Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Benny R. Bailey Docket No. A-19-31 Decision No. 2935 April 12, 2019

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Benny R. Bailey (Petitioner) appeals a decision by an Administrative Law Judge (ALJ) upholding on the written record the Inspector General's (I.G.) exclusion of Petitioner from participation in all federal health care programs for a period of five years. *Benny R. Bailey*, DAB CR5210 (2018) (ALJ Decision). The ALJ concluded that the I.G. properly excluded Petitioner pursuant to section 1128(a)(3) of the Social Security Act (Act),¹ which, pursuant to section 1128(c)(3)(B), requires a minimum exclusion period of five years.

For the reasons set out below, we affirm the ALJ's decision.

Legal Background

Section 1128(a)(3) of the Act provides that the Secretary of Health and Human Services "shall exclude" from participation in federal health care programs an individual who "has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program . . . operated by or financed in whole or in party by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct."

¹ The current version of the Act can be found at <u>https://www.ssa.gov/OP_Home/ssact/ssact-toc.htm</u>. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at <u>https://www.ssa.gov/OP_Home/comp2/G-APP-H.html</u>.

When an exclusion is imposed under section 1128(a), section 1128(c)(3)(B) requires that the "minimum period of exclusion . . . be not less than five years[.]" An excluded individual may request a hearing before an ALJ, but only on the issues of whether the I.G. had a basis for the exclusion and whether an exclusion longer than the mandatory minimum period is unreasonable in light of any of the aggravating and mitigating factors specified in the regulations that apply to the case before the ALJ. 42 C.F.R. §§ 1001.2007(a), 1005.2(a). A party dissatisfied with the ALJ's decision may appeal it to the Board. *Id.* § 1005.21.

Case Background²

Petitioner was the office manager of Clarion Health and Wellness (Clarion), a pain management clinic located in Hazard, Kentucky. ALJ Decision at 3 (citing I.G. Ex. 2, at 2). On July 10, 2014, Petitioner was charged in an indictment, along with two alleged coconspirators, with two felony counts of conspiring to distribute and unlawfully dispense controlled substances in violation of 21 U.S.C. § 846, and one felony count of maintaining a pain management clinic for the purpose of distributing and unlawfully dispensing controlled substances in violation of 21 U.S.C. § 856(a). *Id.* (citing I.G. Ex. 2). On March 23, 2015, Petitioner was charged in an information with a single felony count of conspiracy to commit money laundering in violation of 18 U.S.C. § 1956(h). I.G. Ex. 3.

On May 25, 2016, Petitioner agreed to plead guilty to one count of money laundering in violation of 18 U.S.C. § 1956(h). ALJ Decision at 3; I.G. Ex. 4. In the plea agreement, Petitioner admitted that he was aware that Clarion physicians "were writing controlled substance prescriptions to patients for illegitimate purposes that were outside the usual course of professional medical practice." *Id.* at 4. Petitioner admitted that "monies from these patients were being deposited into a Clarion bank account" and Petitioner "caused financial transactions involving the above-referenced Clarion account to occur, either by check or electronic transfer, to pay physicians and staff, to keep Clarion clinic ongoing, and to satisfy various operating expenses." *Id.* Petitioner admitted that he "knew and intended" that his actions "would conceal that portion of Clarion's income that came from the unlawful dispensation of controlled substances by illegitimate prescriptions." *Id.* Petitioner admitted that he "held back thousands of dollars from Clarion's cash income on a monthly basis" which "were paid in an 'under the table fashion' to parties designated to him by Clarion's owner" (Dr. Chaney). *Id.* Petitioner also admitted that he "personally received the sum of \$40,000 of the laundered funds" *Id.*

² The factual information in this section is drawn from the ALJ Decision and the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact.

On August 29, 2016, Petitioner appeared in the U.S. District Court for the Eastern District of Kentucky to testify at the sentencing hearing for Dr. Chaney.³ ALJ Decision at 3. Petitioner testified that he routinely withheld cash payments made by patients, and personally took between \$30,000 and \$40,000 in cash during the time that he worked at Clarion. *Id.* at 3-4 (citing I.G. Ex. 5, at 14-15, 18-21). Petitioner also testified that he fraudulently obtained prescriptions for controlled substances between six and twelve times. *Id.* at 4 (citing I.G. Ex. 5, at 4-5, 27).

On September 21, 2016, a United States District Judge accepted Petitioner's guilty plea, entered a judgment of conviction, and sentenced Petitioner to 12 months and one day of incarceration followed by one year of supervised release. ALJ Decision 4 (citing I.G. Ex. 6; I.G. Ex. 4, at 8).

By letter dated March 30, 2018, the I.G. notified Petitioner that, pursuant to section 1128(a)(3) of the Act, he was being excluded from Medicare, Medicaid, and all federal health care programs for a minimum period of five years. ALJ Decision at 1 (citing I.G. Ex. 1). The I.G. advised Petitioner that he was being excluded due to his felony conviction "of a criminal offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or with respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local Government agency." I.G. Ex. 1, at 1.

Petitioner requested a hearing before an ALJ. ALJ Decision at 1. On June 18, 2018, Petitioner filed three motions: 1) Petitioner's Request for Discovery; 2) Petitioner's Motion to Compel the Implementation of a Litigation Hold (to prevent the destruction of documents related to Petitioner's Request for Discovery); and 3) Petitioner's Motion for Access to the Departmental Appeals Board (DAB) E-File System (Pet. Motion for E-File Access). *Id.* a 3. In his motion for DAB E-File access, Petitioner argued that his "inability to access the DAB E-File database to examine all ALJ final decisions, discovery rulings, various other pre-hearing rulings or orders, and case pleadings deprives him of his regulatory right to a 'fair [and] just' hearing." Pet. Motion for E-File Access at 3 (citing 42 C.F.R. §§ 1005.4 and 1005.6). Petitioner also asserted that the "prejudice" is compounded "by the fact that the I.G. has full access to these documents and may rely upon them in the instant proceeding." *Id*.

³ We discuss, and reject, later in this decision Petitioner's arguments that his sworn testimony at his codefendant's sentencing should not have been admitted or considered. We therefore include this information in the background based on the ALJ's findings, even though, as the ALJ noted, it was not essential to the result. *See* ALJ Decision at 5.

On June 25, 2018, the ALJ issued an order denying Petitioner's three motions (ALJ Order). Regarding Petitioner's request for discovery, the ALJ stated:

Discovery is limited to those documents that are "relevant and material" to the issues before me. 42 C.F.R. §§ 1005.7(a) and (c). Petitioner identifies no specific documents but instead describes broad categories of documents. He has not shown that any particular document is relevant or material to the narrow issues before me, which are: whether Petitioner was convicted of a criminal offense and, if so, whether that offense is related to "fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service."

