Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Kimbrell Colburn
Docket No. A-16-34
Decision No. 2683
March 24, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Kimbrell Colburn (Petitioner) appeals the December 3, 2015 decision by an Administrative Law Judge (ALJ) sustaining Petitioner's five-year exclusion from federal health programs pursuant to section 1128(a)(1) of the Social Security Act (Act), 42 U.S.C. § 1320a-7(a)(1). *See Kimbrell Colburn*, DAB CR4479 (2015) (ALJ Decision). The ALJ sustained the exclusion because he concluded that Petitioner meets the criteria for exclusion under section 1128(a)(1); that the statutory minimum duration of an exclusion imposed under section 1128(a)(1) is five years; and that Petitioner's case is appropriate for summary judgment. Because these conclusions are correct, we affirm the ALJ Decision.

Legal Background

Section 1128(a)(1) states that the Secretary of the Department of Health & Human Services "shall exclude" from participation in federal health care programs "[a]ny individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program." 42 U.S.C. § 1320a-7(a)(1). When an exclusion is validly imposed under section 1128(a)(1), section 1128(c)(3)(B) requires (with exceptions not relevant here) that the "minimum period of exclusion . . . be not less than five years[.]" *Id.* § 1320a-7(c)(3)(B). (Exclusions imposed under section 1128(a) of the Act are known as "mandatory" exclusions. *See* 42 U.S.C. § 1320a-7(a); 42 C.F.R. § 1001.101.)

A person may challenge her exclusion by requesting a hearing before an administrative law judge. 42 C.F.R. § 1001.2007(a). If the exclusion is mandatory and imposed for the statutory minimum five-year period, the only issue on which the excluded person may request a hearing is whether the "basis" for imposing the exclusion "exists." *Id.* § 1001.2007(a)(1)(i), (a)(2); *Nenice Marie Andrews*, DAB No. 2656, at 2 (2015).

Upon the motion of either party, an administrative law judge may "decide [a] case[ ], 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). A party dissatisfied with an administrative law judge's decision may appeal to the Board. *Id.* § 1005.21.

Case Background

In 2014, Petitioner was convicted in a federal court, based on a guilty plea, of violating section 1128B(a)(3)(B) of the Act, a provision of the federal anti-kickback statute. *See* Petitioner's Brief in Support of Appeal (P. Br.) at 3; Inspector General Exhibits (I.G. Exs.) 2, 4. Section 1128B(a)(3)(B) makes it a crime for any person "having knowledge of the occurrence of any event affecting . . . the initial or continued right to any such benefit or payment [under a Federal health care program] of any other individual in whose behalf he has applied for or is receiving such benefit or payment" to "conceal[ ] or fail[ ] to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized."[1] 42 U.S.C. § 1320a-7b(a)(3)(B).

On May 29, 2015, the Department of Health & Human Services' Office of Inspector General (I.G.) notified Petitioner that, based on her 2014 conviction, she was being excluded from participation in federal health care programs for five years pursuant to section 1128(a)(1). I.G. Ex. 1. Petitioner challenged the exclusion by requesting a hearing before the ALJ. In response to the hearing request, the I.G. filed a motion for summary judgment, supported by, among other material, Petitioner's written plea agreement and judgment of conviction. I.G. Exs. 2, 4. Section II of the plea agreement indicates that the following facts formed the "Factual Basis" for Petitioner's guilty plea:

- Petitioner was a physician's assistant to Dr. A, a surgeon. I.G. Ex. 2, at 3.
- Dr. A prescribed bone growth stimulators for patients, who included Medicare beneficiaries, to wear after spinal fusion surgery. *Id.*
- During the period relevant to Petitioner's case, Medicare covered bone growth stimulators as "durable medical equipment" (DME). *Id.*
- Company A was a Medicare-enrolled DME supplier that provided bone growth stimulators to Medicare beneficiaries. *Id.*

[1] The phrase "any such benefit or payment" in section 1128B(a)(3)(B) refers back to the phrase "benefit or payment under a Federal health care program (as defined in subsection (f))" in section 1128B(a)(1). Subsection (f) of section 1128B states in relevant part that the term "Federal health care program" means "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government." 42 U.S.C. § 1320a-7b(f).

