Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Melissa Michelle Phalora
Docket No. A-17-9
Decision No. 2772
February 22, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner Melissa Michelle Phalora appeals the decision of an Administrative Law Judge (ALJ) granting summary judgment and affirming her exclusion from participating in Medicare, Medicaid, and all other federal health care programs. *Melissa Michelle Phalora*, DAB CR4716 (2016) (ALJ Decision). The Inspector General of the Department of Health and Human Services (I.G.) excluded Petitioner for three years under section 1128(b)(3) of the Social Security Act (Act) based on her conviction for a misdemeanor criminal offense – the theft of a drug from the hospital that employed her – that the I.G. determined was related to the unlawful distribution or dispensing of a controlled substance. The ALJ affirmed the I.G.'s determination.

We affirm the ALJ Decision.

Legal background

Under section 1128(b)(3) of the Act, 42 U.S.C. § 1320a–7(b)(3), the Secretary of Health and Human Services (Secretary) may exclude from participation in all federal health care programs any individual or entity that "has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." The regulation implementing section 1128(b)(3) states that it applies to "any individual or entity that [as relevant here] . . . [i]s, or has ever been, a health care practitioner, provider or supplier" or "[i]s, or has ever been, employed in any capacity in the health care industry." 42 C.F.R. § 1001.401(a)(1), (3) (2014). The regulation also states that "[f]or purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction." *Id*. § 1001.401(b).

An exclusion under section 1128(b)(3) is for three years "unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances." Act § 1128(c)(3)(D); *see* 42 C.F.R. § 1001.401(c) (implementing regulation).

An excluded individual may request a hearing before an ALJ to challenge the exclusion, but only on the issues of whether the basis for the imposition of the exclusion exists, and whether the length of the exclusion is unreasonable. 42 C.F.R. § 1001.2007(a)(1). When the exclusion is based on a criminal conviction, the basis for the underlying conviction "is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal." 42 C.F.R. § 1001.2007(d). The ALJ "may affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion." 42 C.F.R. § 1005.20(b). The excluded individual or the I.G. may appeal the ALJ's decision to the Board. 42 C.F.R. § 1005.21(a).

Case background

The I.G., by notice of January 29, 2016, excluded Petitioner, a registered nurse in Indiana, from all federal health care programs under section 1128(b)(3) of the Act "due to [Petitioner's] misdemeanor conviction . . . in the State of Indiana, Lake Superior Court, of a criminal offense related to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance as defined under Federal or State law."[1] I.G. Ex. 1, at 1; ALJ Decision at 1, 4. The I.G. excluded Petitioner for two years, based on the "mitigating circumstances" that she had been "convicted of three or fewer offenses and the entire amount of financial loss to a Government program or to other individuals or entities was less than $1,500." I.G. Ex. 1, at 1. Petitioner timely requested an ALJ hearing on March 1, 2016. ALJ Decision at 1-2. By notice of April 22, 2016, the I.G. informed Petitioner that the I.G. was "amend[ing] . . . the period of exclusion" to three years. I.G. Ex. 2, at 1. The amendment, the notice stated, was based on the I.G.'s having "initially reduced your exclusion period from 3 years to 2 years based on a mitigating factor that is not applicable to exclusions imposed under section 1128(b)(3) of the Act." I.G. Ex. 2, at 1; ALJ Decision at 2.

[1] The name of the Indiana Superior court that convicted Petitioner is actually "Superior Court of Lake County." I.G. Exs. 4-9.

Before the ALJ, the I.G. filed a brief and nine exhibits (I.G. Exs. 1-9) and declined to offer testimony. ALJ Decision at 2. Petitioner filed a brief in response (P. Br.), objected to the I.G.'s Exhibit 5 (a probable cause affidavit that a state trooper filed in Petitioner's criminal case) and asked to testify at a hearing; in response, the I.G. filed a reply brief and asked the ALJ to decide the case on the written record. The ALJ permitted Petitioner to file written testimony and permitted the I.G. to object to Petitioner's testimony and to ask to cross-examine Petitioner and/or move for summary judgment. *Id.* Petitioner filed her written testimony, the I.G. filed a motion for summary judgment, and Petitioner filed a response (P. Resp.). *Id*. The ALJ stated that because he decided the case on summary judgment, he did not base his decision on the statements in I.G. Exhibit 5, the probable cause affidavit, "due to Petitioner's objections to that document" as "based on double hearsay" and containing "allegations of criminal conduct for which Petitioner was never charged and not found guilty." *Id*. at 6, 7.

