Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Linda Bunch, M.D., (NPI: 1285610279).

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-17-338

Decision No. CR4894

Date: July 19, 2017

DECISION

Petitioner, Linda Bunch, M.D., is a physician, licensed in the State of Louisiana, who participated in the Medicare program until December 12, 2011, when CMS revoked her enrollment and imposed a three-year bar on reenrollment. CMS took this action because, on December 9, 2011, Petitioner Bunch agreed to plead guilty to conspiracy to import and distribute human growth hormone (hGH), a felony. She recently reapplied for program enrollment but, because of her felony conviction, the Centers for Medicare & Medicaid Services (CMS) denied her application. Petitioner now appeals the denial.

I find that CMS is authorized to deny Petitioner Bunch's reenrollment application because, within the ten years preceding her filing, she was convicted of a felony that CMS reasonably determined is detrimental to the best interests of the Medicare program and its beneficiaries. I therefore affirm CMS's determination.

Background

By letter dated July 25, 2016, the Medicare contractor, Novitas Solutions, denied Petitioner Bunch's application for reenrollment in the Medicare program. CMS Exhibit

(Ex.) 7. As the letter explains, the contractor acted pursuant to 42 C.F.R. § 424.530(a)(3) because Petitioner was convicted of a felony that CMS determined is detrimental to the best interests of the program and its beneficiaries.

Petitioner requested reconsideration. CMS Ex. 9. In a reconsidered determination, dated December 8, 2016, the contractor upheld the denial, citing Petitioner's felony conviction for conspiracy to import human growth hormone from China and to distribute it for unapproved uses (18 U.S.C. § 371). CMS Ex. 11; *see* CMS Ex. 4. Petitioner timely appealed and that appeal is now before me.¹

CMS moves for summary judgment, which Petitioner opposes. Because neither party proposes any witnesses, an in-person hearing would serve no purpose. *See* February 9, 2017 Acknowledgment and Pre-hearing Order at 5 (¶¶ 8, 9, 10). The matter may therefore be decided based on the written record, without considering whether the standards for summary judgment are satisfied.

CMS has submitted its brief (CMS Br.) and 13 exhibits (CMS Exs. 1-13).

Petitioner submitted no written argument and did not follow my pre-hearing order nor Civil Remedies procedures. Her submissions include additional copies of her request for review by an Administrative Law Judge, CMS's reconsideration determination, and her request for reconsideration (which includes a legal argument). She did not mark proposed exhibits nor submit an exhibit list. Instead, she submitted documents that are "tabbed" 1-7, 9, and 11-23. There is nothing behind Tab 8; there is no Tab 10. I will consider these proposed exhibits 1-7, 9, and 11-23 (P. Exs. 1-7, 9, 11-23).

In the absence of any objections, I admit CMS Exs. 1-13 and P. Exs. 1-7, 9, and 11-23.

Discussion

CMS may deny Petitioner enrollment in the Medicare program because, within the last ten years, she was convicted of conspiracy to import and distribute human growth hormone, a felony that CMS finds detrimental to the best interests of the Medicare program and its beneficiaries.²

<u>Statute and regulations</u>. CMS may deny a provider's or supplier's enrollment in the Medicare program if, within the preceding ten years, she was convicted of a felony

¹ Throughout its brief, CMS refers to its action as a "revocation." Petitioner did not appeal the December 2011 revocation; that action became final and is not before me. I now review CMS's denial of Petitioner's reenrollment application.

² I make this one finding of fact/conclusion of law to support my decision.

offense that CMS "has determined to be detrimental to the best interests of the program and its beneficiaries." 42 C.F.R. § 424.530(a)(3); *see also* Social Security Act (Act) §§ 1842(h)(8) (authorizing the Secretary to deny enrollment to a physician who has been convicted of a felony offense that the Secretary has determined is "detrimental to the best interests of the program or program beneficiaries") and 1866(b)(2)(D) (authorizing the Secretary to deny enrollment after he ascertains that the provider has been convicted of a felony that he "determines is detrimental to the best interests of the program or program beneficiaries"). Offenses for which billing privileges may be denied include – but are not limited to – felony crimes against persons, such as murder, rape, assault, and similar crimes; financial crimes such as extortion, embezzlement, income tax evasion, insurance fraud, and similar crimes; a felony that places the Medicare program or its beneficiaries at immediate risk (such as malpractice); and felonies "outlined in section 1128 of the Act." 42 C.F.R. § 424.530(a)(3)(i)(A)-(D).

Section 1128 crimes include: program-related crimes; crimes related to the neglect or abuse of patients in connection with the delivery of a healthcare item or service; crimes relating to health care fraud; and crimes relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. *See* 42 C.F.R. § 1001.101.

<u>Petitioner's felony offense</u>. In a 2010 indictment, Petitioner Bunch and two others were charged with twenty-two felony counts of conspiracy to import and distribute hGH, in violation of 18 U.S.C. § 371. CMS Ex. 1. The indictment describes Petitioner Bunch as a physician practicing at the Northeast Louisiana Anti-Aging and Wellness Center, which "provided anti-aging services to patients." CMS Ex. 1 at 2. Among the specific allegation to which she pled guilty:

- Petitioner Bunch conspired, knowingly and *fraudulently*, to bring hGH into the United States. The human growth hormone came from China and was not approved by the United States Food and Drug Administration. The conspirators imported the drug for unapproved uses. CMS Ex. 1 at 3 (Indictment ¶ II A1);
- Petitioner Bunch conspired to possess with the intent to distribute hGH for a purpose other than the treatment of a disease or other recognized medical condition authorized by the Secretary of Health and Human Services and pursuant to a physician's order. CMS Ex. 1 at 3-4 (Indictment ¶ II A2).

The conspiracy's purpose was to sell hGH for anti-aging and other unapproved uses. CMS Ex. 1 at 4 (Indictment ¶ III). To accomplish their objectives, the conspirators purchased the hormone from manufacturers in the United States and China; they caused vials to be delivered to the Northeast Louisiana Anti-Aging and Wellness Center; they provided the vials to *patients*, employees, and other customers; and they tracked its distribution. CMS Ex. 1 at 4 (Indictment ¶ IV).

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On December 9, 2011, Petitioner Bunch entered into a plea agreement, agreeing to plead guilty to one count of the indictment and, among other conditions, to cooperate with the government's investigation. CMS Ex. 2. On February 1, 2013, the court accepted the guilty plea and sentenced Petitioner to twenty-seven months in prison followed by two years of supervised release. CMS Ex. 4 at 1-3. The court also ordered her to pay \$200,000 as a "forfeiture money judgment." CMS Ex. 4 at 5. After one year of supervised release, the court granted her request that it be ended. P. Ex. 6.

<u>Petitioner's Medicare enrollment</u>. Based on her guilty plea, CMS revoked Petitioner's Medicare enrollment, effective December 12, 2011, and imposed a three-year bar on reenrollment. CMS Ex. 6.

Following her release from prison and the termination of her supervised release, Petitioner and her potential new employer, West Carroll Hospital Systems, have applied for her reenrollment in the Medicare program. CMS Ex. 8. Notwithstanding the undisputed facts surrounding her conviction, Petitioner maintains that her Medicare enrollment should not be denied.³ She argues that her felony conviction does not fall within any of the offenses enumerated in section 424.530(a)(3) and is therefore not *per se* detrimental to the best interest of the program or its beneficiaries. In fact, she was convicted of conspiracy to commit fraud in connection with the delivery of a healthcare item, which certainly seems to fall squarely within the ambit of section 1128(a)(3). CMS Ex. 1 at 3 (charging that Petitioner Bunch "fraudulently" conspired to import hGH from China and to dispense the hormone to her clinic patients, among others); *see* Act § 1128(a)(3); 42 C.F.R. § 1001.101(c)(1).

Astonishingly, CMS seems to agree with Petitioner on this, maintaining that "[i]n denying her reconsideration request, CMS acknowledged that 'conspiracy to import and distribute hGH' did not fall within any of the enumerated offenses listed in 42 C.F.R. § 424.530(a)(3)." CMS Br. at 7. I find this statement baffling, not only because Petitioner was, in fact, convicted of a crime related to fraud in connection with the delivery of a healthcare item (the term "fraudulently" is explicitly in the charge to which she pled guilty), but also because the reconsideration determination makes *no* such concession. The reconsideration determination simply does not reach the issue. It acknowledges, generally, that "not every felony conviction will result in the denial of billing privileges" and concludes that "in this case, denial is necessary to protect Medicare beneficiaries, and, ultimately, the Medicare program." CMS Ex. 11 at 4.