- "In order to bill Medicare for services rendered, DME companies . . . submitted a claim form to CMS [the Centers for Medicare & Medicaid Services]," the federal agency that administers the Medicare program. *Id.* In addition, "[t]o obtain payment from Medicare for a bone growth stimulator, Company A was required to obtain, among other records, a Certificate of Medical Necessity." *Id.*
- "As Dr. A's physician's assistant, [Petitioner] was in a position to recommend and assure that Company A's bone growth stimulator would be used by Dr. A for patients, including Medicare beneficiaries, to wear after spinal fusion surgery." *Id.*
- Petitioner "assisted in filling out the Certificate of Medicare Necessity and submitting the Certificate of Medical Necessity and other records to Company A, for submission to CMS." *Id.* at 3-4.
- Petitioner "was paid, directly and indirectly, by Company A for each bone growth stimulator used by Dr. A for patients, including Medicare patients. The total amount of these remunerations, associated with Federal health care programs, including Medicare, was at least approximately $17,863.42." *Id.* at 4.
- "The Anti-Kickback Act [section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b)] prohibited, among other things, the solicitation and receipt of any remuneration in return for which payment would be made, in whole and in part, under the Medicare program or other Federal health care programs." *Id.*
- "From in or about October 2006, and continuing through in or about October 2011, . . . [Petitioner], *having knowledge of an event* that affected the initial or continued right of any other individual not herself, to receive any such benefit or payment from a federal health care program, that is, Medicare, *the event being the receipt of remunerations* in violation of 42 U.S.C. § 1320a-7b(b)(l)(B), as disallowed by law, *concealed and failed to disclose that event* with the intent to assist any other person in fraudulently securing Medicare payments when none would be authorized, by assisting in submitting claims for payments to Medicare in violation of 42 U.S.C. § 1320a-7b(b)(l)(B)." *Id.* (italics added).

In response to the I.G.'s summary judgment motion, Petitioner submitted (in addition to legal argument) her affidavit and a letter of reference from a current employer. Petitioner's affidavit states in relevant part:

> I began my career with [Dr. A]. During my employment, some of my responsibilities included applying bone growth stimulators for patients at the discretion of [Dr. A]. During the time frame of my employment, [Dr. A] advised me that we would be using [Company A's bone growth stimulators] for post spinal surgeries. . . . [Dr. A] would prescribe the bone stimulator and I would assist the representative [of Company A] in getting the necessary paperwork for pre-approval. I would then apply the stimulator to the patient and give instructions on use. . . . Patients did not

> receive a stimulator unless it was prescribed by [Dr. A] and was medically necessary. [Dr. A] also stated to me that this was a way for him to add an additional income to my salary because he could not give me the salary that he "wanted to pay me." . . . [The representative from Company A] always seemed very pleased with my performance. The last time we spoke, he said the payments for application of bone stimulators would have to stop. He would not give me a reason. I did not understand why and he would not explain. I told [Dr. A] the situation and he said he would not refer anymore patients to him. I no longer received any compensation from [Company A] and I did not receive any increase in my salary from [Dr. A].
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> [In an interview with federal agents, Dr. A] freely acknowledged to them that he would prescribe these stimulators and that he would tell me to administer these stimulators to patients post-surgery. He also acknowledged that I was not allowed to prescribe a stimulator, nor was I allowed to file an application for a stimulator unless it was prescribed by him. . . .

Petitioner's Exhibit (P. Ex.) 2.