The ALJ found that the parties did not dispute the following facts about the case, and these facts remain undisputed on appeal. In November 2014, Petitioner was charged in an Indiana Superior Court under Indiana law with one felony count of theft of Fentanyl Citrate (Fentanyl), a controlled substance under Indiana law, from St. Mary Medical Center where she worked (Count I), and one count of possession of a narcotic drug (Count II). *Id*. at 4, 5-6, citing I.G. Ex. 4; and P. Written Testimony at 11. In a Stipulated Plea and Agreement (plea agreement), Petitioner agreed to plead guilty to Count I. *Id*. at 4. The plea agreement provided that the judgment of conviction would be entered as a misdemeanor, Count II would be dismissed, and Petitioner would enroll in and complete a drug counseling program. *Id*. citing I.G. Ex. 7, at 2 (plea agreement); and P. RFH Ex. B, at 2 (also plea agreement).

In the plea agreement, Petitioner stipulated and agreed "that between March 4, 2015, and March 5, 2015, while she was employed as a registered nurse at St. Mary Medical Center, Petitioner 'took vials of medication, Fentanyl Citrate, that were the property of St. Mary Medical Center' with the 'intent of depriving St. Mary Medical Center of any part of the medication's use or value,' even though Petitioner had no permission to take the Fentanyl Citrate." ALJ Decision at 4, citing I.G. Ex. 6 ("Stipulated Factual Basis" attached to plea agreement); P. RFH Ex. B, at 4 (also Stipulated Factual Basis); and P. Resp. at 2 (agreeing to those facts). Petitioner also admitted that on March 5, hospital management staff met with her concerning her taking vials of Fentanyl. She also admitted that management staff subsequently searched the "lead apron" she had worn while working and found vials of Fentanyl that were not full but contained varying amounts of the medication. P. Written Testimony at 7-11; ALJ Decision at 6.

On June 16, 2015, the court accepted Petitioner's guilty plea, entered a judgment of a misdemeanor conviction under Count I, sentenced Petitioner to six months in jail, suspended the jail term and placed Petitioner on probation for six months and ordered Petitioner to enroll in and successfully complete a drug counseling program. ALJ Decision at 4, citing I.G. Ex. 9 (sentence order); P. Written Testimony at 11; and RFH at 2.

ALJ Decision

The ALJ noted his authority to grant summary judgment "where there is no disputed issue of material fact" and "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." ALJ Decision at 3-4, citing 42 C.F.R. § 1005.4(b)(12) and *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The ALJ recognized his obligation, in determining "whether there are genuine issues of material fact for an in-person hearing," to "view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Id*. at 4, citing *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010) (citations omitted). He also noted "that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Id*. at 3-4, citing *Anderson v. Liberty Lobby, Inc*. (Court's emphasis).

The ALJ found that Petitioner did not dispute the presence of three of "the four essential elements necessary to support" an exclusion under section 1128(b)(3) of the Act, i.e., that "Petitioner was convicted of a criminal offense for purposes" of section 1128(b)(3); that the offense was a misdemeanor; and that she was "a health care practitioner and was employed in the health care industry." ALJ Decision at 3, 5, 8, citing 42 C.F.R. § 1001.401(a). Thus, the only disputed issue before the ALJ with respect to the I.G.'s basis for the exclusion was whether Petitioner's criminal offense "[was] related to the unlawful dispensing of a controlled substance." *Id*. at 5. The ALJ concluded it was, and that summary judgment was appropriate because "the undisputed facts in this case support the conclusion that Petitioner was convicted of a crime related to the unlawful dispensing of a controlled substance." *Id*. at 7. He rejected Petitioner's arguments that her criminal conviction "is not for an offense that specifically relates to the unlawful dispensing of a controlled substance" and that the I.G. "has otherwise failed to factually prove that Petitioner's conviction relates to the unlawful dispensing of a controlled substance." *Id*. at 3, citing P. Resp. at 3-4.

For purposes of summary judgment, the ALJ "accept[ed] as true that Petitioner . . . never stole drugs that were meant for a patient or use in a procedure" but, rather that the drugs Petitioner pled guilty to stealing "were the waste of the drug." *Id*. at 4-5, citing P. Written Testimony at 12. "Waste of the drug" means "the remainder of a patient's drug after the patient received it – i.e., the remainder after the drug is dispensed and administered to the patient" which "has no medical use and was routinely discarded by the hospital and its personnel." *Id*. The ALJ also noted that "Petitioner stated that she never unlawfully dispensed or administered drugs that were meant for a patient and only pled guilty to stealing the waste of the drug." *Id*. at 6, citing P. Written Testimony at 11.

The ALJ concluded that Petitioner's crime was "related to" the unlawful dispensing of the drugs because the undisputed facts showed that she had been convicted of theft for stealing the drugs and had "dispensed" them to herself. *Id.* at 7.

The ALJ pointed out that although Petitioner "was convicted of theft under a general criminal law prohibiting theft[,]" Petitioner admitted that "the theft was for Fentanyl Citrate"; that "she stole Fentanyl that was the excess of the drug not administered to patients"; and that she had been ordered, and agreed, to complete a drug counseling program. *Id*. The ALJ then concluded that:

> These undisputed facts are sufficient to show that Petitioner's criminal offense was related to Petitioner unlawfully dispensing (i.e., distributing) the remaining portions of Fentanyl Citrate not used by patients at the Medical Center to herself. It is unnecessary for the IG to prove that Petitioner physically administered the medication to herself as part of her criminal conviction. It is sufficient that Petitioner's criminal offense involved intentionally and illegally diverting a controlled substance from the Medical Center's possession to Petitioner's possession. IG Exs. 4, 6.

Id. In reaching this conclusion, the ALJ rejected Petitioner's argument that the ALJ should apply the definition of "dispense" in the federal Controlled Substances Act (CSA). Petitioner argued that the CSA definition means "that dispensing involves providing a controlled substance to the ultimate user and administering that controlled substance to that user," whereas here "there is no evidence in the record that Petitioner used the controlled substance she stole." *Id*. at 6-7, citing P. Br. at 11. The ALJ found "no compelling reason" to apply the definition of "dispense" from the CSA, because it is "a statute not applicable to this case," and "[h]ad Congress wanted the definition of 'dispense' in the Controlled Substances Act to apply to section 1320a-7, it would have so indicated." *Id*. at 7. The ALJ instead applied "[t]he ordinary meaning of the word 'dispense' [which] is 'to prepare and distribute (medication).'" *Id.*, citing Merriam-Webster Dictionary.[2]

[2] http://www.merriam-webster.com/dictionary/dispense.

Applying that dictionary definition, the ALJ concluded that "the undisputed facts in this case support the conclusion that Petitioner was convicted of a crime related to the unlawful dispensing of a controlled substance." *Id.* In doing so, the ALJ found it "significant that the terms 'related to' and 'relating to' in 42 U.S.C. § 1320a-7 simply mean that there must be a nexus or common sense connection." *Id.* (citations omitted). The ALJ therefore concluded "that a basis exists to exclude Petitioner pursuant to section 1320a-7(b)(3)" (Act § 1128(b)(3)). *Id.* at 9.

The ALJ also found that because "the record does not support a finding of any mitigating or aggravating factors listed in 42 C.F.R. § 1001.40l(c), Petitioner must be excluded for a minimum period of three years."[3] *Id.* He accordingly concluded that the two-year exclusion the I.G. initially set due to having "erroneously believed that Petitioner's single misdemeanor conviction was a basis to mitigate Petitioner's exclusion . . . was unreasonable" as a matter of law. *Id.*

Petitioner appealed the ALJ Decision by filing a notice of appeal with a brief (NA), and the I.G. filed a response. Petitioner then filed a reply brief, together with a motion seeking permission to file the brief, in order to "respond to issues raised" in the I.G.'s response. *See Guidelines – Appellate Review of Decisions of Administrative Law Judges in Cases to Which Procedures in 42 C.F.R. Part 1005 Apply* ("party that filed the notice of appeal may request permission from the Board to file a reply brief.").[4] Absent any objection by the I.G., we grant the motion and accept Petitioner's reply brief into the record for decision.

