Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:

(Note: The Case of:

(Note: January 8, 2008)

(Note: J

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Kevin J. Bowers (Petitioner) appealed the September 27, 2007 decision by Administrative Law Judge (ALJ) Steven T. Kessel.

Kevin J. Bowers, DAB CR1661 (2007) (ALJ Decision). The ALJ Decision affirmed the determination of the Inspector General (I.G.) excluding Petitioner from participation in Medicare, Medicaid, and all other federal health care programs for five years pursuant to section 1128(a)(3) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(a)(3)).¹ Section 1128(a)(3) requires the exclusion of any individual convicted of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct, under federal or state law, in connection with the delivery of a health care item or service,

¹ The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. 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 42 U.S.C.A. Ch. 7, Disp Table.

for an offense which occurred after August 21, 1996. Section 1128(c)(3)(B) provides that an exclusion pursuant to section 1128(a) must be for a minimum of five years. These statutory provisions are implemented in regulations at 42 C.F.R. §§ 1001.101 and $1001.102.^2$

On appeal, Petitioner argues that the ALJ erred in finding that his theft of a controlled substance while practicing pharmacy was "in connection with the delivery of a health care item or service" within the meaning of section 1128(a)(3). Petitioner also sets forth a laches argument based on the delay between his conviction and the I.G.'s notice of the proposed statutory exclusion.

For the reasons explained in detail below, we uphold the ALJ Decision. Petitioner's theft of medication from the pharmacy where he was employed fits squarely within the statutory definition of a criminal offense "in connection with the delivery of a health care item or service," and thus provides the basis for a mandatory exclusion of five years. Act, sections 1128(a)(3) and 1128(c)(3)(B). With respect to Petitioner's laches argument, the Board has no authority to shorten the minimum period of exclusion or to assign an earlier starting date for the exclusion. Accordingly, the beginning date of the exclusion remains the date assigned by the I.G.

The ALJ Decision

The ALJ made the following findings of fact and conclusions of law (FFCLs):

- 1. Petitioner was convicted of a felony for which section 1128(a)(3) of the Act mandates exclusion.
- 2. The five-year exclusion imposed by the I.G. is reasonable as a matter of law.

ALJ Decision at 2, 4.

The ALJ found that on or about November 30, 2004, Petitioner pled guilty to two felony offenses, including one count of theft of drugs, in Ohio State court. ALJ Decision at 2, citing I.G. Ex. 3, at 3, and I.G. Ex. 5, at 1. Although Petitioner contended

² We cite to the 2006 Code of Federal Regulations throughout this decision; all the relevant regulations were unchanged during the times at issue here.

that his theft of the drugs was not "in connection with the delivery of a health care item," the ALJ analyzed the facts underlying Petitioner's conviction and found that his theft of drugs was in connection with the delivery of a health care item. ALJ Decision at 2-3. In response to Petitioner's argument of laches, the ALJ explained that he was without authority to adjudicate the issue (citing 42 C.F.R. § 1001.2007(a)(1)(i)). Id. at 3. Because an exclusion imposed by the I.G. pursuant to sections 1128(a)(3) and 1128(c)(3)(B) must be for a minimum of five years, the ALJ found the five-year exclusion in this case reasonable as a matter of law. Id. at 4.

Standard of Review

The Board's standard of review of an ALJ decision to uphold the I.G.'s exclusion is set by regulation. The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. 42 C.F.R. § 1005.21(h). The standard of review on a disputed issue of law is whether the initial decision is erroneous. Id.

Analysis

I. Petitioner's theft of drugs was "in connection with the delivery of a health care item or service."

The first issue we address is whether the ALJ correctly ruled that Petitioner's theft of drugs was "in connection with the delivery of a health care item or service" within the meaning of section 1128(a)(3) of the Act. As the ALJ explained, sections 1128(a)(3) and 1128(c)(3)(B) require the exclusion of any individual whose conduct meets four specified elements. In the instant case, Petitioner admitted his conduct met three of the four specified elements - that he had been convicted of an offense occurring after August 21, 1996, that it was a felony, and that it was theft. ALJ Decision at 2. However, Petitioner argued before the ALJ, and argues on appeal, that because he stole the drug, Tussionex (a controlled substance), for his personal use, his theft was not in connection with the delivery of a health care item. ALJ Decision at 2-3; Petitioner's Brief on the Merits (Pet. ALJ Brief) at 4-5; Brief of Petitioner in Support of Appeal (Pet. Appeal Brief) at 1.

