine Has Nonetheless Shown Harm, Detriment, and Prejudice.

The Medicare Integrity Program ("Program") is established by 42 U.S.C. §1395ddd. Under this Program, the Secretary "shall promote the integrity of the Medicare program" by entering into contracts with eligible entities to carry out prescribed activities. The eligible entities are known as Medicare contractors ("Contractors"). A Contractor acting on behalf of the Secretary to promote the integrity of the nation's Medicare program must adhere to the Program requirements. The activities the Contractors are authorized to perform include: reviewing the activities of Medicare providers and suppliers for which payment may be made; medical and utilization review and fraud review; auditing cost reports; determining and recovering payments that should not have been made; educating providers, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues; developing (and periodically updating) a list of durable medical equipment subject to prior authorization; and activities involving the Medicare-Medicaid Data Match Program.

Section (f) of the statute governs the recovery of overpayments. 42 U.S.C. §1395ddd(f). Subsection (7) of Section (f) addresses payment audits, a tool which may be used in the overpayment recovery process. This subsection begins by

unambiguously requiring the Medicare contractor to give a provider written notice "of the intent to conduct" a post-payment audit. 42 U.S.C. §1395ddd(f)(7)(A). Only one exception is provided; notice is not required if the provision of notice would compromise pending law enforcement activities. 42 U.S.C. §1395ddd(f)(7)(C). The statute provides in relevant part:

> **(7) Payment Audits**
>
> **(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.
>
> * * *
>
> **(C) Exception**
>
> Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits. [2]

Here, General Medicine alleges that it did not receive notice of the audit until two and a half years after it was initiated; by that time, the audit had been completed and an extrapolated overpayment assessed. General Medicine argues that the failure

[2] Subparagraph (B) requires the Medicare contractor to provide a full review and explanation of the audit findings, inform the provider or supplier of appeal rights and consent settlement options, *give the provider or supplier an opportunity to provide additional information*, and *take into account information provided by the provider or supplier on a timely basis.* 42 U.S.C. §1395ddd(f)(7)(B).

to give notice was intentional and violated CMS's own policies and procedures. The statute does not prescribe a remedy for non-adherence to the notice requirement, but when the title of the Act is the Medicare **Integrity** Program and its purpose is to establish the protocol "under which the Secretary shall promote the **integrity** of the medicare program," it unquestionably follows that the **integrity** of this governing statute must likewise be respected. Selective enforcement of selective provisions undermines confidence that the purposes of the Program are being advanced and creates an environment for potential abuse.[3]

It appears that no reported case has previously considered the remedy for failure to give notice in the context of 42 U.S.C. §1395ddd(f)(7)(A). In the District Court, General Medicine relied in part upon the rules of statutory construction in urging that the failure to give notice invalidated the overpayment assessment. The District Court rejected that assertion, holding – as had the tribunals earlier in the chain of administrative appeals - that relief would not be provided absent a showing of prejudice. However, there is no clear articulation of what that showing must

[3] The Medicare Integrity Program (42 U.S.C. §1395ddd), was originally enacted in 1996. In 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA), Public Law 108-173, was enacted to modernize the Medicare Program. The MMA added section (f) Recovery of Overpayments to the Medicare Integrity Program. As a result, 42 U.S.C. §1395ddd was amended in 2003 to reflect the addition of the Recovery of Overpayments section.

establish and the District Court differs substantively from the other tribunals as to the showing that must be made.

A. The Prejudice Standards Articulated at the Various Levels of Administrative and Judicial Review are Inconsistent and Unclear.

There was no consensus among the various levels of administrative review as to the showing that must be made to warrant a remedy for failure to give notice. The ALJ concluded that there was no evidence that any lack of notice "*caused any detriment* to the Appellant or *adversely affected the validity of the sampling or the audit*" or that the procedural errors and misrepresentations in failing to give notice and misleading General Medicine's president regarding the existence of the audit *caused any harm* to plaintiff (emphasis added). ALJ Op. dated 12/17/2009, p. 11, Page ID. 3196 (Dkt. 15-1). General Medicine's objection based upon the lack of notice was therefore overruled. *Gen. Med., P.C. v Azar*, No. 17-cv-12777, 2019 WL 1207588 at *1.

The Medicare Appeals Council ("MAC") found that General Medicine was not *irreparably harmed* by the lack of formal notice of the pending audit, which is a much higher standard than "detriment" or "adverse effect." See June 21, 2017 Decision of MAC at 21. The MAC concluded that the form of notice General Medicine received did not "*compromise its ability to present its case*" and it has "*ably and thoroughly argued the principal issues* resulting from the audit, the

validity of the sampling methodology, and the coverage of the reviewed claims." *Id.* (emphasis added).

The District Court opined that General Medicine would have a stronger argument for dismissal if it were able to show that it had been *prejudiced* by the lack of notice:

> General Medicine only offers vague allegations of prejudice in this Court, contending that it was "denied the opportunity to influence [the extrapolation] decision." Pl. Mot. at 9. But General Medicine *has not shown that the outcome of the process would have been different had it been given that opportunity*. Further, General Medicine has had the opportunity to present its arguments in over a decade of litigation regarding these claims, and thus it cannot be said that it has been wholly without opportunity to argue its case. Cf. *Jefferson v. Jefferson City Public School Sys*., 360 F.3d 583, 587-588 (6th Cir. 2004) ("If satisfactory state procedures are provided in a procedural due process case, then no constitutional deprivation has occurred despite the injury.") [*Gen. Med*. at *3 (emphasis added)].

In the District Court, the Secretary argued that the fact that the notice requirement exists does not necessarily mean a remedy exists and that "the remedy is the thorough appeal process in which General Medicine engaged." The Secretary further argued that there was no evidence that the CMS acted deceptively in failing to provide notice of the audit.

Considered charitably, there is an unquestionable murkiness as to how the failure to give notice is to be addressed and what a plaintiff must show to warrant a remedy:

- Must the plaintiff show that it was *irreparably harmed* by the lack of notice?
- Must the plaintiff show *detriment* or an *adverse affect on the sampling or the audit*?
- Must the plaintiff show that the ability to present its case was *compromised*?
- If plaintiff attempts to *ably and thoroughly argue against the audit findings, the principal issues* resulting from the audit, the *validity of the sampling methodology*, and the *coverage of the reviewed claims*, will the plaintiff, for that reason, forgo a remedy?
- Must the plaintiff show that the *outcome of the process would have been different had it been given notice?*
- Must the plaintiff show that it was *wholly without opportunity to argue* its case?
- Does the *availability of an appeal* substitute for notice?
- Should a remedy be awarded only if the CMS *acted deceptively*?

Certainly, the lack of precision in this grab bag of standards fails to inform General Medicine of the necessary showing and consequently fails the test of due process. The right to be heard on the failed notice issue is hollow when the litigant cannot ascertain in advance the showing that must be made. This Court should resolve the standard applicable to how the failure to give notice should affect the parties' rights in this context, and remand to the appropriate lower court and/or administrative agency to apply that standard.

B. General Medicine Has Shown Harm, Detriment, and Prejudice.

Irrespective of the showing required at the various levels of administrative and judicial review, General Medicine has shown more than enough to warrant relief. In the District Court, General Medicine argued that it was prejudiced by the lack of notice because it was denied the opportunity to negotiate a pre-audit resolution, to present the best evidence to justify its billings, and to provide input before the decision to extrapolate was made. Subsection (B) of 42 U.S.C. §1395ddd(f)(7) supports General Medicine's argument; it requires the Medicare Contractor to consider information that is submitted by the provider *on a timely basis*. The subsection states:

> **(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—
>
> > (i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;
> >
> > (ii) inform the provider of services or supplier of the appeal rights under this subchapter as well as consent settlement options (which are at the discretion of the Secretary);
> >
> > (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)* [42 U.S.C. §1395ddd(f)(7)(B) (emphasis added)].

This provision likely assumes that the notice required by the preceding Subsection (A) will have been given and that the information can be provided in time to impact the decision. In fact, Subsections (A) and (B) are tied together in Subsection (C), which states that "Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits."

