Jennifer Smith, M.D. to renew or modify this registration, as well as any other pending application of Jennifer Smith, M.D., for additional registration in New York. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–17]

Gilbert Y. Kim, D.D.S.; Decision and Order

On May 26, 2021, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Gilbert Y. Kim, D.D.S. (hereinafter, Respondent) of Oakland Gardens, New York. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1 and 3. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration No. W20055916C (hereinafter, COR or registration) and the denial of any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(5) because Respondent has been excluded from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.* at 1.

On June 7, 2021, Respondent timely requested a hearing, which commenced (and ended) on August 17, 2021, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On October 12, 2021, Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ) issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD). By letter dated November 8, 2021, the ALJ certified and transmitted the record to me for final Agency action. In the letter, the ALJ advised that neither party filed exceptions. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law, and recommended sanction with minor modifications, where noted herein.*[A]

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Teresa A. Wallbaum, Administrative Law Judge, October 12, 2021

*[B] Respondent proceeded *pro se* throughout the entire case.[1] Respondent timely filed a Request for Hearing. ALJ Ex. 2 at 1. A Prehearing Conference was conducted on July 13, 2021, by video teleconference (VTC). A Merits Hearing of the OSC allegations was conducted on August 17, 2021, via VTC at the DEA Hearing Facility in Arlington, Virginia. The Government filed a Post-Hearing Brief on October 6, 2021.

The ultimate issue in these proceedings is whether Respondent's application should be denied pursuant to 21 U.S.C. 823 and 824(a)(5) based upon his exclusion from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

I. Findings of Fact

A. Allegations

The Government alleges that the denial of Respondent's application is supported by incontrovertible record evidence that he has been excluded from participation in Medicare, Medicaid, and all federal health care programs. ALJ Ex. 1 at 1. Specifically, the Government alleges that judgment was entered against Respondent in the United States District Court for the Eastern District of New York (the District Court) after pleading guilty to one count of Conspiracy to Commit Health Care Fraud in violation of 18 U.S.C. 1349. *Id.* at 1–2 (citing *United States* v. *Gilbert Kim,* No. 1:11–CR–073 (E.D.N.Y. May 12, 2014)). The Government alleges that, due to this conviction, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG) mandatorily excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a).[2] ALJ Ex. 1 at 2. According to the Government, this exclusion was effective as of August 29, 2014,[3] and runs for a period of ten years.[4] ALJ Ex. 1 at 2.

B. Stipulations

The parties mutually agreed upon the following stipulations, and they were conclusively accepted as fact in the proceedings:

1. On or about June 9, 2020, Respondent applied to DEA for registration as a practitioner in Schedules II through V with a proposed registered address of 22902 Horace Harding Expressway, Fl. 2, Oakland Gardens, New York 11364.

2. Respondent's Application was assigned Control Number W20055916C.

3. Respondent was previously registered with DEA as a practitioner under DEA Certificate of Registration No. AK2569284.

4. DEA Certificate of Registration No. AK2569284 was surrendered for cause on or about August 15, 2018.

5. On or about May 12, 2014, judgment was entered against Respondent in the United States District Court for the Eastern District of New York based on his conviction on one count of ''Conspiracy to Commit Health Care Fraud,'' in violation of 18 U.S.C. 1349.

6. By letter dated August 29, 2014, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG), mandatorily excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a).

7. Respondent's exclusion under 42 U.S.C. 1320a–7(a) was effective on September 18, 2014, and runs for a period of ten years.

8. Respondent is currently excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a).

9. By letter dated March 23, 2020, the Office of Professional Discipline of the New York State Education Department informed Respondent that he may resume the practice of Dentistry in the State of New York no earlier than March 29, 2020.

*[B] I have omitted a section of the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] Respondent was advised during the Prehearing Conference that, under 21 CFR 1316.50, he had the right to seek representation by a qualified attorney at his own expense. Respondent was also advised that, if he continued to represent himself, he would be held to the same standards and procedural requirements of an attorney, including adherence to the procedural orders and rulings of this tribunal and to the procedural rules set forth in 21 CFR 1316.41–1316.68. ALJ Ex. 6 at 1, n.1. During the merits hearing, Respondent acknowledged that he had been so advised and confirmed that he wanted to proceed *pro se.* Tr. 8–9.

[2] Respondent has stipulated to the factual basis underlying this allegation. *See* Stip. 6.

[3] The OSC states that the exclusion was effective on August 29, 2014; however, per the HHS/OIG letter, the exclusion was effective on September 18, 2014. See Gov. Ex. 6.

[4] Respondent has stipulated to the factual basis underlying this allegation. *See* Stip. 7.

C. Government's Case-in-Chief

The Government's case-in-chief consisted of the testimony of a single witness, a DEA Diversion Group Supervisor (hereinafter, the GS). The GS testified that her duty station is the New York Field Division, located in New York City, where she has served in her capacity as a Group Supervisor for approximately one year. Tr. 24–25. Before the GS became a Group Supervisor, she was a Diversion Investigator for approximately six-and-a-half years. *Id.* at 25. As a Diversion Investigator, the GS's responsibilities included preventing and detecting the diversion of controlled substances through administrative, civil, and criminal investigations. *Id.* at 26. Additionally, the GS conducted scheduled investigations of DEA registrants. *Id.*

Respondent came to the GS's attention when a Diversion Investigator under her supervision was assigned his application for DEA registration. *Id.* at 29. Through the GS's testimony, the Government laid the foundation for introducing multiple exhibits in support of its allegations.[5] The parties agree, and the evidence demonstrates, that on April 25, 2014, Respondent pleaded guilty to one count of Conspiracy to Commit Health Care Fraud in violation of 18 U.S.C. 1349. Gov. Ex. 5; Stip. 5; Tr. 68. The HHS/OIG sent Respondent a letter informing him that he had been excluded from Medicare, Medicaid, and all federal health care programs for a period beginning on September 18, 2014 and lasting a minimum of ten years. Gov. Ex. 6; Tr. 31.

The GS testified that, on June 16, 2021, she ran a new search on a web page of the HHS/OIG and confirmed through that search that Respondent was excluded from Medicare, Medicaid, and all federal health care programs. Gov. Ex. 7; Tr. 38–39. The GS again searched the database the morning before her testimony and confirmed that Respondent was still excluded from Medicare, Medicaid, and all federal health care programs. Tr. 39.

The GS presented as an objective investigator, with no discernable motive to mislead, fabricate, or exaggerate. The testimony of this witness was primarily focused on the uncontroversial and unopposed introduction of documentary evidence and her contact with this case.[6] Her testimony was sufficiently detailed, plausible, and internally consistent to be afforded full credibility.

D. Respondent's Case

Respondent, proceeding *pro se,* presented his own testimony and offered eight exhibits in support of his case.[7] According to Respondent, he graduated from the University of Illinois College of Dentistry in 1983. *Id.* at 55. He obtained a license to practice dentistry in Illinois in 1983 and then a license in New York on or around 1986; however, Respondent only ever practiced in New York City. *Id.* at 55–56. Respondent practiced general dentistry and primarily did so in a solo practice. *Id.* at 57. Respondent is not board-certified. *Id.*

Respondent testified that prior to 2014, he had no criminal convictions. *Id.* Additionally, prior to 2014, Respondent had no disciplinary proceedings for his Illinois license, but he was disciplined once in New York. *Id.* Specifically, Respondent was disciplined in or around 1993 for using a dirty cup while doing mobile dentistry for a nonprofit. *Id.* at 57–58. Respondent blamed the incident on a child and explained that the child had taken a dirty cup from the garbage and returned it to the cuspidor. *Id.* Respondent received one year of probation and twenty-five hours of community service as discipline. *Id.* at 58.

Respondent admitted that he pleaded guilty to one count of Conspiracy to Commit Health Care Fraud in violation of 18 U.S.C. 1349. *Kim,* No. 1:11–CR–073; Stip. 5. Respondent was sentenced to one year of home confinement, three years of supervised release, and 300 hours of community service and ordered to pay $5,991,417.13 in restitution. Tr. 71–73; Gov. Ex. 5 at 2–5. Respondent's New York Dentistry license was suspended for three years and was reinstated on March 29, 2020. Stip. 9; Resp't Ex. 1 at 2.

According to Respondent's own exhibits from his criminal case, Respondent was a manager in the conspiracy. Prior to Respondent's sentencing, he was described as ''an active manager at the clinics with deep involvement in the planning and execution of the scheme.'' Resp't Ex. 3 at 4.[8] ''For example, [Respondent] was present at a meeting with other managers at the clinic where they discussed how to bill Medicare for lesion removals, when, in fact, they would only provide cosmetic facial services that would entice beneficiaries to come to the clinic.'' *Id.; see also* Resp't Ex. 4 at 8. Additionally, Respondent's Presentence Report (PSR) stated that he was a manager of the clinics and that he managed employees involved in the conspiracy. Resp't. