**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Linda Schmidt,
(O.I. File No.: 4-08-40761-9),

Petitioner,

v.

Inspector General,
U.S. Department of Health and Human Services,
Respondent.

Docket No. C-14-1991

Decision No. CR3746

Date: March 31, 2015

# DECISION

Petitioner, Linda Schmidt, is excluded from participating in Medicare, Medicaid, and all federal health care programs pursuant to section 1128(a)(1) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(a)(1)), effective August 20, 2014. There is a proper basis for Petitioner's exclusion based upon her conviction of a criminal offense related to the delivery of an item or service under Medicare or a state health care program. Petitioner's exclusion for the minimum period of five years is mandatory pursuant to section 1128(c)(3)(B) of the Act (42 U.S.C. § 1320a-7(c)(3)(B)).[1]

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[1] Pursuant to 42 C.F.R. § 1001.3001, Petitioner may apply for reinstatement only after the period of exclusion expires. Reinstatement is not automatic upon completion of the period of exclusion.

## I. Background

The Inspector General for the Department of Health and Human Services (I.G.) notified Petitioner by letter dated July 31, 2014, that she was being excluded from participation in Medicare, Medicaid, and all federal health care programs for a period of five years. The I.G. cited section 1128(a)(1) of the Act as the basis for Petitioner's exclusion, and stated that the exclusion was based upon her conviction in the United States District Court, Western District of Kentucky, Louisville Division, of a criminal offense related to the delivery of an item or service under Medicare or a state health care program, including the performance of management or administrative services relating to the delivery of items or services, under any such program. I.G. Exhibit (Ex.) 1.

Petitioner timely filed a request for hearing (RFH) on September 26, 2014. The case was assigned to me for hearing and decision on October 15, 2014. A telephone prehearing conference was convened on October 28, 2014, the substance of which is memorialized in my Prehearing Conference Order and Schedule for Filing Briefs and Documentary Evidence (Prehearing Order) issued on October 29, 2014.

The I.G. filed a motion for summary judgment and a brief in support of its motion (I.G. Br.) on December 12, 2014, with I.G. Exs. 1 through 5. Petitioner filed her opposition to the I.G. motion for summary judgment on January 26, 2015 (P. Br.), with Petitioner's exhibits (P. Exs.) 1 through 7. The I.G. filed a reply brief on February 10, 2015 (I.G. Reply), with I.G. Ex. 6. No objections have been filed to my consideration of I.G. Exs. 1 through 6 and P. Exs. 1 through 7 and they are admitted as evidence.

## II. Discussion

### A. Applicable Law

Section 1128(f) of the Act (42 U.S.C. § 1320a-7(f)) establishes Petitioner's right to a hearing by an administrative law judge (ALJ) and judicial review of the final action of the Secretary of Health and Human Services (the Secretary).

Pursuant to section 1128(a)(1) of the Act, the Secretary must exclude from participation in any federal health care program any individual convicted under federal or state law of a criminal offense related to the delivery of an item or service under Medicare or a state

health care program. The Secretary has promulgated regulations implementing this provision of the Act. 42 C.F.R. § 1001.101(a).[2]

Section 1128(c)(3)(B) of the Act provides that an exclusion imposed under section 1128(a) of the Act will be for a period of not less than five years. Pursuant to 42 C.F.R. § 1001.102(b), the period of exclusion may be extended based on the presence of specified aggravating factors. Only if the aggravating factors justify an exclusion of longer than five years are mitigating factors considered as a basis for reducing the period of exclusion to no less than five years. 42 C.F.R. § 1001.102(c).

The standard of proof is a preponderance of the evidence, and there may be no collateral attack of the conviction that is the basis for the exclusion. 42 C.F.R. § 1001.2007(c), (d). Petitioner bears the burden of proof and the burden of persuasion on any affirmative defenses or mitigating factors, and the I.G. bears the burden on all other issues. 42 C.F.R. § 1005.15(b).