The Board has previously concluded that a pharmacist's theft of a drug for personal use or purposes is "in connection with the delivery of a health care item," pursuant to section 1128(a)(3) of the Act. See, e.g., Erik D. DeSimone, R.Ph., DAB No. 1932

(2004) (theft of drugs for personal use); Kenneth M. Behr, DAB No. 1997 (2005) (attempted embezzlement of drugs); Andrew D. Goddard, DAB No. 2032 (2006) (theft of drug). In these cases, the Board analyzed whether there was a "common sense connection" or nexus between the theft and the delivery of a health care item. See DeSimone at 5; Behr at 8-9; Goddard at 4-6. The Board found a "common sense connection" in facts such as that the drugs were health care items, that the drugs were intended for delivery to individuals for health care purposes, that the pharmacist interfered with (or precluded) the delivery of the drugs by taking them for his or her own use, and that the pharmacist had access to the drugs by virtue of his or her professional responsibilities in connection with delivering health care items to the public. See, e.g., DeSimone at 5.

The ALJ in this case applied a similar common sense analysis, and we agree with his reasoning. The following facts are undisputed and stated in the ALJ Decision. Petitioner stole the drug Tussionex from his employer a number of times while working as a pharmacist. Petitioner had access to the drug because he was working as a pharmacist. The drug was in a stream of commerce from the manufacturer, via the pharmacy, to its ultimate destination, patients with legitimate prescriptions for the drug. The drug was a health care item that, but for Petitioner's theft, would have been delivered to a patient. Thus, Petitioner's crime of theft was related to the delivery of a health care item because, while employed as a pharmacist, he diverted a drug from lawful delivery and use. The ALJ correctly decided this legal issue based on the undisputed facts in the case.³

II. The Board does not have authority to review the date the exclusion was imposed, or to modify the dates of exclusion.

Petitioner also was convicted of one felony count of tampering with drugs. I.G. Exs. 4, 5. The Ohio State Board of Pharmacy order suspending Petitioner's pharmacist license indicates that Petitioner had been observed drinking Tussionex directly from the stock bottle at the pharmacy and replacing the bottle's contents with tap water to avoid detection. I.G. Ex. 3, at 2-3. The ALJ did not address whether this additional felony conviction provided a basis for the exclusion independent of the theft conviction, and the parties have not addressed the issue on appeal, apart from the I.G.'s mentioning the tampering conviction in its brief. For these reasons, we do not decide the issue here.

Before the ALJ, Petitioner argued laches, claiming that the I.G. did not impose the exclusion in this case until more than two years after the date of Petitioner's guilty plea. ALJ Decision at 3; see also Pet. Request for Hearing at 2.4 As a remedy for this delay, Petitioner seeks "a credit against the five-year exclusion for the time that [his] license to practice pharmacy was suspended." Pet. Request for Hearing at 2. However, Petitioner concedes that the ALJ and the Board are without authority to review and decide this laches issue (based on the narrow grant of authority in 42 C.F.R. § 1001.2007(a)(1)(i), (2)). ALJ Decision at 3. Petitioner states that he has set forth this issue to preserve it, should he need to pursue a further appeal in the United States district court. Pet. Appeal Brief at 2.

The ALJ concluded that he lacked the authority to address this delay issue because the regulation at 42 C.F.R. § 1001.2007 (a) (1) (i) restricts the issues an ALJ can hear, in a case where a mandatory five-year exclusion has been imposed, to the issue of whether a basis exists for the exclusion. ALJ Decision at 3. In addition, the ALJ found the five-year exclusion in this case reasonable as a matter of law, because it represents the statutory minimum. $\underline{\text{Id.}}$ at 4, citing Act, section 1128 (c) (3) (B).

The ALJ was correct. The applicable regulations provide that when the I.G. has imposed a mandatory five-year exclusion, the

The I.G. notified Petitioner of his proposed exclusion on November 2, 2006, slightly less than two years after the entry of Petitioner's guilty plea on November 30, 2004. I.G. Ex. 7. The I.G. gave Petitioner an opportunity to submit additional information. Id. Petitioner availed himself of that opportunity and the I.G. notified him of the exclusion on April 30, 2007. I.G. Exs. 8, 1.

 $^{^{5}}$ 42 C.F.R. §§ 1001.2007(a)(1) and (2) provide:

⁽a) (1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

⁽i) The basis for the imposition of the sanction exists, and

⁽ii) The length of exclusion is unreasonable.

⁽²⁾ When the OIG imposes an exclusion under subpart B of this part for a period of five years, paragraph (a)(1)(ii) of this section will not apply.

ALJ is restricted to considering whether there was a basis for imposing the exclusion. 42 C.F.R. \$ 1001.2007(a)(1)(i), (2).