Standard of review

Regulations governing Board review of ALJ decisions involving the I.G.'s determination to impose an exclusion provide, "The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record . . . [and] . . . on a disputed issue of law is whether the initial decision is erroneous." 42 C.F.R. § 1005.21(h). The regulations also provide that an ALJ may "[u]pon motion of a

[3] The aggravating factors that may increase an exclusion under Act § 1128(b)(3) are: the acts resulting in the conviction or similar acts "were committed over a period of one year or more;" those acts "had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or the Medicare, Medicaid or other Federal health care programs;" the sentence "included incarceration;" the individual or entity "has a documented history of criminal, civil[] or administrative wrongdoing;" and the individual or entity was "convicted of other offenses besides those [that] formed the basis for the exclusion" or "has been the subject of any other adverse [governmental] action . . . based on the same set of circumstances that serves as the basis for the imposition of the exclusion." 42 C.F.R. § 1001.401(c)(2). The mitigating factors are: the individual or entity's "cooperation with Federal or State officials resulted in" others being "convicted or excluded" and other specified results, and, during the time period relevant to this appeal, "[a]lternative sources of the type of health care items or services furnished by the individual or entity are not available." 42 C.F.R. § 1001.401(c)(3) (2014).

[4] https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-board/guidelines/procedures/index.html.

party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact . . . ." 42 C.F.R. § 1005.4(b)(12). Whether summary judgment is appropriate is a legal issue the Board addresses de novo, viewing the proffered evidence in the light most favorable to the non-moving party. *Timothy Wayne Hensley,* DAB No. 2044, at 2 (2006).

Analysis

Petitioner concedes the presence of three of the four elements the ALJ correctly found are necessary for an exclusion under section 1128(b)(3): she "is a health care practitioner, or is or was employed in the health care industry"; she was "convicted of a criminal offense"; and that offense was a misdemeanor. NA at 3; *see* 42 C.F.R. § 1001.401(a); ALJ Decision at 3, 5, 8. Petitioner argues that her conviction "was, in fact, not 'related to the unlawful . . . dispensing of a controlled substance' as the Act requires" because she was convicted only of theft of property under a law that does not address controlled substances or dispensing, and because there was no "dispensing" to which her theft could relate. NA at 4; *see also id.* at 6 ("dispensing involves providing a controlled substance to the ultimate user and administering that controlled substance to that user, and . . . there is no evidence in the record that Petitioner used the controlled substance she stole"). Petitioner argues that the ALJ erred by granting summary judgment without taking and evaluating evidence to determine whether or not she actually used any of the stolen Fentanyl. *See* P. Reply at 5 ("[i]t was certainly improper for [the ALJ] to base his summary judgment ruling on this contested fact when there is no evidence in the record to support his factual conclusion"). As we explain below, we conclude that the ALJ did not err in deciding this case on summary judgment and concluding that the I.G. was authorized to exclude Petitioner under section 1128(a)(3) of the Act for a period of three years.

A. The ALJ did not err in concluding that Petitioner was convicted of a crime relating to the dispensing of a controlled substance under section 1128(b)(3) of the Act.

1. *The label of Petitioner's conviction does not determine whether the basis for an exclusion exists.*

Petitioner argues, in essence, that her offense did not relate to unlawfully dispensing a controlled substance because the state law's label and description of the crime do not mention dispensing or controlled substances. It is not disputed that she was convicted under Indiana Code § 35-43-4-2(a) which, in a chapter titled "Theft, Conversion, and Receiving Stolen Property," states that "A person who knowingly or intentionally exerts unauthorized control over property of another person, with intent to deprive the other

person of any part of its value or use, commits theft, a Class A misdemeanor." Petitioner argues that this law "which defines theft" of property "contains no definition of 'controlled substance'" and that the theft she was convicted of under that law "did not involve manufacture, distribution, prescription or dispensing of a controlled substance." NA at 4.

Petitioner' argument is incorrect. The Board has repeatedly confirmed that section 1128's references to offenses "relating to" a specified crime such as fraud, theft or patient abuse (or "related to the delivery of" a Medicare item or service) require only a "common sense connection" or "nexus" between the offense and the crimes or actions named in the statute. *See, e.g.*, *George John Schulte*, DAB No. 2649, at 7 (2015) (citations omitted) ("long-standing Board precedent in exclusions under section 1128 . . . 'requir[es] only a 'common sense connection or nexus' between a conviction and the action or conduct specified in section 1128"). The Board has applied this approach in sustaining the exclusions of pharmaceutical company executives for misdemeanor convictions of introducing a misbranded drug, OxyContin, into interstate commerce, in violation of the federal Food, Drug, and Cosmetic Act. The Board held that those offenses were related to both fraud (Act § 1128(b)(1)) and to the unlawful distribution of a controlled substance (§ 1128(b)(1)). *Paul D. Goldenheim, M.D., et al.*, DAB No. 2268 (2009), *aff'd*, *Friedman v. Sebelius*, 755 F. Supp. 2d 98 (D.D.C. 2010), *rev'd on other grounds & remanded*, 686 F.3d 813 (D.C. Cir. 2012). As relevant here, the Board rejected the petitioners' argument that their offense was not "related to" fraud because they were not convicted of fraud and had not participated in their company's felony fraudulent misbranding. *Id*. at 2. The Board instead found "a nexus or common sense connection between Petitioners' misdemeanor misbranding offense and [their company]'s fraudulent misbranding." *Id*. at 11. The D.C. Circuit agreed with this analysis. 686 F.3d at 818-24.