Upon examining Petitioner's plea agreement and other proffered evidence, the ALJ determined that the record presented no genuine dispute of material fact and that the undisputed material facts establish that the statutory criteria for exclusion under section 1128(a)(1) – having been "convicted of a criminal offense related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program" – are satisfied in Petitioner's case. ALJ Decision at 3-7. Accordingly, the ALJ held that Petitioner's exclusion is "required" under section 1128(a)(1) and that the length of her exclusion is the statutory minimum period of five years under section 1128(c)(3)(B). *Id.* at 7, 9.

Petitioner then filed this appeal. Her chief contention on appeal is that the grant of summary judgment is improper because it is "based on incorrect and mischaracterized information involving [her] plea agreement and conviction." P. Br. at 8.

Discussion

"Whether summary judgment is appropriate is a legal issue the Board addresses de novo." *West Texas LTC Partners, Inc.*, DAB No. 2652, at 5 (2015). "Summary judgment is appropriate when the record shows there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law." *Id.* In deciding whether there is a genuine dispute of material fact, we view proffered evidence

in the light most favorable to the non-moving party. *Id.* The applicable "substantive law will identify which facts are material," and "[o]nly disputes over facts that might affect the outcome of the [case] under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see also Livingston Care Ctr.*, DAB No. 1871, at 5 (2003) (stating that "[t]o defeat an adequately supported summary judgment motion, the non-moving party . . . must furnish evidence of . . . a fact that, if proved, would affect the outcome of the case under governing law"), *aff'd*, *Livingston Care Ctr. v. U.S. Dept. of Health & Human Servs.*, 388 F.3d 168 (6th Cir. 2004).

Because the I.G. excluded Petitioner under section 1128(a)(1) for a statutory minimum period of five years, the only issue before us, as it was before the ALJ, is whether the I.G. had a "basis" for excluding Petitioner. 42 C.F.R. § 1001.2007(a)(1)(i), (a)(2). The I.G. has a basis for excluding a person under section 1128(a)(1) if the person was "convicted" of a criminal offense and the offense is "related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program." Petitioner does not deny that she was "convicted" of a criminal offense within the meaning of section 1128(a)(1), nor does she dispute the evidence that the offense implicates the Medicare program. Thus, our discussion focuses on whether Petitioner's offense is related to the delivery of an item or service under Medicare. We address that issue, as the ALJ did, by considering whether there is a "common sense connection or nexus between [Petitioner's] offense and the delivery of an item or service under the [Medicare] program." *James O. Boothe*, DAB No. 2530, at 3 (2013); *see also Lyle Kai, R. Ph.*, DAB No. 1979, at 5 (2005), *aff'd*, *Kai v. Leavitt*, No. 05-00514 BMK (D. Haw. July 17, 2006). In deciding whether the requisite nexus exists, "evidence as to the nature of an offense may be considered, such as "facts upon which the conviction was predicated." *Lyle R. Kai, R. Ph.*, DAB No. 1979, at 5 (internal quotation marks omitted).

In our view, the nexus between Petitioner's offense and the delivery of an item or service under Medicare is inherent in the crime's statutory elements. Section 1128B(a)(3)(B), the provision under which Petitioner was convicted, makes it a crime to conceal or fail to disclose an "event" affecting the right to receive a "payment" or "benefit" under a federal health care program (such as Medicare) with the "intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized." 42 U.S.C. § 1320a-7b(a)(3)(B). Crimes that facilitate or increase the risk of false, fraudulent, or otherwise improper billing of Medicare – as a violation of section 1128B(a)(3)(B) does – are intimately related to the delivery of a health care item or service because a bill (or claim) for Medicare payment is a representation that some medical provider has delivered a covered item or service to a program beneficiary. *See Francis Shaenboen, R. Ph.*, DAB No. 1249, at 4 (1991) (holding that the filing of a false claim, even when no item or service was actually

provided, was "inextricably intertwined" with the delivery of an item or service "since a claim by its very nature alleges such delivery" (internal quotation marks omitted)); *Timothy Wayne Hensley*, DAB No. 2044, at 3, 7-15 (2006) (upholding a section 1128(a)(1) exclusion based on a misdemeanor conviction for making a false statement or representation of fact material to determining a right to payment under a federal health care program); *James O. Boothe* at 4 (holding that the excluded person's criminal offense had the requisite nexus with delivery of a health care item or service because it "helped ensure" the continued receipt of Medicaid payment for the items and services).