But even accepting CMS's apparent concession that Petitioner's crime is not among those specifically enumerated in the regulation, CMS legitimately determined that Petitioner's

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³ At this level, Petitioner Bunch submitted no written brief. I rely on the arguments her attorney presented at reconsideration. CMS Ex. 9.

felony conviction is detrimental to the Medicare program and its beneficiaries. The Departmental Appeals Board and federal courts have affirmed CMS's exercise of its discretion to revoke or deny enrollment based on felony convictions that were even further removed from those listed in the regulation. In *Abdul Razzaqued Ahmed, M.D.*, DAB No. 2261 (2009), *aff'd Ahmed v. Sebelius*, 710 F. Supp. 167, 174 (D. Mass. 2010), the Board (and district court) agreed that obstruction of a criminal health care fraud investigation was "similar to" insurance fraud, for which the physician's Medicare enrollment could be revoked. In *Fady Fayad, M.D.*, DAB No. 2266 (2009), *aff'd*, *Fayad v. Sebelius*, 2011 WL 1120036 (E.D. Mich., March 25, 2011), where a physician falsified immigration forms, the Board noted that the petitioner's crime was detrimental to the Medicare program "because it evidenced a lack of trustworthiness in his dealings with the federal government."

Here, Petitioner's conviction comes so close to several of the enumerated categories as to be virtually indistinguishable from them and, at a minimum, must be considered an "other similar crime," for which CMS may deny her enrollment.

- First, as discussed above, Petitioner's crime related to fraud in connection with the delivery of a healthcare item. Act § 1128(a)(3). See Vinod Chandrashekhar Patwardhan, M.D., DAB No. 2454 at 8 n.5 (2012) (upholding a 12-year exclusion under sections 1128(a)(1) and (a)(3), the Board opined that Dr. Patwardhan's participation in a drug-smuggling scheme that "resulted in beneficiaries receiving misbranded and unregulated chemotherapy drugs is strong evidence of [a] high level of untrustworthiness");
- Second, as CMS points out, serious risks are associated with hGH (increased risk of cancer, nerve pain, elevated cholesterol and glucose levels), even where the hormone complies with the FDA's strict standards. Petitioner was importing an unapproved substance from China and providing it to patients for unapproved uses, a practice that could be considered patient neglect or abuse in connection with the delivery of a healthcare item. Act § 1128(a)(2);
- Third, whether Petitioner's crime could be considered a crime relating to the unlawful distribution or dispensing of a "controlled substance" is debatable. *See* Act § 1128(a)(4). The regulations define a "controlled substance" as a "drug, or other substance, or immediate precursor" that is: a) included in the schedules listed in 21 U.S.C., chapter 13, subchapter I, Part B; or b) deemed a controlled substance by the law of *any state*. 42 C.F.R. § 1001.2. Human growth hormone is not defined as a controlled substance in the Controlled Substances Act (21 U.S.C.

chapter 13).⁴ On the other hand, hGH is deemed a controlled substance in many states, including Maryland, Idaho, Rhode Island, West Virginia, Colorado, and Maine, although, apparently, not Louisiana (which defines controlled substances as those included in the Controlled Substances Act). La. Rev. Stat. Title 40, Ch. 4, Part X, § 961(7). Depending on how you read section 1001.2, Petitioner's crime could fall within section 1128(a)(4). Certainly, if she had committed the crime in a state that included hGH among its statutorily-defined controlled substances, the section would apply. But even if it doesn't, her crime is comparably serious.

Thus, CMS justifiably determined that Petitioner was convicted of a felony detrimental to the best interests of the Medicare program and its beneficiaries.

Conclusion

CMS may deny Petitioner Bunch's Medicare enrollment application because she was convicted of a felony that CMS reasonably determined is detrimental to the best interests of the Medicare program and its beneficiaries. I therefore affirm CMS's determination.

_____/s/___ Carolyn Cozad Hughes Administrative Law Judge

⁴ The Anabolic Steroids Control Act amended the Food, Drug, and Cosmetics Act and criminalized possessing or distributing hGH for any use not authorized by the Secretary of Health and Human Services.