Consistent with this analysis and with the purpose of the exclusion statute, the Board has held that in reviewing an exclusion, "we must consider evidence regarding ***the nature of the offense***, ***rather than the state's labeling of the offense***, to determine whether it involved conduct warranting exclusion." *Michael S. Rudman, M.D.*, DAB No. 2171, at 9 (2008) (emphasis added), *aff'd*, *Rudman v. Leavitt*, 578 F. Supp. 2d 812 (D. Md. 2008); *see also Lyle Kai, R.Ph.*, DAB No. 1979, at 5 (2005) ("[i]t is not the labeling of the offense under the state statute which determines whether the offense is program-related"; instead, "evidence as to the nature of an offense may be considered," such as "facts upon which the conviction was predicated"); *aff'd*, *Kai v. Leavitt*, No. 05-00514 BMK (D. Haw. July 17, 2006). This approach is consistent with the "purpose of section 1128 . . . to protect federal health care programs and the programs' beneficiaries and recipients from untrustworthy providers" (*Susan Malady, R.N.*, DAB No. 1816, at 9 (2002)), and Congress's "intent that the mandatory exclusion authority be used broadly to protect the

integrity of covered programs" (*Kenneth M. Behr*, DAB No. 1997, at 7 (2005), citing *Napoleon S. Maminta, M.D.*, DAB No. 1135 (1990), discussing the legislative history of section 1128(a) and its support for broad coverage). The Board's approach has been upheld by federal courts. *See, e.g.*, *Bohner v. Burwell*, CA No. 15-4088, at 8 (E.D. Pa. Dec. 1, 2016) (affirming *Richard E. Bohner*, DAB No. 2638 (2015) and upholding Board's analysis "which considers the conduct underlying one offense to determine its relatedness to another offense"); *see also id.* at 21 ("Where an individual is convicted of an offense under circumstances that share a common sense connection to fraud, theft, embezzlement, breach of fiduciary responsibility, or financial misconduct, that individual is eligible for exclusion under" § 1128(b)(1)); *Friedman v. Sebelius*, 686 F.3d at 818-24 (sustaining Board's analysis in *Goldenheim* that there was a nexus or common sense connection between Petitioners' misdemeanor misbranding offense and their company's fraudulent misbranding).

2. *Undisputed facts support the ALJ's conclusion that Petitioner's theft of Fentanyl was related to unlawful dispensing of that drug within the meaning of the exclusion statute and regulations.*

As discussed above, the ALJ correctly looked to the conduct underlying Petitioner's conviction, rather than how Indiana law labeled her offense. Based on undisputed evidence, the ALJ correctly concluded that Petitioner's conviction of theft was related to the unlawful dispensing of a controlled substance, notwithstanding that Petitioner was convicted only "under a general criminal law prohibiting theft." ALJ Decision at 7. Specifically, the ALJ relied on Petitioner's admissions (and failure to dispute) that the theft was of Fentanyl, a controlled substance; that "she stole Fentanyl that was the excess of the drug not administered to patients"; and that she "agreed to enroll in and complete a drug counseling program" and was ordered by the court to complete such a program within six months. *Id*., citing I.G. Exs. 4; 6; 7, at 2; 9; and P. Written Testimony at 11-12. The ALJ concluded that "[t]these undisputed facts are sufficient to show that Petitioner's criminal offense was related to Petitioner unlawfully dispensing (i.e., distributing) the remaining portions of Fentanyl Citrate not used by patients at the Medical Center to herself." *Id*.