ALJ Order at 2. The ALJ also stated that "the I.G.'s decision-making processes are irrelevant and thus not subject to discovery," and that complying with Petitioner's request "would be unduly costly and burdensome" and "would unduly delay" the proceedings. *Id.* at 2-3. Regarding the request for a litigation hold, the ALJ concluded that she has "no authority to impose on the [I.G.] a 'litigation hold'" and "would find it wholly unreasonable to direct the [I.G.] to preserve virtually all documents relating to" the discovery request because "the documents requested are not identified with any specificity and are irrelevant to the issues in this case" *Id.* at 3. Regarding the request to access the DAB's E-File system, the ALJ concluded that "[t]he provisions Petitioner cites do not grant me the authority to interfere with the DAB's polices regarding e-file access" and "ALJ final decisions and significant rulings are posted and available on the DAB's public website." *Id.*

On July 23, 2018, the I.G. filed a pre-hearing brief, an exhibit list, and seven proposed exhibits (I.G. Exs. 1-7). On August 22, 2018, Petitioner filed a prehearing brief (Pet. Pre-hearing Br.), an exhibit list, and eleven proposed exhibits (Pet. Exs. 1-11). In his pre-hearing brief, Petitioner admitted he was convicted of a felony offense, but otherwise disputed that the conviction provided a basis for exclusion under section 1128(a)(3). Pet. Pre-hearing Br. at 3. Petitioner's arguments included:

- that the I.G. failed to establish that Petitioner's felony offense was related to financial misconduct or fraud, or in connection with the delivery of a health care item or service (*id.* at 5-14);
- that the ALJ's denial of Petitioner's discovery request denied Petitioner the right to a fair hearing (*id.* at 14-19);
- that the I.G. unreasonably delayed excluding Petitioner until nine months after Dr. Chaney was excluded (*id.* at 19-21);
- that the I.G.'s decision was arbitrary and capricious, in part because the I.G. applied a different exclusion provision to Dr. Chaney (section 1128(a)(4)) (*id.* at 5-7, 21-22); and

• that the ALJ's ruling denying Petitioner access to the DAB E-File system was in error (*id.* at 23-24).

Petitioner indicated that he intended to call as witnesses three officials from the Office of Inspector General (OIG). Petitioner asserted that the three officials "were responsible for: (1) collecting and reviewing documents supporting Dr. Chaney and Petitioner's exclusions; and (2) selecting the applicable exclusion authority." *Id.* at 24. Petitioner stated that he intended to "elicit testimony regarding the OIG's deviation from past interpretations of the statute," and "the reasonableness of the I.G.'s delay" in excluding Petitioner. *Id.*; *see also id.* at 21 (citing *Connell v. Sec'y of Health & Human Servs.*, Case 4:05-cf04122, [2007 WL 1266575,] Magistrate Report and Recommendation at 4-5 (S.D. III. 2007)).

On September 5, 2018, the I.G. filed a reply brief (I.G. Reply). The I.G. asserted, among other things, that a basis for exclusion under section 1128(a)(4) of the Act also exists, and "the ALJ has the authority to consider section 1128(a)(4) as a basis for Petitioner's fiveyear exclusion . . . even though the I.G. did not identify it as a basis for Petitioner's exclusion in the notice letter." I.G. Reply at 7-8 (citing 42 C.F.R. §§ 1005.7(a)(1), 1005.15(f)(1), 1005.4(b); Mary Ann Jimenez, DAB CR304 (1994), William I. Cooper, M.D., DAB No. 1534 (1995), aff'd, Cooper v. Dep't of Health & Human Servs., Civ. No. 95-6992, 1996 WL 571398 (E.D. Pa. Sept. 30, 1996)). On September 5, 2018, the I.G. filed an objection to Petitioner's witnesses and exhibits (I.G. Objection). The I.G. objected to Petitioner's exhibits 1-2, 5-8, and 10-11 on the ground that the exhibits were irrelevant and immaterial. I.G. Objection at 1-4. The I.G. also objected to the elicitation of testimony from three OIG officials on the ground that the testimony would be irrelevant and immaterial to the basis of Petitioner's exclusion because "evidence related to the I.G.'s decision making process is irrelevant, especially as it relates to the I.G.'s decision to exclude individuals convicted of the same or similar crimes." Id. at 4-6 (citing Robert Kolbusz, M.D., DAB No. 2759, at 9-10 (2017) and Mohamed Basel Aswad, M.D., DAB No. 2741, at 13 (2016), aff'd, Aswad v. Hargan, No. 2:16-cv-1367, 2018 WL 704370 (D.N.M. Feb. 2, 2018)).

On September 19, 2018, Petitioner filed a motion to dismiss, arguing that "the I.G.'s introduction of a new basis for exclusion via reply pleading is unprecedented, improper, and contrary to the governing regulations." Pet. Motion to Dismiss at 3. Petitioner argued that if the ALJ did not dismiss the case, she should, in the alternative, strike the portion of the I.G.'s reply brief that addressed exclusion under section 1128(a)(4). *Id.* at 4. On October 1, 2018, the I.G. filed a response to Petitioner's motion to dismiss.

ALJ Decision

On November 16, 2018, the ALJ issued a decision affirming the I.G.'s determination to exclude Petitioner from all federal healthcare programs for five years in accordance with section 1128(a)(3) of the Act. The ALJ admitted I.G. Exs. 1-7 and Pet. Exs. 3, 4, and 9, but excluded Pet. Exs. 1-2, 5-8, and 10-11, writing in pertinent part:

In the absence of any objections, I admit into evidence IG Exs. 1-7.

The IG objects to P. Exs. 1-2, 5-8, and 10-11. P. Exs. 1-8 include documents from the criminal case and exclusion of Petitioner's codefendant. P. Ex. 7 includes press releases and related information regarding exclusions imposed in other cases. I agree that these documents are irrelevant and immaterial and decline to admit them. 42 C.F.R. § 1005.17(c). P. Ex. 11 is a list of published decisions issued by the Departmental Appeals Board and its administrative law judges. It is not evidence. I therefore admit P. Exs. 3-4, and 9.

ALJ Decision at 2. The ALJ determined that an in-person hearing was unnecessary and would "serve no purpose" because the testimony that Petitioner sought to elicit from the three OIG officials "would be irrelevant and therefore inadmissible." *Id.* (citing 42 C.F.R. § 1005.17(c)). The ALJ also determined not to revisit her June 25, 2018 order because "Petitioner presents no new or compelling arguments" *Id.* at 3.