In the context of tax audits, 26 U.S.C. §7602(c) contains an advance notice requirement which provides that "[a]n officer or employee of the Internal Revenue Service may not contact any person other than the taxpayer with respect to the determination or collection of the tax liability of such taxpayer without providing *reasonable notice in advance* to the taxpayer that contacts with persons other than the taxpayer may be made" (emphasis added). The Ninth Circuit recently considered the §7602(c)(1) requirement in *J.B. v. United States*, 916 F.3d 1161 (9th Cir. 2019). The issue was whether the transmission of a pamphlet about the audit process generally satisfied the requirement of "reasonable notice in advance." In concluding that it did not, the Ninth Circuit held that advance notice means notice "reasonably calculated, under all the relevant circumstances, to apprise interested parties of the possibility that the IRS may contact third parties, and that *affords interested parties a meaningful opportunity to resolve issues and volunteer information before third-party contacts are made*." *Id*. at 1164 (emphasis added).

Similarly, the IRS, in *Gangi v. United States*, gave advance notice to Mr. Gangi prior to contacting third parties via summonses regarding the tax liability of Mr. Gangi. However, the summonses also sought documents concerning Mr. Gangi's wholly-owned businesses, BABP and Ferrous Miner, which had not received advance notice that they were taxpayers under investigation; only contemporaneous notice had been given to these entities. In quashing the summonses as to BABP and Ferrous Miner, the District Court explained:

> The Court is not persuaded that contemporaneous notice of Ferrous Miner and BABP under IRC § 7609 suffices, because Ferrous Miner and BABP are currently "taxpayers" under investigation, and the summonses sought documents from third-parties that would be relevant to an assessment of their tax liabilities. One of the motivating purposes for IRC § 7602(c) was Congress's concern that IRS contacts with third-parties "may have a chilling effect on the taxpayer's business and could damage the taxpayer's reputation in the community. *Accordingly, ... taxpayers should have the opportunity to resolve issues and volunteer information before the IRS contacts third parties*." S.Rep. No. 105–174, at 77 (1998); see also *United States v. Jillson*, No. 99–Civ–14223, 1999 WL 1249414, at *3 (S.D.Fla. Oct.28, 1999).

Gangi v. United States, No. CIV.A. 10-24, 2011 WL 1363816, at *8 (D.N.J. Jan. 7, 2011), *aff'd*, 453 F. App'x 255 (3d Cir. 2011).

In *United States v. Jillson*, No. 99-14223-CIV, 1999 WL 1249414, (S.D. Fla. Oct. 28, 1999), the United States sued to enforce summonses served upon two officers of QI Corporation in aid of an ongoing investigation into the legality of deductions paid to the officers as compensation. The respondents argued that the IRS had not complied with the administrative requirements of the Tax Code thus

warranting that the summonses be quashed. Agreeing with respondents, the Court noted:

> As part of the Internal Revenue Service Restructuring and Reform Act of 1998, Congress established a series of procedural safeguards to protect taxpayers from overreaching by IRS investigations. One of the most important of these safeguards is codified at 26 U.S.C. § 7602(c), and provides, "[a]n officer or employee of the Internal Service [sic] may not contact any person other than the taxpayer with respect to the determination or collection of the tax liability of such taxpayer without providing reasonable notice in advance to the taxpayer that contacts with persons other than the taxpayer may be made." In this case the IRS did not issue a notice of contact letter to QI Corporation until September 17, 1999, four-months after the issuance of the summonses and over a month after the commencement of these proceedings. As such, *the IRS has failed to comply with the administrative requirements of the Tax Code by not issuing the notice of contact letter prior to third-party contact, and therefore has not established a prima facie case for enforcement* [*Id*. at *2 (emphasis added)].

The Court rejected the contention that the IRS's good faith in issuing the summonses removed the bar to enforcement. The Court explained:

> One of Congress' purposes in enacting Section 7602(c) was to provide the taxpayer the opportunity to volunteer whatever information is sought before the IRS contacts a third-party. See *S.Rep. No.* 105–174, at 77 (1988) ("... taxpayers should have the opportunity to resolve issues and volunteer information before the IRS contacts third-parties"). By failing to provide a notice of contact letter prior to serving the summonses, QI Corporation *was denied the opportunity to resolve issues and volunteer information prior to contact, and as such was not only harmed, but was harmed in the very way Section 7602(c) was enacted to remedy*. As such, despite the good faith on the part of the IRS, *we must quash the summonses* [*Id.* at *3 (emphasis added)].

