Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Melissa Michelle Phalora,
(O.I. File No. H-15-42596-9),

Petitioner,

v.

The Inspector General.

Docket No. C-16-360

Decision No. CR4716

Date: September 30, 2016

DECISION

The Inspector General (IG) of the United States Department of Health and Human Services notified Melissa Michelle Phalora (Petitioner) that she was being excluded from participation in Medicare, Medicaid, and all other federal health care programs for two years under 42 U.S.C. § 1320a-7(b)(3). Petitioner requested a hearing before an administrative law judge (ALJ) to dispute the exclusion. Subsequently, the IG disclosed that he erroneously set the exclusion length for two years when it should have been for three years. For the reasons stated below, I affirm the IG's determination to exclude Petitioner and increase the length of exclusion to three years.

I. Background

By letter dated January 29, 2016, the IG notified Petitioner that she was being excluded from Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. § 1320a-7(b)(3) for the period of two years because Petitioner was allegedly convicted in an Indiana Superior Court (Superior Court) of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. IG Exhibit (Ex.) 1. On March 1, 2016, Petitioner

requested a hearing. The case was assigned to me for a hearing and decision. On March 16, 2016, I convened a prehearing conference by telephone, the substance of which is summarized in my Order and Schedule for Filing Briefs and Documentary Evidence (Order), dated March 16, 2016.

On April 22, 2016, the IG issued a notice stating that he was increasing the length of Petitioner's exclusion to three years because the IG applied the incorrect regulation when he issued the exclusion notice. IG Ex. 2.

On April 27, 2016, the IG submitted a brief (IG Br.) together with nine exhibits (IG Exs. 1-9). The IG indicated that he did not want to offer any testimony at a hearing. IG Br. at 6. In response to the IG's brief, Petitioner submitted a brief (P. Br.) and a witness list in which Petitioner indicated that she wanted to testify as a witness at a hearing. Petitioner also objected to IG Ex. 5. P. Br. at 4. The IG submitted a reply brief in which he requested that I issue a decision based on the written record without a hearing.

In response to Petitioner's request to testify, I afforded her the opportunity to submit her testimony in written form, and the IG an opportunity to object to the testimony, request to cross-examine Petitioner, and/or move for summary judgment. *See* 42 C.F.R. § 1005.16(b). Petitioner timely submitted her written direct testimony (P. Written Testimony). In response, the IG moved for summary judgment or, in the alternative, to cross-examine Petitioner (IG Mot.). Petitioner filed a response to the motion for summary judgment (P. Response).

II. Issues

1. Whether summary judgment is appropriate;

2. Whether the IG has a basis to exclude Petitioner under 42 U.S.C. § 1320a-7(b)(3).[1] 42 C.F.R. § 1001.2007(a)(1)(i).

3. Whether the length of exclusion is unreasonable. 42 C.F.R. § 1001.2007(a)(1)(ii).

III. Jurisdiction

I have jurisdiction to adjudicate this case. 42 U.S.C. § 1320a-7(f)(1); 42 C.F.R. §§ 1001.2007, 1005.2.

[1] Unlike mandatory exclusions under 42 U.S.C. § 1320a-7(a), the IG imposes exclusions under 42 U.S.C. § 1320a-7(b) at his discretion. I have no authority to review that exercise of discretion. 42 C.F.R. § 1005.4(c)(5).

IV. Findings of Fact, Conclusions of Law, and Analysis

The IG excluded Petitioner based on 42 U.S.C. § 1320a-7(b)(3), which permits the IG to exclude "[a]ny 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." Further, the regulations implementing this statute state that this exclusion provision applies to health care practitioners and to anyone who is, or has ever been, employed in any capacity in the health care industry. 42 C.F.R. § 1001.401(a)(1).

Therefore, the four essential elements necessary to support the IG's exclusion are: (1) the individual to be excluded must have been convicted of a criminal offense; (2) the criminal offense must have been a misdemeanor; (3) the conviction must have been for conduct relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance; and (4) the individual to be excluded is a health care practitioner, or is or was employed in the health care industry. 42 C.F.R. § 1001.401(a).

A. Summary judgment is appropriate.

The IG moved for summary judgment asserting that there is no issue of material fact that is in dispute. The IG asserts that although Petitioner disputes that her conviction is related to dispensing of a controlled substance, the IG does not believe Petitioner's dispute is factual in nature. IG Mot. at 4-5. In response, Petitioner asserts that Petitioner's criminal conviction is not for an offense that specifically relates to the unlawful dispensing of a controlled substance and that the IG has otherwise failed to factually prove that Petitioner's conviction relates to the unlawful dispensing of a controlled substance. P. Response at 3-4.