The ALJ concluded that "Petitioner must be excluded from program participation for a minimum of five years because he was convicted of felony financial misconduct in connection with the delivery of a healthcare item or service." Id. (emphasis removed). In coming to her conclusion, the ALJ rejected Petitioner's argument that the I.G. could not exclude Petitioner under section 1128(a)(3) because the I.G. excluded Dr. Chaney under section 1128(a)(4) and not (a)(3), concluding that Dr. Chaney's exclusion "is irrelevant." Id. at 4. Moreover, the ALJ declined to add section 1128(a)(4) as a basis for Petitioner's exclusion. Id. at 4 n.2. The ALJ also rejected Petitioner's argument that the I.G. "impermissibly relied on 'underlying facts' to conclude that his criminal activity related to financial misconduct in connection with the delivery of a healthcare item or service." Id. at 4. The ALJ noted that the "Departmental Appeals Board has long rejected efforts to limit section 1128 review to the bare elements of the criminal offense." Id. (citing, inter alia, Patel v. Thompson, 319 F.3d 1317 (11th Cir. 2003), aff'ing Narendra M. Patel, M.D., DAB No. 1736 (2000), and Timothy Wayne Hensley, DAB No. 2044 (2006)). Nonetheless, the ALJ found that the money laundering statute and Petitioner's plea agreement were enough to conclude that Petitioner's conviction provided a basis for exclusion under section 1128(a)(3), writing in relevant part:

Moreover, while the underlying facts are instructive, the IG need not go beyond the four corners of the money laundering statute and Petitioner's plea agreement to conclude that his conviction satisfies the requirements of section 1128(a)(3). Money laundering is, by definition, "financial misconduct" because it necessarily involves a "financial transaction." 18 U.S.C. § 1956(a). Petitioner admitted that he conspired "to conduct financial transactions" involving the proceeds from "the unlawful distribution and [dispensing] of controlled substances." IG Ex. 4 at 1. Controlled substances are "health care items." His crime thus falls squarely within the parameters of section 1128(a)(3).

Id. at 5.

Standard of Review

Our standard of review of an exclusion imposed by the I.G. is established by regulation. We review a disputed issue of fact as to "whether the initial decision is supported by substantial evidence on the whole record." 42 C.F.R. § 1005.21(h). We review a disputed issue of law as to "whether the initial decision is erroneous." *Id*.

Analysis

In his Request for Review (RR) and Reply briefs, Petitioner challenges several of the ALJ's evidentiary rulings and legal conclusions. For the reasons explained below, we conclude that Petitioner's arguments have no merit and affirm the ALJ's ultimate conclusion that a 5-year exclusion is warranted under section 1128(a)(3) of the Act. In Section I, we address the scope of this appeal and the basis for Petitioner's exclusion under section 1128(a)(3). In Section II, we discuss the ALJ's evidentiary rulings. In Section III, we consider Petitioner's argument that the ALJ issued the initial decision past the regulatory deadline.

I. Petitioner's exclusion under Act § 1128(a)(3) is supported by substantial evidence and free of legal error.

A. Petitioner's criminal conviction establishes a basis for exclusion.

The only issue before the ALJ in this matter was whether "[t]he basis for the imposition of the sanction exists" 42 C.F.R. § 1001.2007(a)(1). The ALJ correctly captured the narrow scope of the appeal when she stated that she must determine "whether Petitioner was convicted of a criminal offense and, if so, whether that offense is related to 'fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service.'" ALJ Order at 2. In other words, the ALJ was tasked solely with determining whether Petitioner's conviction established a basis for exclusion under section 1128(a)(3).

Petitioner argues that the I.G. and ALJ improperly relied on "non-adjudicated acts and prior bad act evidence" found in I.G. exhibits 2 and 5 to establish that a basis for exclusion exists. RR at 15-18; Reply at 10-11. In reaching her conclusions, however, the ALJ held, and we agree, that "the four corners of the money laundering statute and Petitioner's plea agreement" sufficed to show the requirements of section 1128(a)(3) were satisfied. ALJ Decision at 5. Petitioner pleaded guilty to one count of conspiracy to commit money laundering, in violation of 18 U.S.C. § 1956(h). I.G. Ex. 7. The money laundering statute contemplates a "financial transaction" that "involves the proceeds" of "unlawful activity." 18 U.S.C. § 1956(a)(1). In Petitioner's plea agreement, he admitted to knowingly handling financial transactions with the proceeds from the "unlawful dispensation of controlled substances by illegitimate prescriptions." I.G. Ex. 4, at 3. Petitioner admitted that he "knew and intended that continuing to process" these transactions would "conceal that portion of Clarion's income that came from the unlawful dispensation of controlled substances " Id. Petitioner admitted that he paid "underthe-table" cash funds to himself, Dr. Chaney, and two other Clarion employees – a portion of which "was traceable to Clarion's illegitimate prescription income." Id.

Before the Board, Petitioner does not dispute that his criminal offense involved "financial misconduct," but argues that his offense does not satisfy the "delivery of a health care item or service" requirement found in section 1128(a)(3). RR at 26. Petitioner is correct in his assertion that "he did not deliver a health care item because his offense involved the depositing of funds into financial institutions subsequent to the issuance of any prescription." RR at 26. Nevertheless, section 1128(a)(3) does not require that an individual actually deliver a health care item or item or service, but, rather, that the individual's criminal offense be in connection with the delivery of a health care item or service. See, e.g., Ellen L. Morand, DAB No. 2436, at 9 (2012) ("For a crime to be committed 'in connection with the delivery of a health care item or service,' the conduct underlying the criminal offense does not necessarily have to involve actual delivery . . . of a health care item or service to the patient or beneficiary.") (citing Charice D. Curtis, DAB No. 2430, at 5 (2011)). "[T]he Board has read the word 'delivery' together with the key modifying language in the phrase, 'in connection with,' to require a 'common sense connection' or 'nexus' between the underlying facts and circumstances of the offense and the delivery of health care items or services to individuals for their health care needs." W. Scott Harkonen, M.D., DAB No. 2485, at 7 (2012) (citing Morand at 9 and Curtis at 5), aff'd, Harkonen v. Sebelius, No. C 13-0071 PJH, 2013 WL 5734918 (N.D. Cal. Oct. 22, 2013)).

Here, the facts of Petitioner's criminal offense demonstrate a clear, common-sense connection with the delivery of a health care item or service. Petitioner admits that he improperly handled financial transactions with the proceeds from the dispensation of

controlled substances by means of illegitimate prescriptions, and does not dispute that the "controlled substances" were health care items or services. Moreover, the funds that Petitioner paid "under-the-table" to himself and his co-conspirators could otherwise have been properly used to furnish health care items or services to Clarion's patients. *See, e.g., Morand* at 8-11 (finding a common-sense connection between a pharmacy technician's theft of evening deposits from of a pharmacy's safe and the delivery of health care items or services because "at least some portion of the evening deposits stolen by Petitioner consisted of money obtained from the sale of health care items or services" and "Petitioner's theft . . . diverted money that could have otherwise been used for the furnishing of" health care items or services); *Curtis* at 5 (holding that an administrator's fraudulent theft of money from her employer, a provider of in-home nursing services, was connected to the delivery of health care items or services because the money "could have otherwise been used to fund the provision of health care items or services.").