The ALJ did not err in his analysis of the undisputed facts, which establish the common sense connection between the conduct underlying her criminal conviction and the unlawful distribution of a controlled substance. The fact that Petitioner was convicted of, and admitted, the theft of a controlled substance, the opioid Fentanyl, by itself establishes a common sense connection to the "controlled substance" component of the unlawful dispensing of a controlled substance addressed in section 1128(b)(3). That Petitioner stole vials of Fentanyl that were the property of the hospital where she worked (which maintained supplies of the drug to use in patient procedures and thus entrusted staff to exercise custodial authority over the drug for that purpose) "with the intent of depriving

[the hospital] of any part of the medication's use or value[,]" and converted it to her own possession, establishes a common sense connection between her offense and the unlawful dispensing of the drug, under the common dictionary definition the ALJ employed ("to prepare and distribute" medication). I.G. Ex. 6 (Stipulated Factual Basis attached to plea agreement); P. Written Testimony at 2, 4 (describing how Petitioner would prepare for "patient procedures" by "pulling . . . medications" including "vials of Fentanyl" that "were needed . . . for patient procedures"); *see* ALJ Decision at 7 ("Petitioner's criminal offense involved intentionally and illegally diverting a controlled substance from the Medical Center's possession to Petitioner's possession").

Petitioner argues that she did not unlawfully "dispense" to herself the Fentanyl she stole because there is no evidence she used any of the stolen narcotic herself. *See, e.g.*, NA at 6 ("dispensing involves providing a controlled substance to the ultimate user and administering that controlled substance to that user, and that there is no evidence in the record that Petitioner used the controlled substance she stole"); P. Reply at 4 ("Nowhere is there any evidence that Petitioner dispensed the medication to herself!"). Petitioner argues that her theft conviction thus "was, in fact, not 'related to the unlawful . . . dispensing of a controlled substance'" under section 1128(a)(3) "because the theft for which she was convicted did not involve . . . dispensing of a controlled substance." NA at 4.

Petitioner's argument rests on her contention that the ALJ erred in applying a dictionary definition of "dispense" instead of the CSA definition which, she noted before the ALJ, includes "to deliver a controlled substance to an ultimate user" and references the "administering of a controlled substance . . . ." P. Br. at 11 (cited in NA at 6), quoting 21 U.S.C. § 802(10).[5] However, we find no error in the ALJ's rejection of Petitioner's argument that he should apply a definition that does not appear in the statute and regulations governing exclusions. As the ALJ noted, "[h]ad Congress wanted the [CSA] definition . . . to apply to section 1320a-7, it would have so indicated." ALJ Decision at 7. Petitioner argues that "[i]t is an equally valid argument to state that, if Congress wanted Merriam Webster's definition to apply to section 1320a-7, it also would have so indicated." NA at 8. Petitioner cites no authority, however, for the notion that federal agencies (or the judiciary) must have specific congressional authorization to apply dictionary definitions of common words not defined in the statute under consideration. Moreover, the ALJ's decision not to use the CSA definition is consistent with the Board's

[5] The entire text of 21 U.S.C. § 802(10) is as follows:

> (10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

analysis in the *Goldenheim* case that language of the CSA does not control or limit the I.G.'s exclusion authority under section 1128(b)(3) of the Act. In *Goldenheim*, the Board rejected the petitioners' argument that the meaning of section 1128(b)(3) "is framed by" the CSA and that that exclusions under section 1128(b)(3) "should be limited to convictions under the CSA or a similar statute" addressing illegal street drugs. *Goldenheim* at 19-20. The Board rejected this demand to limit section 1128(b)(3) to the scope of the CSA, in part "because section 1128(b)(3) does not refer to, adopt or incorporate the CSA for the purpose of determining whether the distribution of a controlled substance is unlawful" and "[t]he language of section1128(b)(3) and the CSA, moreover, are not coextensive . . . ." *Id*. at 20. The Board pointed out that the petitioners in that case – like Petitioner here – "point[] to nothing in the statute or legislative history that would limit an exclusion under section 1128(b)(3) to convictions under the CSA or similar statutes." *Id*.

We also note that even applying the CSA definition of dispense (21 U.S.C. § 802(10)) would not benefit Petitioner, as federal courts have confirmed that a controlled substance does not have to be used to be considered illegally "dispensed" under the CSA definition. A court of appeals that upheld a physician's conviction for unlawfully dispensing controlled substances in violation of the CSA held that "[t]he statute only requires that [the recipient of the drug] *obtain* the drug for his own use, and not that he must in fact use it" and that "[w]e do not agree that in order for one to be deemed an ultimate user he must in fact ingest the drug, or that there must be an intent to use the drug when it is obtained." *U.S. v. Bartee*, 479 F.2d 484, 487 (10th Cir. 1973), citing 21 U.S.C. § 802 (CSA definitions of "dispense" and "ultimate user"). Another appeals court concluded that a physician's unlawful "dispensing" occurred when he illegally prescribed a controlled substance, even though the prescriptions were never filled. *U.S. v. Tighe*, 551 F.2d 18, 20 (3rd Cir. 1977) ("'dispense' is defined [by § 802] as delivery of a controlled substance to an ultimate user. . . . and delivery is defined . . . as their actual, constructive, or attempted transfer").

Accordingly, we conclude that the ALJ committed no error by applying the dictionary definition of the word "dispense" which, as the ALJ stated, "is 'to prepare and distribute (medication).'" *Id*. Applying that definition, we agree with the ALJ that "[i]t is unnecessary for the IG to prove that Petitioner physically administered the medication to herself as part of her criminal conviction." ALJ Decision at 7. As the ALJ concluded, "[i]t is sufficient that Petitioner's criminal offense involved intentionally and illegally diverting a controlled substance from the Medical Center's possession to Petitioner's possession." *Id*. In other words, the "dispensing" occurred when Petitioner distributed the "waste" in vials of the Medical Center's Fentanyl to herself.

None of the material facts on which the ALJ relied (i.e. the facts showing her admitted stealing of Fentanyl from the hospital's possession and converting it to her own possession) are in dispute as Petitioner conceded them in the Stipulated Factual Basis in the criminal proceeding (I.G. Ex. 6), and in her written testimony to the ALJ.[6] As the ALJ based his decision on undisputed facts, including Petitioner's own statements of the facts in her agreed stipulations and written testimony, there was no need for him to take evidence on what use Petitioner made of the drugs she stole, as Petitioner contends. Absent any dispute about the facts actually material to the outcome of the case, summary judgment in the I.G.'s favor was appropriate. There was thus no legal error in the ALJ's conclusion that "the undisputed facts in this case support the conclusion that Petitioner was convicted of a crime related to the unlawful dispensing of a controlled substance." ALJ Decision at 7.

In concluding that summary judgment is appropriate, we have taken note of Petitioner's suggestions in her written testimony that she came to possess the stolen Fentanyl through the innocent act of "wasting" the portions of the drug that were not used in or needed for medical procedures and that the vials of the drug that were found in her lead apron could have been placed there by other hospital staff who used the apron. P. Written Testimony at 4-12. These suggestions of her innocence, however, are collateral attacks on her conviction that the regulations bar in this appeal. 42 C.F.R. § 1001.2007(d). These suggestions thus do not raise any material dispute of fact that would render summary judgment inappropriate, as the ALJ was not required draw in Petitioner's favor any inferences contrary to the facts she admitted in her criminal case.

B. Petitioner is barred from arguing that the ALJ improperly used the Indiana definition of "controlled substance" because she did not argue below that Fentanyl was not a controlled substance and, in fact, conceded it was.

Petitioner argues that "[w]ithout a definition for 'controlled substance' being provided for in the law forming the basis of Petitioner's exclusion, no basis exists upon which to sustain the exclusion." NA at 5. Petitioner notes that the implementing regulation, 42 C.F.R. § 1001.401(b), "requires that 'the definition of controlled substance will be the definition that applies to the law forming the basis for the conviction[,]'" and argues that the ALJ and the I.G. erred in citing the definition in Indiana law on controlled substances (Ind. Code § 35-48-2-6(c), which includes Fentanyl), because she was convicted under a

[6] Although Petitioner disputed some of the statements by the state trooper in his probable cause affidavit (I.G. Ex. 5), the ALJ, to decide the case on summary judgment, pointedly did "not base [his] decision on the statements in the probable cause affidavit (IG Ex. 5) due to Petitioner's objections to that document." ALJ Decision at 7.

different Indiana law (Ind. Code § 35-43-4-2(a)) concerning theft of property. P. Reply at 2, 6. She argues that "[i]f the drafters [of § 1001.401(b)] intended it to mean what the IG asserts, it would have stated something more like, 'the definition of controlled substance will be the law **of the forum** forming the basis for the conviction.'" *Id*. at 6 (Petitioner's emphasis).