At the request of a party, an ALJ may decide an exclusion case by summary judgment "where there is no disputed issue of material fact." 42 C.F.R. § 1005.4(b)(12). "Matters presented to the ALJ for summary judgment will follow Rule 56 of the Federal Rules of Civil Procedure and federal case law . . . ." Civil Remedies Division Procedures § 19(a). As stated by the United States Supreme Court:

> Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment 'shall be rendered forthwith 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 a judgment as a matter of law.' By its very terms, this standard provides 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."

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original). To determine whether there are genuine issues of material fact for an in-person hearing, the ALJ must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. *See Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300 at 3 (2010) (citations omitted). However, in order to defeat a well-pleaded motion for summary judgment, the non-moving party must come forward with some evidence of a dispute concerning a material fact; mere denials in its pleadings are not sufficient. *Id*.

Based on my review of the record, the parties do not dispute the following facts. Petitioner is a registered nurse in Indiana. IG Ex. 3; P. Written Testimony at 1. On November 5, 2014, an Information was filed in the Superior Court charging Petitioner with one count of theft of Fentanyl Citrate from St. Mary Medical Center in violation of Indiana Code § 35-43-4-2(a) (Count I) and one count of Possession of a Narcotic Drug (i.e., Fentanyl Citrate) in violation of Indiana Code § 35-48-4-6(a) (Count II). IG Ex. 4; P. Written Testimony at 11. Through a Stipulated Plea and Agreement, Petitioner agreed to plead guilty to Count I of the Information. IG Ex. 7; P. Response at 2. Further, the plea agreement specified that: the judgment of conviction would be entered as a Class A Misdemeanor; Count II of the Information would be dismissed; and Petitioner would enroll in and complete a drug counseling program. IG Ex. 7 at 2; Request for Hearing Supporting Documents, Exhibit B at 2. As part of the plea agreement, Petitioner stipulated 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. IG Ex. 6; Request for Hearing Supporting Documents, Exhibit B at 4; P. Response at 2. On June 16, 2015, the Superior Court accepted Petitioner's guilty plea; entered a judgment of conviction to a Class A misdemeanor; 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. IG Ex. 9; *see also* P. Witness Testimony at 11; Hearing Request at 2.

For purposes of summary judgment, I accept as true that Petitioner:

> never stole drugs that were meant for a patient or use in a procedure. The drugs that [Petitioner] pled guilty of stealing were the waste of the drug. The waste is 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.

> The waste has no medical use and was routinely discarded by the hospital and its personnel.

P. Written Testimony at 12.

I conclude that there are no genuine issues of material fact in dispute in this case. This case presents a narrow issue: whether Petitioner was convicted of a misdemeanor that permits the IG to exclude Petitioner under 42 U.S.C. § 1320a-7(b)(3). As discussed below, based on the undisputed facts in this case, I conclude that the IG was authorized to exclude Petitioner. Accordingly, I grant the IG's motion for summary judgment.

B. Petitioner was convicted of a criminal offense.

For exclusion purposes, the term "convicted" is defined as including those circumstances: "when a judgment of conviction has been entered against the individual . . . by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged" or "when a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court." 42 U.S.C. § 1320a-7(i)(1), (3); *see also* 42 C.F.R. § 1001.2. There is no dispute that Petitioner pled guilty to violating Indiana Code § 35-43-4-2(a) and that the Superior Court entered a judgment of conviction based on Petitioner's guilty plea. IG Exs. 6, 7, 9; Request for Hearing Supporting Documents, Exhibit B; P. Written Testimony at 11; P. Response at 2. Therefore, I conclude that Petitioner was convicted of a criminal offense for purposes of 42 U.S.C. § 1320a-7(b)(3).

C. Petitioner was convicted of a misdemeanor.

Petitioner was originally charged with committing a Class D Felony for violating Indiana Code § 35-43-4-2(a). IG Ex. 4; P. Written Testimony at 11. Petitioner's plea agreement specified that she would plead guilty to that charge, but that the court would enter a judgment of conviction to a Class A misdemeanor. IG Ex. 7 at 2; Request for Hearing Supporting Documents, Exhibit B at 2; P. Written Testimony at 11. The Superior Court entered its judgment of conviction as a Class A misdemeanor violation of Indiana Code § 35-43-4-2(a). IG Ex. 9; Request for Hearing at 2. Therefore, I conclude that Petitioner was convicted of a misdemeanor offense.

D. Petitioner's criminal offense is related to the unlawful dispensing of a controlled substance.

Petitioner was charged with one count of theft of vials of Fentanyl Citrate from St. Mary Medical Center in violation of Indiana Code § 35-43-4-2(a) (Count I) and one count of Possession of a Narcotic Drug (i.e., Fentanyl Citrate) in violation of Indiana Code § 35-48-4-6(a) (Count II). IG Ex. 4; P. Written Testimony at 11. Petitioner pled guilty to the

theft offense (Count I), admitting that she "took vials of medication, Fentanyl Citrate, that were the property of St. Mary Medical Center." IG Ex. 6; Request for Hearing Supporting Documents, Ex. B at 4. Indiana Code § 35-48-2-6(c) classifies Fentanyl as a Schedule II controlled substance.

In the present case, Petitioner testified that her duties as a nurse involved obtaining medications needed for various procedures taking place at St. Mary Medical Center and then accounting for those medications in hospital records. P. Written Testimony at 2. She stated that when Fentanyl was needed, she "usually pulled a 5ml vial . . . because the 2ml vial was an ampoule, which required you to break the top of the glass vial. I unfortunately had cut myself using ampoules and was afraid to use them afterwards." P. Written Testimony at 5. Petitioner testified that "[i]f a case was cancelled after the medication was pulled, the nurse would need to . . . waste the entire medication, and mark that it was cancelled." P. Written Testimony at 4. However, Petitioner indicated that it was difficult to record in the Medical Center's computer system when she needed to "waste" medicine. P. Written Testimony at 5. When working, Petitioner "wore a lead apron to hold my supplies and any medication I would be administering." P. Written Testimony at 7.

On March 5, 2014, management personnel at St. Mary Medical Center met with Petitioner because earlier that day she pulled Fentanyl for a patient who did not have a procedure scheduled for that day; however, Petitioner speculated "there was likely a procedure that was cancelled or rescheduled after I withdrew the medication." P. Written Testimony at 7-8. The management personnel also were concerned that Petitioner had pulled Fentanyl on March 4, 2014, but Petitioner indicated that the limitations on reporting the final disposition of wasted drugs in the Medical Center's computer records was to blame. P. Written Testimony at 8. The management personnel located and searched the lead apron Petitioner had been wearing earlier. P. Written Testimony at 9-10. "The Fentanyl vials in the lead apron had varying degrees of medication in them, but were not full. This means that the vials were already used in a procedure and contained the remainder/waste of the drug, but those vials were not wasted yet." P. Written Testimony at 11. 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. P. Written Testimony at 11.

Petitioner argues that the IG failed to prove that Petitioner's crime related to the unlawful dispensing of a controlled substance. Specifically, Petitioner urges me not to consider the probable cause affidavit signed by a state police officer (IG Ex. 5) who investigated Petitioner because it is based on double hearsay and provides allegations of criminal conduct for which Petitioner was never charged and not found guilty. P. Br. at 16-18. Petitioner also argues that while the term "dispense" is not defined in the Social Security Act, it is defined in the Controlled Substances Act, and that I should apply that definition in this case. Petitioner avers that 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. Br. at 11.

Although Petitioner urges me to apply the definition for the word "dispense" from a statute not applicable to this case, Petitioner provides me with no compelling reason to do so. Had Congress wanted the definition of "dispense" in the Controlled Substances Act to apply to section 1320a-7, it would have so indicated. The ordinary meaning of the word "dispense" is "to prepare and distribute (medication)." Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/dispense (last visited Sept. 27, 2016). This is the definition I will use in this case.

Because I decide this case on summary judgment, I do not base my decision on the statements in the probable cause affidavit (IG Ex. 5) due to Petitioner's objections to that document. However, even without that document, 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. In reaching this conclusion, it is 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. *Friedman v. Sebelius*, 686 F.3d 813, 820 (D.C. Cir. 2012) (describing the phrase "relating to" as "deliberately expansive words," "the ordinary meaning of [which] is a broad one," and one that is not subject to "crabbed and formalistic interpretation") (internal quotes omitted); *Quayum v. U.S. Dep't of Health and Human Servs.*, 34 F. Supp. 2d 141, 143 (E.D.N.Y. 1998).

It is true that Petitioner was convicted of theft under a general criminal law prohibiting theft. However, Count I of the information specifically alleged, and Petitioner later admitted, that the theft was for Fentanyl Citrate. IG Exs. 4, 6. Petitioner admits that she stole Fentanyl that was the excess of the drug not administered to patients. P. Written Testimony at 11-12. Significantly, in her plea agreement, Petitioner agreed to enroll in and complete a drug counseling program. IG Ex. 7 at 2. Further, the Superior Court ordered Petitioner to enroll in and complete such a program within six months. IG Ex. 9.

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.

To the extent that Petitioner, through her testimony, summarized in part above, attempts to claim that she was not responsible for the theft of the Fentanyl Citrate, I cannot

consider such a claim because it is an impermissible collateral attack on her conviction. 42 C.F.R. § 1001.2007(d).

E. Petitioner is subject to exclusion under 42 U.S.C. § 1320a-7(b)(3) because, as a registered nurse, she is a health care practitioner and/or a person who is or was employed in the health care industry.

The regulations implementing 42 U.S.C. § 1320a-7(b)(3) state that an exclusion under that section applies to "a health care practitioner" or anyone who "[i]s, or has been, employed in any capacity in the health care industry." 42 C.F.R. § 1001.401(a)(1), (3).

It is undisputed that Petitioner is licensed as a registered nurse, that she was employed for approximately ten years as a Cardiac Catheterization Laboratory and Electrophysiology Laboratory Nurse at St. Mary Medical Center in Hobart, Indiana, and that she was on duty at St. Mary Medical Center when she took the Fentanyl Citrate. IG Exs. 3, 6; Request for Hearing Supporting Document, Ex. B at 4; P. Written Testimony at 1. Therefore, Petitioner is subject to exclusion under 42 U.S.C. § 1320a-7(b)(3) because she is a health care practitioner and was employed in the health care industry.

F. Petitioner must be excluded for three years.

I conclude that Petitioner's conviction meets the four elements for a permissive exclusion under 42 U.S.C. § 1320a-7(b)(3). 42 C.F.R. § 1001.401(a). Therefore, the IG was authorized to impose a permissive exclusion.

In the exclusion notice, the IG imposed a two-year length of exclusion because Petitioner was convicted of three or fewer misdemeanors. IG Ex. 1 at 1. On April 20, 2016, the day that the IG's prehearing exchange was to be filed (Order § 5; 42 C.F.R. § 1005.8), the IG requested a week-long extension to amend his notice of exclusion to increase the length of Petitioner's exclusion to three years because he had incorrectly applied a mitigating factor to Petitioner's case that is only applicable to mandatory exclusions. On April 21, 2016, I granted the extension of time, but questioned the IG's authority to amend the length of exclusion less than 15 days before the IG's exchange was due. On April 22, 2016, the IG issued a notice amending the length of Petitioner's exclusion to three years. IG Ex. 2. On April 27, 2016, the IG filed his prehearing exchange; however, the IG did not address my concerns related to unilaterally raising the length of exclusion less than 15 days before the IG's prehearing exchange was due.

The length of exclusion for a permissive exclusion under section 1320a-7(b)(3) "shall be 3 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" 42 U.S.C. § 1320a-7(c)(3)(D). When the IG reduced Petitioner's length of exclusion to two years, he did so based on a

mitigating factor that is only applicable to mandatory exclusions under section 1320a-7(a). *See* 42 C.F.R. §§ 1001.102(c)(1); *see also* 42 C.F.R. § 1001.401(c)(3).

I agree with the IG that he erroneously believed that Petitioner's single misdemeanor conviction was a basis to mitigate Petitioner's exclusion. However, no later than 15 days prior to the prehearing exchange may the IG amend the exclusion notice to change the period of exclusion. 42 C.F.R. § 1001.2002(e). After that time, the IG may request that the ALJ increase or decrease the length of exclusion. *See* 42 C.F.R. §§ 1005.15(f)(1), 1005.20(b).

I accept the IG's notice amending the length of exclusion to three years along with his explanation for that change as a request that I increase the length of exclusion. *See* IG Ex. 2. Because I conclude that a basis exists to exclude Petitioner pursuant to section 1320a-7(b)(3) and that the record does not support a finding of any mitigating or aggravating factors listed in 42 C.F.R. § 1001.401(c), Petitioner must be excluded for a minimum period of three years. 42 U.S.C. § 1320a-7(c)(3)(D). Therefore, the IG's two-year period of exclusion was unreasonable, but a three-year length of exclusion is reasonable as a matter of law.

V. Conclusion

I affirm the IG's determination to exclude Petitioner from participating in Medicare, Medicaid, and all other federal health care programs under 42 U.S.C. §§ 1320a-7(b)(3). However, I increase the length of exclusion from two to three years.

/s/
Scott Anderson
Administrative Law Judge