In sum, Petitioner's conviction for conspiring to launder proceeds from the illicit dispensation of controlled substances established a valid legal basis for exclusion under section 1128(a)(3).

B. Petitioner's other arguments go beyond the scope of this appeal.

Petitioner argues that the I.G.'s application of section 1128(a)(3) was arbitrary and capricious under the APA because Dr. Chaney, who was also convicted of money laundering, was excluded under section 1128(a)(4) rather than (a)(3). RR at 24-27. Petitioner asserts that "[t]he I.G.'s application of two different exclusion authorities based on a review of the same statutory charge and near identical plea agreement was implausible and produced an absurd result." Id. at 26. The ALJ considered this argument and held that "Dr. Chaney's exclusion, which is not before me, is irrelevant." ALJ Decision at 4. Petitioner's theory appears to be that, because the I.G. proceeded against him under a mandatory exclusion authority but had not invoked that authority as to Dr. Chaney, the I.G. must have originally determined that the offense of which they were both convicted did not trigger the requirements of that mandatory authority. Petitioner now argues that "the ALJ was required to address the [I.G.]'s change in agency precedent and the conclusion that Dr. Chaney's exclusion is irrelevant is legally erroneous." Id. at 25-26 (citing Friedman v. Sebelius, 686 F.3d 813, 827 (D.C. Cir. 2012), reversing and remanding 755 F. Supp. 2d 98 (D.D.C. 2010), aff'g Paul D. Goldenheim, M.D., et. al, DAB No. 2268 (2009)). In a similar vein, Petitioner states that he "offered examples of no less than 13 individuals convicted of a money laundering offense related to controlled substances that were not excluded" by the I.G. (citing Pet. Ex. 10), and that the "failure of the [I.G.] to exclude these individuals, where the statute purportedly required a mandatory exclusion, is a change in agency interpretation regarding the application of section 1128(a)(3) of the Act." Id. at 28-29 (citing Kabins v. Sebelius, Case No. 2:11-cv1742, Order at 4 ¶ 29 (D. Nev. 2012), *reversing Mark B. Kabins, M.D.*, DAB No. 2410 (2011)).

To begin with, Petitioner's attempt to apply the APA's arbitrary and capricious standard in this forum is misguided. Section 706 of the APA provides for courts to "hold unlawful and set aside agency action, findings, and conclusions found to be" "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law" and "unsupported by substantial evidence" after a hearing on the record. 5 U.S.C. § 706(2)(A), (E). The Supreme Court has described the arbitrary and capricious standard of review as "narrow," empowering courts only to look at whether an agency has considered the relevant evidence and articulated a "satisfactory explanation for its action." F.C.C. v. Fox Television Stations, Inc., 566 U.S. 502, 513 (2009) (quoting Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 43 (1983)). As the Board has explained in the past, this is not the standard of review applicable to administrative appeals of I.G. exclusions, however. "The Board is not a court; it is an appellate adjudicative body in an administrative appeal process." Arizona Health Care Cost Containment Sys., DAB No. 2824, at 8 (2017), appeal docketed, 2:17-cv-04462, Dist. of AZ; see also Hanover Hill Health Care Ctr., DAB No. 2507, at 7 (2013) ("Nothing in the APA . . . applies the 'arbitrary and capricious standard' to Board review of an ALJ decision on behalf of the Secretary"); Cal Turner Extended Care Pavilion, DAB No. 2030, at 7-8 (2006) (drawing a distinction between "the oversight role of a federal court reviewing agency decisions to determine if an adequate basis is articulated and the internal agency appeals process for formulating final agency action").

Moreover, the I.G.'s enforcement action against Dr. Chaney – or any other individual – has no bearing on whether the I.G. had a valid basis to exclude Petitioner under section 1128(a)(3) in this circumstance. The ALJ's review was limited to the exclusion action before her, not to determining the I.G.'s reasons for not applying mandatory authority in a different case. In her review of Petitioner's exclusion, the ALJ did "not have the authority to . . . refuse to follow Federal statutes or regulations" 42 C.F.R. § 1005.4(c)(1). The ALJ, therefore, was required to affirm Petitioner's exclusion "regardless of what transpired in any other case." Lena Lasher, aka Lena Contang, aka Lena Congtang, DAB No. 2800, at 3 (2017) (citing Lee G. Balos, DAB No. 1541, at 9 (1995) ("The issue before us (as before the ALJ) is not whether the I.G. erred in determining that mandatory exclusions were not applicable in some other cases, but whether Petitioner's convictions required the I.G. to impose a mandatory exclusion in this case."), aff'd, Lena Lasher v. U.S. Dept. of Health & Human Servs., 2019 WL 1382961 (D.D.C. Mar. 27, 2019); Jewish Home of Eastern Pa., DAB No. 2254, at 14 (2009) ("[A]llegations by a party against which an action has been taken that the treatment accorded to it is harsher than that accorded to others similarly situated do not prohibit an agency of this Department from exercising its responsibility to enforce statutory

requirements.") (internal quotation omitted)), *aff'd*, *Jewish Home of Eastern Pa. v. Ctrs.* for Medicare & Medicaid Servs., 693 F.3d 359 (3rd Cir. 2012)).

The ALJ's review authority is thus fundamentally different than that of the district court in Kabins. In Kabins, the Court reversed the petitioner's exclusion on the ground that the convicted offense was not in connection with the delivery of a health care item or service. *Kabins* at 3 ¶ 27-28. The Court then noted examples provided by the petitioner "of convictions that appear to bear a much more direct connection to the delivery of health care" but where "the convicted individual had not been excluded by the Secretary." Id. ¶ 29. The Court stated that the "variable application of the exclusion sanction could be viewed as either arbitrary or, given the amorphous nature of the 'common sense nexus' approach, lending itself to arbitrary and certainly selective enforcement." Id. Not only was the Court's discussion on "selective enforcement" dicta, and not otherwise controlling in the case before us, but the Court was applying an arbitrary and capricious standard which, as we have discussed, is not applicable in this forum. Here, the ALJ concluded that the I.G. had a valid legal basis to exclude, and she had no authority to look beyond that basis to determine if the I.G. arbitrarily applied this particular mandatory exclusion authority to Petitioner but not to other individuals convicted of similar offenses.

Petitioner also argues that he should have been allowed to develop a record regarding the I.G.'s "delay" in excluding Petitioner, "particularly the 9 months between his and Dr. Chaney's exclusion." RR at 27-29. Neither the ALJ nor the Board, however, has the authority to review the timeliness of the I.G.'s imposition of an exclusion, and nothing in the statute or regulations precludes the I.G. from imposing the exclusion when it did. See, e.g., Shaikh M. Hasan, M.D., DAB No. 2648, at 9 (2015) (holding that "the ALJ correctly determined that she had no authority to review the timing of the I.G.'s determination to impose an exclusion or to change the starting date of the exclusion."), aff'd, Hasan v. Sec'y of Health & Human Servs., No. 1-15-CN-04687 (E.D. N.Y. Jul. 12, 2017); Kailash C. Singhvi, M.D., DAB No. 2138, at 5-7 (2007) ("[T]he ALJ and this Board do not have the authority to review the I.G.'s decision on when to impose the exclusion (including the decision to exclude Petitioner some eight months after he was sentenced), and may not grant Petitioner the essentially equitable relief he seeks."), aff'd, Kailash C. Singhvi, M.D. v. Inspector General Dep't of Health & Human Servs., No. CV-08-0659 (SJF) (E.D. N.Y. Sept. 21, 2009). Moreover, there is no governing authority that guarantees prompt notice or prompt action on exclusions. Rita Patel, DAB No. 2884, at 7 (2018) (citing Samuel W. Chang, M.D., DAB No. 1198, at 13-14 (1990) and Seide v. Shalala, 31 F. Supp. 2d 466, 469 (E.D. Pa. 1998) ("Neither the Social Security Act nor its implementing regulations set any deadline within which the Inspector General must act."), affirming Charles Seide, DAB CR525 (1998)), appeal docketed, Rita Patel v. Sec'y of Health & Human Servs., 18-3227, 3d Cir. (transferred to D.N.J. on March 27, 2019).

Petitioner acknowledges that ALJs do not have the authority to review the timing of the I.G.'s decision to impose exclusion (RR at 28), but states that the ALJ was nevertheless required to "develop a full administrative record regarding the agency's delay to allow a reviewing court the opportunity to determine whether the delay was explained, justified, or unreasonable " Id. at 28-29 (citing Connell v. Sec'y of Health & Human Servs., Case No. 4:05-cv4122, 2007 WL 1266575 (S.D. Ill. 2007)). In Connell, the Southern District of Illinois adopted a magistrate judge's report and recommendation to reverse and remand the Board's decision in Jeffrey Knute Connell, DAB No. 1971 (2005). Before the ALJ, Connell argued that the three year lapse of time between his conviction and the I.G.'s notice of exclusion was untimely and barred by laches. The ALJ held that there was no statute of limitations on the I.G.'s imposition of exclusions and that he had no authority to consider whether Connell's exclusion was equitable in light of the delay. Jeffrey Knute Connell, DAB CR1271, at 4 (2005). The Board declined to review and summarily affirmed the ALJ's decision. DAB No. 1971 (2005). The district court held that under the applicable substantial evidence standard of review, it was "not empowered to weigh evidence itself and make factual findings," so it remanded for the Secretary to make factual findings "about whether the delay between Connell's conviction and his exclusion was reasonable 2007 WL 1266575, at 2 (citing Magistrate Judge's Report and Recommendation). The court instructed the Secretary to "evaluate the reasonableness of the 35-month delay between Connell's criminal conviction" and his exclusion, and to "consider the relevant circumstances, including the complexity of the issues considered, the volume of materials reviewed, any justification for delay, and the adverse impact on Connell." Id.⁴ Petitioner interprets the court's remand instructions in *Connell* as requiring ALJs in future exclusion appeals to develop a record on the reasonableness of the I.G.'s timing of an exclusion. We reject this interpretation. The Connell court acknowledged "that the relevant regulations do not permit an administrative law judge to consider such questions" but placed "the burden on the Secretary to determine the appropriate manner of making the necessary factual findings within the agency." *Id.* We do not read *Connell* as somehow imposing a burden on ALJs to develop a record for issues not properly before them. See Randall Dean Hopp, DAB No. 2166, at 4 (2008) ("Connell is not a basis for reversing the ALJ Decision regardless of the I.G.'s failure to explain the reason for the delay in imposing the exclusion on Petitioner."); Singhvi at 6 ("We do not view the court's decision in Connell as compelling either reversal of the exclusion here or findings by the Board (or the ALJ) as to whether the delay in this case was reasonable.").

⁴ On remand, Connell's case was dismissed pursuant to a motion to withdraw his hearing request. *See Singhvi* at 6 n.7.; *Jeffrey Knute Connell*, Docket No. C-2007-440 (withdrawn May 16, 2007).

Petitioner also argues that an in-person hearing was necessary to elicit testimony from three OIG officials "regarding: (1) the collection of evidence [by the I.G.]; (2) the selection of the [I.G.]'s exclusion authority for [Petitioner] and Dr. Chaney; and (3) the circumstances surrounding the [I.G.]'s 9 month delay between imposing Dr. Chaney's and [Petitioner]'s exclusion." RR at 32. All of the testimony Petitioner sought to elicit goes to issues beyond the scope of this appeal. The ALJ, therefore, did not err when she determined that an in-person hearing was not necessary because the testimony that Petitioner sought to elicit was irrelevant. *See* ALJ Decision at 2.

II. The ALJ did not err or abuse her discretion in her evidentiary rulings.

A. The ALJ did not err in denying Petitioner's Request for Discovery.

The governing regulations provide that "[a] party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ." 42 C.F.R. § 1005.7(a). The regulations further provide:

When a request for production of documents has been received, within 30 days the party receiving that request will either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part will be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. (The party receiving a request for production may also file a motion for protective order any time prior to the date the production is due.)

Id. § 1005.7(e)(1). Here, Petitioner filed a request for discovery on June 18, 2018.⁵ The I.G. made an oral objection to the request in the June 21, 2018 pre-hearing conference, and the ALJ later denied the request in her June 25, 2018 Order. Order at 2.

Petitioner argues that the ALJ erred in denying Petitioner's discovery request for four reasons. RR at 18-24. First, Petitioner argues that the I.G. made an improper objection to the discovery request. *Id.* at 19. Petitioner asserts that while the I.G. "was required to object to each request and state the reason or reasons for the objection," the I.G. instead made a general oral objection. *Id.* Petitioner further argues that "[t]he I.G.'s categorical and nonspecific objection failed to provide any legal basis or reasoning." *Id.* (citing *Howard v. Sec'y of Health & Human Servs.*, 932 F.2d 505, 509 (6th Cit. 1991)). The regulations require a party to state 1) that the discovery request is being objected to and 2) the reasons for that objection. *42* C.F.R. § 1005.7(e)(1). Petitioner admits that the I.G.