The facts upon which Petitioner's conviction rests confirm that her offense is related to delivery of an item or service under Medicare. According to her plea agreement, Petitioner concealed or failed to disclose "remunerations" prohibited by the federal anti-kickback statute. By legal definition, those remunerations were received "in return for" action ("purchasing, leasing, ordering, or arranging for" or "recommending" such action) that resulted in the use – to wit, the delivery – of Company A's bone growth stimulators to treat Dr. A's patients, who included Medicare beneficiaries.[2] A key purpose of the anti-kickback law is to ensure that decisions by physicians about what medical items or treatments to prescribe, furnish, or arrange (and hence "deliver") under federal health care programs are not tainted by improper financial considerations. *United States v. Patel*, 17 F. Supp. 3d, 814, 826 (N.D. Ill. 2014) (describing the "overarching purpose of the statutory scheme of which the Anti-Kickback Statute" is a part), *aff'd*, 778 F.3d 607 (7th Cir. 2015) (indicating that the anti-kickback statute "protect[s] patients from doctors whose medical judgments might be clouded by improper financial considerations"). Petitioner's crime undermined, or had the potential to undermine, that statutory purpose. Other undisputed facts about Petitioner's offense satisfy the common-sense-nexus standard. Petitioner admitted in her plea agreement that she concealed or failed to disclose the unlawful remunerations with the "intent to assist" another (evidently, Company A) in "fraudulently securing Medicare payments when none would be authorized." I.G. Ex. 2, at 4. (Compliance with the federal anti-kickback law is a

[2] The provision of the anti-kickback statute referenced in the plea agreement, section 1128B(b)(1)(B), makes it a crime to –

> knowingly and willfully solicit[ ] or receive[ ] any *remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . *in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering* any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. . . .

42 U.S.C. § 1320a-7b(b)(1)(B) (italics added). Section 1128B(b)(2)(B) prohibits the knowing and willful payment of such a remuneration. *Id.* § 1320a-7b(b)(2)(B).

condition on payment of a claim submitted to Medicare.[3]) Petitioner also admitted to helping Company A complete Certificates of Medical Necessity that enabled it to "fraudulently" claim Medicare payment for bone growth stimulators for which it paid unlawful remunerations. That conduct undoubtedly increased the risk that Medicare would be "fraudulently" or otherwise improperly billed for medical items and services (in this case, for bone growth stimulators). As noted, such conduct is related to the delivery of an item or service precisely because "the submission of a bill or claim for Medicaid [or Medicare] reimbursement is the necessary step, following the delivery of the item or service, to bring the 'item' within the purview of the program." *Jack W. Greene*, DAB No. 1078, at 7 (1989), *aff'd, Greene v. Sullivan*, 731 F. Supp. 835 (E.D. Tenn. 1990); *see also Paul R. Scollo, D.P.M.*, DAB No. 1498, at 9-10 (1994) (discussing *Jack W.V. Greene*).[4]