**B. Issues**

The Secretary has by regulation limited my scope of review to two issues:

Whether there is a basis for the imposition of the exclusion; and

Whether the length of the exclusion is unreasonable.

42 C.F.R. § 1001.2007(a)(1). If the I.G. imposes the minimum authorized five-year period for exclusion under section 1128(a) of the Act, there is no issue as to whether or not the period of exclusion is unreasonable. 42 C.F.R. § 1001.2007(a)(2).

**C. Findings of Fact, Conclusions of Law, and Analysis**

My conclusions of law are set forth in bold followed by the pertinent findings of fact and analysis.

**1. Petitioner's request for hearing was timely and I have jurisdiction.**

**2. Summary judgment is appropriate in this case.**

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[2] References are to the revision of the Code of Federal Regulations (C.F.R.) in effect at the time of the I.G. action, unless otherwise indicated.

There is no dispute that Petitioner timely requested a hearing and that I have jurisdiction pursuant to section 1128(f) of the Act and 42 C.F.R. pt. 1005.

Pursuant to section 1128(f) of the Act, a person subject to exclusion has a right to reasonable notice and an opportunity for a hearing. The Secretary has provided by regulation that a sanctioned party has the right to hearing before an ALJ, and both the sanctioned party and the I.G. have a right to participate in the hearing. 42 C.F.R. §§ 1005.2-.3. Either or both parties may choose to waive appearance at an oral hearing and to submit only documentary evidence and written argument for my consideration. 42 C.F.R. § 1005.6(b)(5). An ALJ may also resolve a case, in whole or in part, by summary judgment. 42 C.F.R. § 1005.4(b)(12).

Summary judgment is appropriate in an exclusion case when there are no disputed issues of material fact and when the undisputed facts, clear and not subject to conflicting interpretation, demonstrate that one party is entitled to judgment as a matter of law. *Tanya A. Chuoke, R.N.*, DAB No. 1721 (2000); *David A. Barrett*, DAB No. 1461 (1994); *Robert C. Greenwood*, DAB No. 1423 (1993); *Thelma Walley*, DAB No. 1367 (1992); *Catherine L. Dodd, R.N.*, DAB No. 1345 (1992); *John W. Foderick, M.D.*, DAB No. 1125 (1990). When the undisputed material facts of a case support summary judgment, there is no need for a full evidentiary hearing, and neither party has the right to one. *Surabhan Ratanasen, M.D.*, DAB No. 1138 (1990); *John W. Foderick, M.D.*, DAB No. 1125 (1990). In opposing a properly-supported motion for summary judgment, the nonmoving party must show that there are material facts that remain in dispute, and that those facts either affect the proponent's prima facie case or might establish a defense. *Garden City Medical Clinic*, DAB No. 1763 (2001)*; Everett Rehab. and Med. Ctr.*, DAB No. 1628 (1997). It is insufficient for the nonmovant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. *See Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247 (1986).

There are no genuine issues of material fact in dispute in this case. Petitioner argues that there are material facts in dispute as to whether her conviction was related to the delivery of an item or service under Medicare or a state health care program. RFH; P. Br. at 1, 8-14. As discussed in more detail in the section of this decision titled "Analysis," I conclude that there is no genuine dispute as to the facts that support the legal conclusion that Petitioner was convicted of a criminal offense related to the delivery of an item or service under Medicare or a state health care program. Furthermore, the period of exclusion imposed is the minimum permitted by Congress for a mandatory exclusion and whether or not the five-year minimum period is unreasonable is not an issue before me. 42 C.F.R. § 1001.2007(a)(2). Petitioner's challenge to her exclusion must be resolved against her as a matter of law. Accordingly, summary judgment is appropriate.

### 3. Petitioner's exclusion is required by section 1128(a)(1) of the Act.

#### a. Facts

The following facts are drawn from the documents which were admitted without objection. The following facts are undisputed and considered true. Prehearing Order ¶ 9.

On August 9, 2011, an Information was filed in the United States District Court, Western District of Kentucky, charging Petitioner and another person with the misdemeanor offense of causing misbranded inhalation drugs to be introduced and delivered for introduction into interstate commerce during the period of on or about July 2006 continuing until at least October 2008, in violation of 18 U.S.C. § 2, and 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a). The Information alleged that Petitioner and another person "introduced compounded inhalation drugs into interstate commerce that bore false and misleading labeling representing them to be of greater strength and potency than they actually had." P. Ex. 4 at 7; I.G. Ex. 2 at 1; I.G. Ex. 3 at 1. Petitioner signed a plea agreement and entered a guilty plea to the single count alleged by the Information on October 19, 2011. P. Ex. 4 at 1; I.G. Exs. 3; 4 at 1. The plea agreement stated that Petitioner's guilty plea was voluntary; she agreed to plead guilty because she was in fact guilty; and she agreed to the following statement of the factual basis for her guilty plea:

> [Petitioner] was employed as a pharmacist at National Respiratory Services. It was her responsibility to prepare medication for patients and ensure that the appropriate medications were sent out to patients. In the course of her employment, [Petitioner] caused compounded medications to be sent out to patients which were adulterated (i.e. sub-potent and non-sterile) and misbranded. This medication was then billed to Medicare as if non-compounded FDA approved (commercially manufactured) medication was being provided.

I.G. Ex. 3 at 1, 2. The plea agreement also states that Petitioner understood that the government would inform the court "that it should set restitution in the amount of $193,931.10 jointly and severally with the co-defendants payable to the Centers for Medicare and Medicaid Services [CMS]." I.G. Ex. 3 at 3.

The district court accepted Petitioner's guilty plea and entered judgment against her on May 10, 2013. The district court sentenced Petitioner to one year of probation, a $25 assessment, and a $1,000 fine but no restitution. I.G. Ex. 4; P. Ex. 4 at 1-6. On July 15, 2013, the district court amended the judgment by adding an order for Petitioner to pay $20,000 in restitution to CMS. I.G. Ex. 5 at 5.

The I.G. notified Petitioner by letter dated May 29, 2013, that based on her conviction, the I.G. was required to exclude her for at least five years pursuant to section 1128(a) of the Act. P. Ex. 1. I note that this I.G. notice is dated nineteen days after the judgment was initially entered against Petitioner by the district court.

The I.G. sent Petitioner another letter dated July 3, 2013. The second letter stated it superseded the May 29, 2013 notice. The July 3, 2013 letter notified Petitioner that the I.G. was considering excluding her pursuant to section 1128(b)(1) of the Act, and gave her the opportunity to submit materials to the I.G. to consider prior to the determination whether or not to exclude. P. Ex. 2. This letter is dated before the July 15, 2013 order which amended the judgment to impose restitution.

The I.G. sent Petitioner a third letter dated August 5, 2013, advising Petitioner that, based on information submitted by her attorney, no exclusion would be implemented at that time. P. Ex. 3.

The I.G. sent Petitioner a letter dated May 14, 2014. The letter advised Petitioner that it superseded the May 29, 2013, July 3, 2013, and August 5, 2013 letters. The letter advised that as a result of the amended judgment and conviction in the U.S. District Court, Western District of Kentucky, the I.G. was required to exclude Petitioner pursuant to section 1128(a) of the Act. The letter further advised Petitioner that she had 30 days to submit information for the I.G. to consider before the I.G. made the final determination. I.G. Ex. 6.

The I.G. notified Petitioner by letter dated July 31, 2014, that she was being excluded for five years pursuant to section 1128(a)(1) of the Act. The letter advised Petitioner that the exclusion was based upon her conviction in the U.S. District Court, Western District of Kentucky. I.G. Ex. 1. Petitioner seeks my review based on this letter notifying Petitioner of her exclusion.

**b. Analysis**

The I.G. cites section 1128(a)(1) of the Act as the basis for Petitioner's mandatory exclusion. The statute provides:

> (a) MANDATORY EXCLUSION. – The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):
>
> (1) Conviction of program-related crimes. – Any individual or entity that has been convicted of a criminal

> offense related to the delivery of an item or service under
> title XVIII or under any State health care program.

The statute requires that the Secretary exclude from participation any individual or entity: (1) convicted of a criminal offense (whether felony or misdemeanor); (2) where the offense is related to the delivery of an item or service; and (3) the delivery of the item or service was under Medicare or a state health care program.

Petitioner does not deny that she was convicted of a criminal offense within the meaning of section 1128(i) of the Act (42 U.S.C. 1320a-7(i)). RFH; P. Br. at 5, 8. An individual or entity is considered to have been "convicted" of an offense if, among other things, "a judgment of conviction has been entered . . . by a Federal, State, or local court," "there has been a finding of guilt against the individual or entity by a Federal, State, or local court," or "a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court." Act § 1128(i)(1), (2), (3) (42 U.S.C. § 1320a-7(i)(1), (2), (3)). Petitioner's guilty plea was accepted by the district court, and she was found guilty pursuant to her plea. The district court issued a judgment of conviction and sentenced Petitioner for the offense of which she was convicted. I conclude that Petitioner was convicted of a criminal offense within the meaning of the Act.

Petitioner disputes that her conviction for introducing misbranded inhalation drugs into interstate commerce was related to the delivery of an item or service under Medicare or a state health care program. I have considered Petitioner's arguments and find they are without merit. I conclude that the undisputed facts establish the requisite connection or nexus between Petitioner's criminal offense and the delivery of a health care item or service under Medicare or a state health care program.

Petitioner argues that the I.G. has presented no facts to establish a nexus or connection between her conviction and Medicare or a state health care program. Petitioner argues that the offense to which she pled guilty does not on its face refer to Medicare or other covered programs. P. Br. at 8. Petitioner argues further that the district court's judgment nowhere states that Medicare or Medicaid was ever billed for the inhalation drugs. P. Br. at 9. The charge of which Petitioner was convicted does not refer to Medicare or Medicaid or contain an element related to the delivery of an item or service under such programs. However, the Departmental Appeals Board (the Board) has long held that the statutory terms of an offense do not control whether that offense is "related to" the delivery of a health care item or service under Medicare or a state health care program for purposes of an exclusion pursuant to section 1128(a)(1) of the Act. *Dewayne Franzen*, DAB No. 1165 (1990) (inquiry is whether conviction is related to Medicaid fraud, not whether the petitioner was convicted of Medicaid fraud). Rather, an ALJ must examine whether there is a "common sense connection or nexus between the offense and the delivery of an item or service under the program." *Scott D. Augustine*, DAB No. 2043 at

5-6 (2006) (citations omitted); *Berton Siegel, D.O.*, DAB No. 1467 (1994). To determine whether there is a nexus or common-sense connection between the offense and the delivery of an item or service under Medicare or Medicaid, "evidence as to the nature of an offense may be considered," including "facts upon which the conviction was predicated." *Siegel*, DAB No. 1467 at 6-7. Therefore it is necessary for me to examine the circumstances surrounding Petitioner's conviction to determine whether it was program-related. *Siegel*, DAB No. 1467 at 6-7; *Franzen*, DAB No. 1165 at 6 (finding that an ALJ's "task is to examine all relevant conduct to determine if there is a relationship between the judgment of conviction and the Medicaid program.")

In this case, the nexus between the offense of which Petitioner was convicted and the Medicare program is obvious from the plea agreement she signed. The plea agreement specifically states:

> *The parties agree to the following factual basis for this plea*:
>
> [Petitioner] was employed as a pharmacist at National Respiratory Services [NRS]. It was her responsibility to prepare medication for patients and ensure that the appropriate medications were sent out to patients. In the course of her employment, [Petitioner] caused compounded medications to be sent out to patients which were adulterated (i.e. sub-potent and non-sterile) and misbranded. *This medication was then billed to Medicare* as if non-compounded FDA approved (commercially manufactured) medication was being provided.

I.G. Ex. 3 at 1-2 (emphasis added). Therefore, Petitioner admitted in her plea agreement that the misbranded drugs which she, a pharmacist, caused or permitted to be distributed to patients were billed to Medicare. Petitioner's confession in her plea agreement clearly shows a nexus between Petitioner's offense and the Medicare program. Petitioner cannot now disavow the admissions she made as part of her plea agreement before the district court. Petitioner's criminal conviction by the federal district court, evidenced by the judgment of conviction, was based upon Petitioner's guilty plea which was supported by the foregoing admission of her criminal conduct. The judgment of the district court and the bases for that judgment are not reviewable by me or subject to collateral attack by Petitioner in this forum. 42 C.F.R. § 1001.2007(d).

Further evidence of the nexus is the fact that Petitioner agreed in her plea agreement that the government would inform the court "that it should set restitution in the amount of $193,931.10 jointly and severally with the co-defendants payable to the Centers for Medicare and Medicaid Services." I.G. Ex. 3 at 3. The fact that the district court entered an amended judgment in which it ordered Petitioner to pay restitution in the amount of

$20,000 to CMS is further evidence of a nexus between Petitioner's criminal conduct and the Medicare program. Petitioner notes that the original court judgment did not order any restitution and argues that the restitution imposed in the amended judgment was a "compromise" to avoid further litigation costs, not based on the facts of the case and her conduct as a pharmacist. P. Br. at 5. But Petitioner's rationalization for why she agreed to make restitution is of no avail. In exclusion cases, restitution has long been considered a reasonable measure of program loss and evidence of the nexus between the offense and the program to which restitution is to be made. *Juan de Leon, Jr.,* DAB No. 2533 at 5 (2013); *Craig Richard Wilder*, DAB No. 2416 at 9 (2011); *Jason Hollady, M.D.*, DAB No. 1855 (2002). Furthermore, the amended judgment is not subject to collateral attack in this forum or review by me. 42 C.F.R. § 1001.2007(d).

Petitioner argues that the offense to which she pled guilty is a strict liability offense that does not require that an individual act knowingly or willfully. The gist of the argument is that there is no judicial finding from the criminal case that Petitioner ever intended to defraud or adversely affect Medicare or Medicaid. Petitioner argues that she had no knowledge of the fraud committed by NRS administrators and she did not participate in any scheme to defraud Medicare. She argues she had no duty to Medicare recipients related to the inhalant medication she compounded. She argues she made no misrepresentations. RFH; P. Br. at 9-13. I accept as true for purposes of summary judgment that Petitioner never intended to defraud Medicare or Medicaid and that she did not knowingly participate in any scheme to defraud, made no misrepresentations, and had no specific duty to Medicare recipients. However, these facts and Petitioner's arguments do not establish a genuine dispute as to any material fact or a defense. "Section 1128(a)(1) does not require that the individual must intend to commit a criminal offense, or indeed fraud, for an exclusion to be proper." *Franzen*, DAB No. 1165 at 8. Petitioner's intent is simply not material under section 1128(a)(1) of the Act. Section 1128(a)(1) of the Act also "does not require any knowledge on the part of a petitioner of the relationship between the offense and the program." *Lyle Kai*, *R.Ph.*, DAB No. 1979 at 7 (2005). In *Kai*, the Board found "irrelevant" whether the petitioner knew that Medicaid was being billed, his specific role in the scheme, and the degree of his responsibility. *Kai*, DAB No. 1979 at 7. All that is required for a criminal offense to be program-related is that there is some nexus between the offense of which one is convicted and the delivery of an item or service under Medicare or a state health care program. There is nothing in the statutory language of section 1128(a)(1) that imposes a requirement of "intent." *Franzen*, DAB No. 1165; *Kai*, DAB No. 1979. A nexus exists in this case between the offense of which Petitioner was convicted and Medicare as shown by the language of her plea agreement. Petitioner pled guilty to the offense of introducing misbranded inhalation drugs into interstate commerce and the drugs were billed to Medicare. I accept as true for purposes of summary judgment that Petitioner did not know at the time that some of the drugs were being billed to Medicare. However, her lack of knowledge of the billing at the time is no defense in this case.