The purpose underlying §7602(c) is equally applicable to the advance notice requirements of §1395ddd(f)(7). Section (f)(7) should be understood to be a

safeguard that permits the provider to volunteer information and negotiate a resolution before the Contractor makes demands upon the long-term care facilities with whom General Medicine has a business relationship and reaches a determination with potentially faulty and incomplete information as to which extrapolation will apply. This purpose is validated by Section (f)(7)(B), which requires the contractor to give the Provider the opportunity to provide additional information on a timely basis and to take that information into account. It is also supported by the policy and rules of the Centers for Medicare and Medicaid Services ("CMS"), which prohibit the solicitation of documentation from a third party unless the contractor first or simultaneously solicits the same information from the billing provider. See e.g., *CMS, Medicare Program Integrity Manual (Internet-Only Manual, Pub. 100-08),* ch. 3 §3.4.1.2 (Rev. 71, 04-09-04).

J.B., *Gangi* and *Jillson* are not undermined by rulings like those in *Phillips v. United States*, 1999 WL 228585, 178 F.3d 1295 (6th Cir. 1999), *Cook v. United States*, 104 F.3d 886 (6th Cir. 1997), or *Sylvestre v. United States*, 978 F.2d 25 (1st Cir. 1992). These cases did not consider the advance notice requirement of §7602(c) but rather addressed the requirement in 26 U.S.C. §7609(a)(1) that notice be given to the taxpayer within three days of issuance of a third-party summons and at least 23 days prior to the summons compliance date to enable the taxpayer to petition to quash.

In *Phillips*, the IRS agent testified that she sent notice of the summonses to the shared residence of the taxpayers by certified mail, one of whom was the registered agent for the corporations of which the individual taxpayers were the sole shareholders. All of the taxpayers joined the petition to quash the summonses. This Court concluded that all taxpayers received proper notice.

In *Cook*, there was a one-day shortfall in the requisite notice period but the taxpayers conceded that they suffered no actual prejudice as a consequence of the delay inasmuch as they were able to initiate their petition to quash in a timely manner. Thus, this Court concluded that the taxpayers "realized every benefit due to them under the statute." *Id*. at 889. However, the ruling came with a warning that the opinion "must not be construed as investing the I.R.S. with a license to ignore statutory deadlines or to negligently violate other legal requirements" and that the Court "shall review future violations of technical legal requirements by the I.R.S. and its agents and attorneys with an increasingly critical eye." *Id*. at 890-891. Similarly, in *Sylvestre*, the Court held that a two-day shortfall in the duration of notice given to Mr. Sylvestre did not require that the summonses be quashed because despite the delay, Mr. Sylvestre did in fact move to quash the summonses.

As is clear from the above cases, the purpose and intent of §7609 differs from that of §7602(c). Rather, §7602(c) mirrors §1395ddd(f)(7)(A), which is similarly structured. Similar to the §7602(c) cases cited above, the Contractor's disregard of

the advance notice requirement thwarted General Medicine's ability to obtain and provide additional information to fully document billings for the claims under audit, which could have avoided the adverse determination, permitted early resolution, and rendered it unnecessary to rely upon third parties (with whom General Medicine had professional and business relationships) for the desired documentation. Under the case law, this deprivation demonstrates the ostensibly requisite harm, prejudice, and detriment.

In addition, General Medicine asserts bad faith and an intentional disregard for the protections required to be given to providers, arguing that where the notice was intentionally not provided, where records were sought from third-parties in violation of CMS's own procedures, and where General Medicine was misled about whether it was being audited, "this Court should not treat the lack of notice as a 'technical violation.'" General Medicine's argument is supported by the ALJ's finding that the Contractor "specifically stated to the Appellant's president, Dr. Prose, that 'the group [the Appellant] was not on review, only one specific provider …,'" further stating that "[n]ot only was the Appellant not informed of the post-payment audit of the Appellant (the group as a whole) or of the statistical sampling of the Appellant's claims, the president of the Appellant may have been misled to believe that the Appellant (the group as a whole) was not the subject of an audit …" ALJ Op. dated 12/17/2009, p. 9. Such findings reflect an intentional

disregard of the notice requirement, calling into question the integrity of the audit and further warranting the requested relief.

II. The District Court's Failure to Afford a Remedy Renders the Notice Requirement Nugatory and Disregards the Purpose of Giving Notice.

The District Court's decision is tantamount to a disregard of the notice requirement. Other courts, to give effect to the plain language of the various statutes under review, have redressed notice violations by invalidating the assessment. Here, General Medicine appropriately argues that because the notice requirement was adopted as part of the statutory amendments that provided for the extrapolation of certain overpayments to other billings, one is a prerequisite for the other and the failure to give notice should invalidate extrapolation. Alternatively, the audit should itself be invalidated.[4]

Matter of Northern Metro. Residential Healthcare Facility v. Novello, 4 Misc. 3d 394, 777 N.Y.S.2d 277 (Sup. Ct. 2004), aff'd sub nom, 24 A.D.3d 1069, 806 N.Y.S.2d 291 (2005), was an action by a residential health care facility (petitioner) against the Department of Health (DOH) in response to the DOH's attempted recovery of Medicaid overpayments. Petitioner alleged that DOH failed to provide proper, timely notice of its *intent to audit* the 1991 rate year and was therefore precluded from recovering any overpayment for that year. *The Court agreed*.

[4] Subsection (3) of Section (f) of §1395ddd addresses limitations on the use of extrapolation. The notice provision is subsection (7) of Section (f).

Noting that the ALJ "did *not* address petitioner's argument that notice of an audit cannot be given after an audit has already been conducted – i.e., that a written notification must provide notice of an 'intent to audit,'" the Court explained in part:

> As argued by petitioner, the written notification is designed to notify providers of an *intent to audit* (*see*, 18 NYCRR § 517.3(c)), *not* a notification that an audit has been completed. To allow DSS to bypass the procedures outlined for an entrance conference (18 NYCRR § 517.3(f)) and a closing conference, including the opportunity to submit documentation before the preparation of a draft audit report (18 NYCRR § 517.5), would deprive petitioner of the due process afforded by DSS' own regulations [4 Misc. 3d at 401 (emphasis in original)].

The Court held that DSS may not circumvent its regulations and procedures by filing a notice of intent to audit additional rate years in a draft audit report for other rate years, stating:

> Following the filing of the draft audit report including the rate year 1991, DSS did not afford petitioner any of the procedures between the "written notification" and the preparation of a "draft audit report." This Court further holds and determines that DSS did not commence its audit within 60 days of providing written notification to petitioner and that the effectiveness of such notice thereby lapsed (18 NYCRR § 517.3(d)). Accordingly, this Court holds and determines that *respondents are precluded from recovering any overpayment for rate year 1991, and that this proceeding is remitted to the respondents for the limited purpose of adjusting the Medicaid overpayment* in compliance herewith [*Id*. at 401-402 (emphasis added)].

In *Ostrow v. Bane*, 213 A.D.2d 651, 624 N.Y.S.2d 220 (1995), petitioner, a provider of medical services to Medicaid patients, submitted various claims to the New York State Department of Social Services for payments for medical procedures provided to patients. The DSS "pended" these claims for further review. Petitioner

waited a year and then commenced a proceeding pursuant to CPLR Article 78, to compel payment for such procedures. The Court found that the delay by DSS in determining the claims violated the relevant procedural requirements and time limits and thus ordered the petitioner to be paid for the claims.

Northern Metro and *Ostrow* are supportive of the relief requested here. The cases the District Court cites in discussing the notice issue are inapposite and do not inform the issue. For example, the District Court cites *Moon v. Newsome*, 863 F.2d 835 (11th Cir. 1989), for the proposition that dismissal is an extraordinary remedy. *Moon* involved a pro se litigant's disregard of a discovery order and his subsequent failure to pay the court-assessed monetary sanction. The Circuit Court affirmed the district court's dismissal of the pro se litigant's case pursuant to Fed. R. Civ. P. 41(b) because he had been "repeatedly and stubbornly defiant" in refusing to acknowledge the magistrate's authority and comply with court orders. The facts and legal issue in *Moon* could not be more unlike the present case.