Petitioner contends that the ALJ, and the I.G. in its motion for summary judgment, incorrectly described the conduct for which she was convicted. In particular, she takes issue with the statement that "she received payment from Company A in exchange for using her 'position to recommend and assure that Company A's bone growth stimulator would be used by Dr. A for patients, including Medicare beneficiaries, to wear after spinal fusion surgery.'" P. Br. at 3 (*quoting* ALJ Decision at 4)). While Petitioner expressly admitted in her plea agreement that she "was paid, directly and indirectly, by Company A for each bone growth stimulator used by Dr. A for patients, including Medicare patients" (I.G. Ex. 2, at 4), and while she also implicitly admits in her affidavit that she received "compensation" from Company A (when stating that she "no longer received" such compensation) (P. Ex. 2, at 1), Petitioner argues that the payments from Company A were not *in exchange for* using her position to "ensure [that] [the company's] bone growth stimulators were used by Dr. A's patients." P. Br. at 6. Claiming that she was compensated merely "for fitting bone growth stimulators," Petitioner asserts that "it was Dr. A who instructed [her] to use Company A's bone growth stimulators"; that "[i]t was Dr. A's decision, and his decision alone, to use Company A's product; and that she (Petitioner) "was not involved in selecting which company or bone growth stimulators Dr. A's patients would use." *Id.* at 2, 6.

[3] *See* 42 U.S.C. § 1320a-7b(g) ("a claim that includes items or services resulting from a violation of this section," which includes the anti-kickback provision in section 1320a-7b(b), "constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code"); *United States ex re. Westmoreland v. Amgen*, 812 F. Supp.2d 39, 54-55 (D. Mass. 2011) (collecting cases).

[4] The criminal offense in *Jack W. Greene* involved the delivery of an item or service under the Medicaid program, which is a "State health care program" within the meaning of section 1128(a)(1). DAB No. 1078, at 5 n.2.

Petitioner submits that her disagreement with the ALJ and I.G. about whether she received Company A's payments in exchange for "using her position to recommend and assure" the use of its product creates or reveals a genuine dispute of material fact.[5] *Id.* at 3. That Petitioner received the payments because she used her position in this way is not an unreasonable inference from the plea agreement. However, because this is summary judgment, we do not rely on such an inference but, instead, accept Petitioner's allegation that she was not paid for "using her position to recommend and assure" the use of Company A's product. However, Petitioner does not explain why this alleged fact is material under the applicable law, section 1128(a)(1). More specifically, she does not contend that her offense, described in the way she asserts is correct, is unrelated to the delivery of a health care item or service under Medicare. Her appeal brief does not even mention, much less discuss, section 1128(a)(1) or the common-sense-nexus test.

While we assume for purposes of our decision that the dispute of fact Petitioner alleges exists, we conclude it is not material. Even if Petitioner did not "use her position to recommend and assure" the use of Company A's bone growth stimulator in return for the Company's payments (an allegation that we assume to be true), the facts to which she expressly admitted in the plea agreement – concealment or failure to disclose unlawful payments from Company A, an intention to assist Company A in "fraudulently securing" unauthorized Medicare payment, and completion of paperwork supporting the company's Medicare claims – unequivocally show the required link between her offense and delivery of an item or service under Medicare. Our conclusion is not undermined by the fact that Petitioner did not make or influence decisions about whether patients used Company A's product. Section 1128(a)(1) does not require an offense in which the excluded person played a decision-making or other direct or influential role in the delivery of medical items or services to program beneficiaries. The statute requires only an offense "related to" such delivery. Consistent with that criterion, the Board has held that the common-sense-nexus test is satisfied "even if the offense did not directly involve" the delivery of an item or service, *James O. Boothe* at 4, or "result in a delivery," *Timothy Wayne Hensley* at 7. *See also Berton Siegel, D.O.*, DAB No. 1467, at 4 (1994) (an offense may be related to the delivery of an item or service under a covered

[5] Petitioner contends that the ALJ mistook her argument for a collateral attack on the factual predicate for her conviction. P. Br. at 4-5. We need not decide whether the ALJ erred in that respect, or in characterizing Petitioner's offense conduct, because we find summary judgment appropriate based on our own de novo review of the record, as explained in the text. *Cf. The Orthotic Ctr.*, DAB No. 2531, at 10 n. 7 (2013) (declining to address a claim of legal error by the ALJ in describing the non-moving party's burden on summary judgment); 42 C.F.R. § 1005.23 (instructing the Board to "disregard any error or defect in the proceeding that does not affect the substantial rights of the parties). Consistent with our obligation on summary judgment to construe the record in the light most favorable to the non-moving party, we treat Petitioner's argument as one concerning the proper interpretation of her plea agreement, not as a collateral attack. Likewise, we accept Petitioner's claim that she did not receive Company A's payments in exchange for "using her position to recommend and assure" the use of Company A's product to treat Dr. A's patients.