⁵ Petitioner filed his discovery request with the ALJ via the DAB E-File system rather than first seeking discovery directly from the I.G.

orally objected to Petitioner's request – which contains 45 individual requests for production of documents (RFPs) – thus satisfying the first element of an objection under section 1005.7(e)(1). The I.G.'s alleged stated basis for the objection, as characterized by Petitioner, is that "this is a 5 year (a)(3) exclusion." RR at 19. We construe this statement (as the ALJ appears to have done) as an argument that the documents sought were not relevant or material to the narrow issue of whether Petitioner's conviction constituted a legal basis for a mandatory 5-year exclusion under section 1128(a)(3) of the Act. *See* 42 C.F.R. § 1001.2007(a)(1). Thus, we conclude that the I.G. also satisfied the second element of an objection under section 1005.7(e)(1) and the objection was not improper.

Second, Petitioner argues that he was denied the opportunity to file a motion to compel in accordance with section 1005.7(e)(1) when the ALJ sustained the I.G.'s oral objection in her June 25, 2018 Order. RR at 19-20. Petitioner contends this process somehow precluded him from meeting "his burden demonstrating discovery was warranted." Id. at 19; see also 42 C.F.R. § 1005.7(e)(4) ("The burden of showing that discovery should be allowed is on the party seeking discovery."). An ALJ is granted broad authority to "[r]egulate the scope and timing of documentary discovery as permitted by" Part 1005. Id. § 1005.4(b)(7). Here, the ALJ treated the submission of Petitioner's Request for Discovery as a motion to compel, and denied the request accordingly under sections 1005.7(e)(2)(i) and (ii). The ALJ stated that she was ruling on the request before the I.G. even filed a written objection "[t]o avoid undue delay, and because Petitioner is plainly not entitled to the relief he seeks" Order at 2 n.1. The ALJ was within her authority under the regulations to issue a ruling on the discovery request. Moreover, Petitioner was not prejudiced by the ALJ's ruling. Even after the ALJ issued her Order, there was nothing precluding Petitioner from narrowing the scope of discovery to comport with the ALJ's conclusions, or from filing a motion to compel to demonstrate why the requested documents were in fact relevant and material.

Third, Petitioner argues that the documents it sought were indeed relevant and material to the issues before the ALJ. RR at 20-22. While we will not detail all 45 requests for production of documents, some of the broad categories of documents sought by Petitioner included: documents relating to the I.G.'s internal processes such as memoranda of understanding (RFP 1-4); guidance on policy and procedure (RFP 5-6, 9-13); training materials (RFP 7-8); OIG employee information (RFP 14-17, 42); and internal communications or work product (RFP 27-30). Petitioner also sought documents relating to the I.G.'s enforcement actions against Dr. Chaney (RFP 31-35) and other individuals (RFP 36-37, 40); documents relating to prior ALJ cases (which are not precedential or binding on Petitioner's appeal) (RFP 38-39, 43-44); and documents relating to his criminal case that were either already in his possession or that were readily available to him (RFP 23-26). After reviewing Petitioner's Request for Discovery, we find nothing that indicates the RFPs were tailored to seek documents relevant and material to the issue of whether the I.G. had a valid basis to exclude Petitioner, or to any affirmative defense

that Petitioner could have raised.

The ALJ correctly rejected Petitioner's suggestion "that the documents are relevant to show how the [I.G.] arrived at his determination." Order at 2. The ALJ stated that "the [I.G.]'s decision-making processes are irrelevant and thus not subject to discovery." *Id.* (citing 42 C.F.R. § 1005.7(e)(2)(i)). The ALJ also stated that her review is "de novo" and that she would base her decision "on the evidence adduced during these proceedings." *Id.* Petitioner argues that "[t]he ALJ's denial of discovery on the basis that her review is *de novo* is legally erroneous." RR at 20 (emphasis removed). Petitioner asserts that "[t]he documents in the [I.G.]'s possession that helped formulate the basis for exclusion are indisputably relevant and material, and therefore, discoverable." *Id.* We disagree. Whether a valid basis exists to exclude Petitioner is a question of law as applied to the facts of Petitioner's conviction. It does not turn on the I.G.'s decision-making process, and the documents on which the I.G. relied would not alter the outcome of the ALJ Decision.

Fourth, Petitioner argues that the ALJ erred in her ruling that the discovery request was too costly and burdensome, and would cause undue delay. RR at 22-24. In reaching her conclusions, the ALJ wrote:

Petitioner's request directs the [I.G.] to identify and produce more than sixyears-worth of documents, falling within more than 40 broad categories; to prepare a detailed log of all materials for which the [I.G.] asserts a privilege; for documents containing both privileged and non-privileged material, to redact the privileged material and then explain the redaction; to mark and number every page of the disclosed documents; to organize all of the documents in the manner preferred by Petitioner, and to comply with multiple other onerous instructions. Petitioner also wants [I.G.] personnel information and internal deliberative documents regarding the decisionmaking process. I find that complying with this request would be unduly costly and burdensome.

* * *

Given the breadth of the request, I find that directing the [I.G.] to comply with it would unduly delay these proceedings.

Order at 2.

Petitioner argues that his "discovery request contained 45 specifications because each was drafted as narrowly as possible to obtain the necessary information to prepare a defense and rebut anticipated arguments." RR at 23. Petitioner also argues that his "discovery instructions are legally sufficient," comply with "ordinary and customary

discovery practice," and "are a near identical version of the [I.G.]'s template production instructions that accompany [I.G.] subpoenas or other request for documents." *Id.* Based on Petitioner's voluminous Request for Discovery – which we have already determined was not relevant and material to the issues before the ALJ – we find no error or abuse of discretion in the ALJ's conclusions. Moreover, Petitioner's comparison of his instructions with the instructions provided during "customary discovery practice," or accompanying the I.G.'s subpoenas, is inapposite. The regulations provide parties to an I.G. exclusion appeal a limited discovery process – and they apply equally to the I.G. and any petitioners.⁶ The administrative discovery process does not afford the same rights and procedures available to parties in a court case governed by the Federal Rules of Civil Procedure. The relatively narrow scope provided for parties to use discovery to obtain relevant and material documents in administrative litigation is entirely unrelated to the authority vested in the I.G. acting as an investigatory arm of the Secretary to use subpoenas, interviews, or visits as part of performing enforcement and compliance responsibilities.

The regulations do not specify how a party should format or organize a response to a discovery request, assert a privilege, or redact material. The I.G.'s oral objection may have been terse but it was clearly understandable. The ALJ reasonably found that complying with Petitioner's expansive list of requests would be unduly costly and burdensome and a source of delay, in accordance with the discretion granted to her by the regulations. Thus, we find no abuse of discretion in the ALJ's ruling and moreover agree with her that the discovery sought was overbroad and far beyond the scope of the proceeding.