Similarly, the District Court relied upon an unpublished, out-of-state district court case to establish that "the Court will not presume that [dismissal] is the intended remedy for a technical statutory violation without clear guidance from Congress." Opinion & Order Denying Pl.'s Mot. For SJ (Dkt. 60) Page ID. 22321, relying upon *Passarell v. Glickman*, No. CIV.A., 95-2122, 1997 WL 118407 at *3 (D.D.C. Mar. 6, 1997). *Passarell* is not a notice case; it addressed a statute requiring

a decision on agricultural disaster benefits within 30 days of an applicant's request for review. The review resulted in a reversal of the hearing officer's decision and remand for a new hearing due to procedural irregularities in the hearing conducted by the hearing officer. However, rather than pursue a new hearing, plaintiffs filed an action against the Secretary of Agriculture for declaratory judgment asserting, *inter alia*, that they were entitled to full disaster payments because the review ruling was not provided within 30 days. The Secretary argued that the deadline in the statute was merely "aspirational, not mandatory." *Id.* at *2. The Court viewed the case as "boil[ing] down to the meaning of the word 'shall'" and as to that issue, explained:

> The plain language of the statute at issue here provides that "the Director shall complete the review ... not later than ... 30 business days after receipt of the request for review." 7 U.S.C. § 6998(b). The word "shall" is generally "imperative or mandatory ... [and] has the invariable significance of excluding the idea of discretion, and has the significance of operating to impose a duty which may be enforced, particularly if public policy is in favor of this meaning, or when addressed to public officials." *Black's Law Dictionary* (6th ed.). B. Garner's *Dictionary of Modern Legal Usage* (2d ed.1995) similarly defines "shall" as "impos[ing] a duty on the subject of the sentence" where the term is used in the same context as in the statute here, *e.g.*, "[t]he court ... *shall* enter an order for the relief prayed for...." *Id*. at 940. Congress clearly ordered the Director of NAD to issue its ruling in 30 days; Congress left no room for the agency to exercise its discretion in the matter. By contrast, the government's construction of the term would render the

> mandatory "shall" meaningless [*Id*. at *2 (emphasis in original) (footnotes omitted)].[5]

The Court then turned to the requested relief, finding that plaintiffs "have presented no evidence to support the proposition that Congress intended for claimants automatically to receive the benefits 30 days after receipt of the request for review." *Id*. at *3. Rather, the Court determined that the appropriate remedy was to remand the case for a new hearing, adding that if the hearing officer does not render a substantive ruling on plaintiffs' claims within thirty days of the issuance of the Court's order, "the Court will award plaintiffs the disaster relief payments which they are seeking." *Id.*

"Shall" is the operative word in this case as well and as *Passarell* concludes, leaves no room for discretion. To hold otherwise is to disregard the plain meaning of the statute and to render nugatory the Congressional intent. In *United States v. Bedford*, 914 F.3d 422, 427 (6th Cir.), cert. denied, 139 S. Ct. 1366 (2019), this Court recited the rules of statutory construction which prohibit such a result, stating:

> When looking at the language of the statute, this court "examines the plain meaning of its words." *In re Corrin*, 849 F.3d 653, 657 (6th Cir. 2017) . . . In doing so, "no clause, sentence, or word of a statute should be read as superfluous, void, or insignificant." *In re City of Detroit*, 841 F.3d 684, 696–97 (6th Cir. 2016) (internal quotation marks and citation omitted).

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[5] The Court added that "the government's construction ignores the numerous precedents in which courts have construed the meaning of the word "shall" in this context as being mandatory." *Passarell* at *3.

Unenforceable disregard should not be gleaned from Congress' failure to specify a remedy. There are innumerable statutory requirements that do not come neatly packaged with a penalty for violation, yet a remedy is afforded, not infrequently, an unwinding of the resulting adverse determination.

CONCLUSION

For the above reasons, Amici Curiae Michigan State Medical Society and the American Medical Association respectfully request that the standard for relief be clarified, that the decision of the District Court be reversed, and that the relief requested by General Medicine be granted.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

As required by Fed.R.App.P. 35(b)(2)(A), I certify that relying on the word count of the word processing system used to prepare this brief, this brief is proportionally spaced, has a 14-point typeface, and contains 5,674 words.

CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2019, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system, which will send notification of such filing to counsel of record.

Respectfully submitted,

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