We do not agree with Petitioner's interpretation of section 1001.401(b). That regulation required the ALJ to use the definition in the law forming the basis for conviction which, in the case of a conviction under state law, is the law of the convicting court's state. This is precisely the law the ALJ applied here. Petitioner was convicted under the Indiana Code and the ALJ applied the definition of "controlled substance" found in the Indiana Code. Petitioner points to no law that would require the state law definition of "controlled substance" to be in the particular Indiana code section under which she was convicted.

In any event, Petitioner did not argue in the ALJ proceeding that Fentanyl was not a controlled substance and, in fact, conceded there that Fentanyl is a controlled substance. *See* P. Br. at 2 (stating that "Fentanyl Citrate is classified as a Schedule II controlled substance") and *id*. at 7 ("Petitioner's conduct only amounts to unlawful possession [vs. dispensing] of a controlled substance.").[7] The regulations forbid the Board from considering an argument Petitioner did not make before the ALJ. 42 C.F.R. § 1005.21(e) ("DAB will not consider . . . any issue in the briefs that could have been raised before the ALJ but was not").

C. The ALJ did not err in affirming the I.G.'s determination to impose a three-year exclusion, the minimum period required by the statute and regulations in this case, and Petitioner's due process argument provides no basis to reverse the ALJ Decision.

Petitioner argues that the ALJ erred by affirming the I.G.'s determination to "increase" the period of exclusion to three years because Petitioner contends that the I.G.'s April 22, 2016 amended notice "increasing" the length of the exclusion did not comply with time frames for issuing an amended notice, in 42 C.F.R. § 1001.2002(e).[8] NA at 10-16.

[7] On appeal, moreover, Petitioner does not actually argue that Fentanyl is not a controlled substance for the purpose of section 1128(b)(3), only that the definition in Indiana law does not apply.

[8] Section 1001.2002(e) permits the I.G. to "amend its notice letter" to impose a different period of exclusion "[n]o later than 15 days prior to the final exhibit exchanges" in the appeal.

Although the ALJ and the I.G. referred to an "increase" in the period of exclusion, ALJ Decision at 8-9; I.G. Ex. 2, in fact the I.G. simply amended its initial notice in order to impose the minimum three-year period of exclusion required by law in this case. The Act and regulations set the period for a permissive exclusion under section 1128(b)(3) at a minimum of three years absent mitigating factors, which do ***not*** include the mitigating factor the I.G. cited in the initial notice, that Petitioner was "convicted of three or fewer offenses and the entire amount of financial loss to a Government program or to other individuals or entities was less than $1,500." I.G. Ex. 1, at 1; Act § 1128(c)(3)(D); 42 C.F.R. § 1001.401(c). That mitigating factor applies ***only*** to mandatory exclusions under section 1128(a) of the Act. 42 C.F.R. § 1001.102(c)(1); Act § 1128(c)(3)(B). Because three years was the legally minimum exclusion period, the ALJ's discussion of the timing of the I.G.'s amended notice is irrelevant. The ALJ did not have authority to refuse to follow the requirements for exclusions under section 1128(b)(3) and was thus bound to affirm Petitioner's exclusion for three years.

Petitioner cites an ALJ decision that Petitioner says affirmed a two-year permissive exclusion the I.G. imposed through the mistaken application of a mitigating factor. NA at 11-13, citing *Srinath Thoompally*, DAB CR3226 (2014). That decision is immaterial in light of our conclusion that a three-year exclusion was required here as a matter of law. Moreover, ALJ decisions have no precedential weight and are not binding on the Board or other ALJs. *Zahid Imran, M.D.*, DAB No. 2680, at 12 (2016), *citing Green Oaks Health & Rehab. Ctr.*, DAB No. 2567, at 9 (2014); and *Lopatcong Ctr.*, DAB No. 2443, at 12 (2012).[9]

Petitioner accuses the ALJ of violating her due process rights, arguing that "the ALJ's actions demonstrate that he abandoned his role as a neutral decision maker" and that "the ALJ placed his figurative thumb on the scales of justice to favor the IG; the government." NA at 17. This accusation is premised, however, on Petitioner's position that the ALJ erred as a matter of law in granting summary judgment and affirming the exclusion. As we have concluded, the ALJ committed no error in granting summary judgment for CMS; accordingly, we find no basis for Petitioner's due process argument.

[9] We also note that before the ALJ Petitioner did not take issue with the I.G.'s issuance of the amended notice, which occurred before Petitioner filed her initial brief on June 1, 2016.

Conclusion

We affirm the ALJ Decision affirming the exclusion for a period of three years.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member