Petitioner also argues that the ALJ erred in determining that Petitioner sought documents covered by the deliberative process privilege because: (1) the I.G. did not raise the privilege when objecting; (2) the ALJ did not specify which requests sought privileged information; and (3) the finding was speculative on the ground that "the ALJ did not review any material in the [I.G.]'s possession." RR at 23-24. Petitioner asserts that he "should have been afforded the opportunity to challenge the assertion [that a requested document was privileged], through a motion to compel, upon review of the [I.G.]'s description of the document and specific privilege asserted." *Id.* at 24. While an ALJ has the authority to deny a motion to compel on the ground that the discovery sought "seeks privileged information" (42 C.F.R. § 1005.7(e)(2)(iv)), the ALJ here did not conclude

⁶ We decline Petitioner's request to "conduct an *in camera* review of the [I.G.]'s request[s] for discovery" in several prior exclusion cases which, Petitioner asserts, would show that the same "stringent discovery burden does not apply when the [I.G.] seeks discovery from an opposing party pursuant to 42 C.F.R. § 1005.7." Reply at 14. The I.G.'s discovery requests in other exclusion matters are irrelevant – they have no bearing on this case or on the burden imposed by the regulations that the party seeking discovery show that discovery should be allowed. *See* 42 C.F.R. § 1005.7(e)(4).

that any specific documents requested by Petitioner were privileged. Rather, the ALJ concluded that "internal deliberative documents regarding the decision-making processes" which Petitioner sought were not relevant in accordance with section 1005.7(e)(2)(i), and a search for them would therefore be unduly costly or burdensome in accordance with section 1005.7(e)(2)(i). Order at 2-3. We agree.

B. The ALJ did not err in her rulings regarding the admissibility of the parties' exhibits.

Petitioner argues that the ALJ erred in admitting the I.G.'s seven exhibits into the record "in the absence of any objections." ALJ Decision at 2. Petitioner asserts that he in fact objected to all seven exhibits offered by the I.G. through comments in his pre-hearing brief. RR at 8 (citing Pet. Pre-hearing Br. at 16-17).

Petitioner argues before the Board, as he did before the ALJ, that the I.G. may not object to Petitioner's discovery requests and then introduce documents that would have been responsive to those requests as exhibits. Pet. Pre-hearing Br. at 16-17; RR at 8-11 ("While a party is entitled to make a lawful objection to a discovery request to shield the production of documents, that party cannot subsequently introduce those documents as a sword after the objection is sustained.") (citing *Kroger Co. v. Am Hi, Inc.*, 2006 WL 2572124, at 8 (W.D. Ky. Aug. 31, 2006)). Petitioner asserts that I.G. Exhibits 1-7 were all responsive to his discovery requests and, because the I.G. objected to the requests, were not admissible as exhibits. *Id.* at 8.

We reject Petitioner's arguments. Petitioner provides no authority, in the regulations or case law, which requires an ALJ to exclude exhibits offered by a party if those exhibits might have been among those responsive to a discovery request to which the party objected. The district court case that Petitioner relies on, *Kroger*, is neither binding on us in this case nor persuasive authority as to any of the issues before us. *Kroger* involved the issue of whether a litigant in a civil matter may assert its Fifth Amendment privilege and later introduce evidence on the matter for which the litigant asserted its privilege. *Kroger* at 2. Here, the I.G. did not invoke the Fifth Amendment, but merely objected to Petitioner's discovery request as irrelevant and immaterial to the issues before the ALJ. Petitioner could have overcome the objection by meeting his burden of showing that discovery should be allowed – a burden which he did not meet at any time during the course of the proceedings.

In any event, Petitioner has not demonstrated that he was prejudiced by the admission of the I.G.'s exhibits. The I.G. introduced the following: the I.G.'s notice of exclusion (I.G. Ex. 1); the July 10, 2014 indictment (I.G. Ex. 2); the March 23, 2015 information (I.G. Ex. 3); Petitioner's September 15, 2016 plea agreement (I.G. Ex. 4); the transcript of

Petitioner's testimony at Dr. Chaney's sentencing hearing (I.G. Ex. 5); the September 21, 2016 judgement against Petitioner (I.G. Ex. 6); and the September 23, 2016 amended judgment (I.G. Ex. 7). All of the I.G.'s exhibits were documents that Petitioner should have already had in his possession or that were readily available to Petitioner as part of his criminal proceedings. Moreover, the I.G. proffered his exhibits as part of his prehearing exchange 30 days prior to the due date for Petitioner's own pre-hearing exchange. Petitioner thus should have had sufficient time to review and analyze the I.G.'s exhibits before his own pre-hearing brief and exhibits were due. *See* Order at 4.

Petitioner also argues that the ALJ's exclusion of Petitioner's exhibits 1-2, 5-8, and 10 was improper. RR at 30-31. Petitioner's exhibits 1-2 and 5-8 are documents regarding Dr. Chaney's criminal conviction and exclusion. Petitioner's exhibit 10 is a "summary" of individuals with similar convictions as Petitioner who had not been excluded from the Medicare program. Petitioner asserts that the documents relating to Dr. Chaney should have been admitted "because the I.G. opened the door to Dr. Chaney's conviction through the admission of evidence relating to Dr. Chaney's indictment ([I.G.] Ex. 2) and sentencing transcript ([I.G.] Ex. 5)." *Id.* Petitioner also states that admission of the documents "is consistent with the rule of completeness contemplated by Rule 106 of the Federal Rules of Evidence." *Id.* at 31. Petitioner also states that all of the excluded documents are relevant and material because they are evidence "of prior agency precedent that the Secretary has now abandoned" and demonstrate that the I.G.'s determination to exclude was arbitrary and capricious under the Administrative Procedure Act (APA). *Id.*

The ALJ was required to exclude "irrelevant or immaterial evidence" (42 C.F.R. § 1005.17(c)) and was not bound by the Federal Rules of Evidence (*id.* § 1005.17(b)). As we explained above, the criminal convictions and exclusions of individuals other than Petitioner are not relevant or material to the issue of whether a valid basis exists to exclude in this instance. The ALJ, therefore, did not err by excluding Petitioner's exhibits which relate solely to issues not properly before the ALJ.⁷

C. The ALJ correctly declined to grant Petitioner access to the entire DAB E-File database.

Petitioner argues that the ALJ erred in denying him access to the entire DAB E-File database, contending "[a]ccess to administrative records maintained in the DAB E-File database is an absolute right afforded to [Petitioner] by the Secretary pursuant to [42 C.F.R.] sections 1005.4, 1005.15 and 1005.18" RR at 13. Petitioner asserts that

⁷ We also note, in response to Petitioner's concerns that, while exhibits are excluded from "the record for the decision" by the ALJ and the Board pursuant to 42 C.F.R. § 1005.18(b), they remain in the administrative record for purposes of any court review. *See Ethan Edwin Bickelhaupt, M.D.*, DAB No. 2480, at 6 (2012), *aff*^{*}d, *Bickelhaupt v. Sebelius*, No. 12-C-9598 (N.D. III. May 29, 2014).