program "even if the crime was committed by someone providing billing or accounting services who did not directly participate in the delivery of an item or service under the program" (*citing Travers v. Sullivan*, 791 F. Supp. 1471, 1481 (E.D. Wash. 1992)); *Lyle R. Kai*, DAB No. 1979, at 5-12 (sustaining an exclusion, under section 1128(a)(1), of a pharmacist whose "tacit involvement" in a drug relabeling "scheme" resulted in the submission of fraudulent claims to the Hawaii Medicaid Program and in his employer's receipt of Medicaid payments to which it was not entitled); *Kai v. Leavitt*, No. 05-cv-514 BMK, slip op. at 12 (D. Haw. July 17, 2006) (unreported) (affirming DAB No. 1979 and holding that an exclusion under section 1128(a)(1) was proper "even if Plaintiff did not personally engage in the scheme or was not aware of the scheme" that resulted in the delivery of mislabeled pharmaceuticals). In addition, the regulation which implements section 1128(a)(1) makes clear that the statute embraces offenses that do not involve medical decision-making or the direct provision of medical care. *See* 42 C.F.R. § 1001.101(a) (authorizing the exclusion of a person "convicted 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*"* (italics added)).

Petitioner contends that the "conduct addressed in her plea agreement and conviction is identical to the actions and behavior enumerated in [section 1128(b)'s] permissive exclusion provisions," to which the five-year statutory minimum period is inapplicable, and that those provisions, rather than section 1128(a)(1), are the "appropriate" bases for excluding her. P. Br. at 6-7. The Board has no authority to vacate a mandatory five-year exclusion on the ground asserted by Petitioner. Based on its analysis of the statutory scheme and related legislative history, "the Board has long held that, when a conviction falls within the scope of section 1128(a)," as it does here, "a minimum five-year exclusion must be imposed," and neither the I.G. nor an administrative law judge (or the Board) may proceed under any other provision of section 1128. *Nenice Marie Andrews* at 5 (*citing Scott D. Augustine*, DAB No. 2043 (2006)); *Boris Lipovsky, M.D.*, DAB No. 1363, at 8-9 (1992) ("[R]eading [sections 1128(a)(1) and 1128(b)] as mutually applicable would negate the mandatory nature of the section 1128(a)(1) exclusions" and "violate Congress's intent to strengthen the mandatory category of exclusion offenses"). In addition, federal courts have "repeatedly held" that, when a criminal offense meets the criteria for a mandatory exclusion, the I.G. must impose a mandatory exclusion "even if an individual's conduct also falls within the scope of a permissive exclusion provision." *Timothy Wayne Hensley* at 15; *see also Gregory J. Salko, M.D.*, DAB No. 2437, at 4 (2012) (*citing Hensley* and relevant federal court decisions, and agreeing with an administrative law judge's observation that the "argument that an offense arguably covered by the permissive exclusion statute cannot be the basis of a mandatory exclusion under section 1128(a) 'has been addressed and rejected' on many occasions"), *aff'd, Salko v. Sebelius,* No. 3:12cv515, 2013 WL 618779 (M.D. Pa. Feb. 19, 2013).

Conclusion

Because undisputed material facts (and indeed the statutory elements of the crime of which Petitioner was convicted) establish that her offense is "related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program," the ALJ properly granted summary judgment to the I.G. Accordingly, we affirm his decision to sustain Petitioner's five-year exclusion from federal health care programs pursuant to section 1128(a)(1) of the Act.

/s/

Christopher S. Randolph

/s/

Leslie A. Sussan

/s/

Sheila Ann Hegy
Presiding Board Member