In addition, the statute and the regulations set the effective date of an exclusion. Section 1128(c)(1) of the Act provides that an exclusion under section 1128(a) "shall be effective at such time and upon such reasonable notice to the public and to the individual or entity excluded as may be specified in regulations . . ." The current regulations specify that an exclusion "will be effective 20 days from the date of the notice." 42 C.F.R. § 1001.2002(b).6

Thus, the Board has repeatedly held that the statute and regulations give an ALJ no authority to adjust the beginning date of an exclusion by applying it retroactively. Thomas Edward Musial, DAB No. 1991, at 4-5 (2005), citing Douglas Schram, <u>R.Ph.</u>, DAB No. 1372, at 11 (1992) ("Neither the ALJ nor this Board may change the beginning date of Petitioner's Exclusion."); David D. DeFries, DAB No. 1317, at 6 (1992) ("The ALJ cannot . . . decide when [the exclusion] is to begin."); Richard D. Phillips, DAB No. 1279 (1991) (An ALJ does not have "discretion . . . to adjust the effective date of an exclusion, which is set by regulation."); Samuel W. Chang, M.D., DAB No. 1198, at 10 (1990) ("The ALJ has no power to change . . . [an exclusion's] beginning date," but even if he did, making the exclusion retroactive would present insuperable practical problems.); accord Lisa Alice Gantt, DAB No. 2065, at 2-3 (2007) (reiterating the Board's holding in these cases and upholding a mandatory exclusion imposed approximately five years after conviction). In Schram, we held that this lack of discretion extends to the Board as well as the ALJs, and we reiterated that holding in Musial and Gantt. DAB No. 1372, at 11; DAB No. 1991, at 4-5; DAB No. 2065, at 2-3.

In a recent decision, <u>Kailash C. Singhvi, M.D.</u>, DAB No. 2138 (2007), the Board again concluded that the ALJ correctly decided he did not have the authority to review the timing of a petitioner's exclusion. DAB No. 2138, at 4-5. In addition to

The earlier regulation, 42 C.F.R. \S 1001.123(a), provided for the suspension (the term in use at that time) to begin 15 days from the date of the I.G.'s notice, but that regulation did not otherwise differ in any material respect from the current regulation, 42 C.F.R. \S 1001.2002(b), which became final in 1992. See 57 Fed. Reg. 3330 (1992).

 $^{^7}$ As the Board pointed out in <u>Musial</u>, the regulations also specifically provide that an ALJ may not decline to follow a regulation of the Secretary. DAB No. 1991, at 4, citing 42 C.F.R. § 1005.4(c)(1).

discussing the Board precedent above, the Board also cited several court decisions declining to modify exclusions based on plaintiffs' complaints of delay in the notification or imposition of exclusions, finding that the statute and the regulations set no deadlines for the I.G. to act. Id. at 6-7, citing Steven R. Caplan, R.Ph. v. Thompson, Civ. No. 04-00251 (D. Haw. Dec. 17, 2004) (affirming Steven R. Caplan, R.Ph., DAB No. CR1112 (2003)); Seide v. Shalala, 31 F. Supp. 2d 466, 469 (E.D. Pa. 1998) (affirming Charles Seide, DAB No. CR525 (1998)). The Board noted another court decision, Connell v. Sec'y of Health and Human Servs., slip op., 2007 WL 1266575 (S.D. Ill. Apr. 30, 2007), which acknowledged that the regulations do not permit an ALJ to consider questions regarding the timing of exclusions but, nevertheless, remanded to the Secretary for fact-finding as to the reasons for a 35-month delay between Connell's criminal conviction and his exclusion pursuant to section 1128(a)(1) of the Act. Id. at *2, 5, 8.8 The Board concluded that Connell did not compel either reversal of Petitioner Singhvi's exclusion or findings on whether the delay in imposing his exclusion was reasonable. Id. at 5-7.9

In summary, the Board does not have the authority to hear equitable arguments such as laches, or to alter the beginning date or length of a mandatory five-year exclusion under section 1128(a)(3) of the Act.

 $^{^{8}}$ On remand, <u>Connell</u> was dismissed pursuant to a motion to withdraw his hearing request. <u>See Singhvi</u>, DAB No. 2138, at 6, n.7.

The Board also concluded that even assuming <u>Connell</u> required such findings, the Board perceived no basis for finding the delay unreasonable or prejudicial in light of the I.G.'s explanation for the delay and Petitioner Singhvi's failure to indicate how any fact-finding proceeding could result in his mandatory exclusion ending any earlier. DAB No. 2138, at 7-10.

In the instant case, the ALJ noted the <u>Connell</u> decision in a footnote but concluded, "that decision notwithstanding, the regulations strictly limit the areas which I may address in hearing and deciding a case involving an exclusion imposed pursuant to section 1128 of the Act, and I have no authority to address Petitioner's laches argument." ALJ Decision at 3, n.1. On appeal, Petitioner has not cited or discussed the ALJ's reference to <u>Connell</u>, the <u>Connell</u> case itself, or any other authority for his laches argument.

Conclusion

Based on the foregoing analysis, we uphold the ALJ Decision, and affirm the $ALJ^{\prime}s$ Findings of Fact and Conclusions of Law.

_____/s/ Judith A. Ballard

_____/s/ Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member