"his inability to access the DAB E-File database to examine prior administrative records deprived him of his regulatory right to a "fair [and] just" hearing." *Id.* at 14. Petitioner further asserts that, "[c]ompounding the prejudice," the I.G. maintains "full access to these documents and was able to rely upon them in the instant proceeding." *Id.* at 10-11. Petitioner states that no ALJ decisions have been "posted to the DAB public website in over 8 months," and that the "website does not contain ALJ pre-hearing orders related to discovery, evidentiary rulings, hearing procedures, and witness testimony." *Id.* at 13.

Petitioner's arguments are without merit. Nothing in the regulations authorizes – much less compels – an ALJ to grant a party access to the entire DAB E-File database. The regulation at section 1005.18 provides that the "record for the decision by the ALJ and the Secretary" consists of "[t]he transcript of testimony, exhibits and other evidence admitted at the hearing, and all paper requests filed in the proceeding" 42 C.F.R. § 1005.18(b). The regulation further provides that "[t]he record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown." *Id.* § 1005.18(c). Petitioner seems to interpret this regulation as somehow requiring an ALJ presiding over an appeal to grant unfettered access to the entire universe of cases at the Departmental Appeals Board through its internal electronic database. It does not.

The DAB provides access to issued decisions and the records of closed cases through the use of Freedom of Information Act (FOIA) requests. *See* 5 U.S.C. 552. If Petitioner wished access to the most recently issued ALJ decisions, or to the documents contained in the records of closed cases, he could have filed a FOIA request seeking such documents. The ALJ was neither authorized nor bound to provide such access as part of the appeal proceedings absent any showing of need or relevance, because "[t]he FOIA process is completely independent from the appeal proceedings in exclusion cases and governed by different legal authorities." *Robert Kolbusz, M.D.*, DAB No. 2759, at 11 (2017) (citing *Wayne E. Imber, M.D.*, DAB No. 1740, at 10 (2000)).

III. Petitioner suffered no harm from the asserted untimeliness of the ALJ Decision.

Petitioner devotes a significant portion of his appeal to argue that the Board must vacate the ALJ Decision and "dismiss" the I.G.'s exclusion determination with prejudice because the ALJ failed to issue a "timely" initial decision. RR at 4-8; Reply at 1-10. The regulations provide that "[t]he ALJ will issue the initial decision to all parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. . . . If the ALJ fails to meet the deadline . . . he or she will notify the parties of the reason for the delay and will set a new deadline." 42 C.F.R. § 1005.20(c).

The ALJ established a briefing schedule in her June 25, 2018 order establishing, among other things, a deadline of September 5, 2018 for the I.G. to file a reply to Petitioner's pre-hearing brief. The ALJ advised that she "will issue a written decision in this matter within 60 days of the record close date, which will be the date my office receives the last submission filed in the case." Order at 6. The timeline regarding the submission of materials is not in dispute. The I.G. filed a reply brief on September 5, 2018. Petitioner filed a motion to dismiss on September 19, 2018, and the I.G. filed a response to the motion to dismiss on October 1, 2018. The ALJ issued an initial decision based on the written record on November 16, 2018.

Petitioner argues that "[t]he ALJ's decision was issued 73 days after the submission of the final post-hearing brief, and the ALJ failed to comply with the regulatory mechanism for extending the 60 day time period." RR at 4-5. Petitioner asserts that "the ALJ set the final post hearing brief submission date as September 5, 2018" and, therefore, "the ALJ's deadline to issue the initial decision or provide notice to the parties that she was extending the decision deadline was November 5, 2018." *Id.* at 6. Petitioner also asserts that the "Secretary did not limit the timeliness of the initial decision" only to cases in which there is a hearing on the record. Reply at 1-5. The I.G. counters that "the 60-day clock" for issuing the decision had not begun to toll due to the fact that there was no hearing and, accordingly, no established deadline for post-hearing briefs or reply briefs. Response at 9. The I.G. states that his September 5, 2018 reply brief was a pre-hearing reply brief rather than a post-hearing reply brief, and that, at the time the ALJ issued her decision, the parties were waiting on the ALJ to rule on Petitioner's request for an inperson hearing. *Id.* at 9-10.

Given that there was no hearing and no deadline for the submission of post-hearing briefs, it is not obvious if and when the 60-day timeframe to issue an initial decision began pursuant to section 1005.20(c). The regulation states that the ALJ will issue a decision "within 60 days after the time for submission of *post-hearing* briefs and reply briefs, if permitted, has expired." (Emphasis added). The regulations are silent regarding a situation in which the ALJ foregoes a hearing or the parties do not file post-hearing briefs. However, the ALJ here expressly notified the parties of when the decision would be issued, i.e., within 60 days of receipt of the last submission. Thus, even if we considered the 60-day timeframe in section 1005.20(c) to apply in this case (or to apply at all to a decision issued without a hearing), the ALJ here would have met the regulatory requirement to notify the parties of an alternate timeframe.

In any case, even if the ALJ issued a decision 13 days after the end of the 60-day timeframe, as Petitioner alleges, it would constitute harmless error. The regulation governing harmless error, 42 C.F.R. § 1005.23, reads in pertinent part:

[N]o error or defect in any ruling or order or in any act done or omitted by the ALJ . . . is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to . . . the [Board] inconsistent with substantial justice. The . . . [Board] at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

We find no evidence the error alleged by Petitioner – that the ALJ issued the initial decision 13 days after the timeframe proscribed by regulation – affected Petitioner's "substantial rights." Petitioner states that he "was harmed by the untimely decision[] because an agency's failure to follow its own regulations causes 'unjust discrimination and den[ies] adequate notice contrary to fundamental concepts of fair play and due process." Reply at 9 (quoting *Herbert v. Burwell*, 2015 U.S. Dist. LEXIS 97297, at 29 (D. Vt. 2015)). Petitioner, however, was advised of the ALJ's intent to issue an initial decision on the record within 60 days of the date of the last submission filed in the case. *See* Order at 6. Petitioner thus submitted his September 19, 2018 motion to dismiss while on notice that his submission would alter the date that the record would be considered closed and could affect the initial decision's date of issuance.

We conclude that the ALJ did not issue her decision untimely and did not prejudice Petitioner's rights, and therefore reject the requested relief.

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

/s/ Christopher S. Randolph

/s/

Constance B. Tobias

/s/

Leslie A. Sussan Presiding Board Member