Petitioner argues that the I.G.'s letters of May 29, 2013, July 3, 2013, and August 5, 2013, reflect that the I.G. initially imposed a mandatory exclusion under section 1128(a); but then determined exclusion should be permissive under section 1128(b)(1); and finally determined that no exclusion was appropriate. Petitioner asserts that the I.G.'s prior letters reflect that the I.G. determined in 2013 that there was no commonsense connection between Petitioner's conviction and the Medicare program, and nothing changed in 2014 that created that connection. P. Br. at 12. For purposes of summary judgment, I draw all inferences in favor of Petitioner. Therefore, based on the I.G. letters from 2013, I infer that the I.G. determined that exclusion was not appropriate under either sections 1128(a) or (b)(1) of the Act in August 2013. However, the evidence does not permit any more specific inference as to the motives or reasoning of the I.G. Drawing the inference in Petitioner's favor does not, however, impact the decision in this case. Regardless of the I.G.'s reasoning in 2013 when the I.G. determined not to exclude Petitioner, Congress has mandated through section 1128(a)(1) that on facts such as the undisputed facts of this case, Petitioner be excluded. The I.G. has no discretion under the Act not to exclude Petitioner once the elements of section 1128(a)(1) are satisfied, as they are by the undisputed facts in this case. The fact that the I.G. waited a year until July 31, 2014, to notify Petitioner of her exclusion also is not a basis for relief for Petitioner. The Act and the regulations do not dictate when the I.G. must impose an exclusion. *Kailash C. Singhvi, M.D.*, DAB No. 2138 at 4-5 (2007). The Board and I have no authority to review the timing of the I.G.'s imposition of an exclusion or to change the effective date of the exclusion. *Randall Dean Hopp*, DAB No. 2166 (2008); *Singhvi,* DAB No. 2138; 42 C.F.R. § 1001.2007(a)(1).

**4. The minimum period of exclusion under section 1128(a) is five years.**

**5. Petitioner's exclusion for five years is not unreasonable as a matter of law.**

I have concluded that there is a basis to exclude Petitioner pursuant to section 1128(a)(1) of the Act. Therefore, Petitioner must be excluded for a minimum period of five years pursuant to section 1128(c)(3)(B) of the Act. The I.G. has no discretion to impose a lesser period, and I may not reduce the period of exclusion below five years. Petitioner concedes that, if exclusion is mandated under section 1128(a), there is no review of the five-year period of exclusion. P. Br. at 2.

Petitioner states that she is the sole provider of her family. She asserts that she has 25 years of experience as a pharmacist and had no professional misconduct prior to her conviction. She states that the exclusion prohibits her from employment in the healthcare field, where her pharmacy experience and knowledge could benefit employers and patients in Kentucky. RFH at 5, 6. I appreciate that an exclusion will adversely impact Petitioner's ability to obtain employment and provide for her family. But the five-year

period of exclusion is the minimum period authorized by Congress and I have no authority to reduce the period of exclusion.

Exclusion is effective 20 days from the date of the I.G.'s written notice of exclusion to the affected individual or entity. 42 C.F.R. § 1001.2002(b).

## III. Conclusion

For the foregoing reasons, Petitioner is excluded from participation in Medicare, Medicaid, and all other federal health care programs for the minimum statutory period of five years, effective August 20, 2014.

/s/

Keith W. Sickendick
Administrative Law Judge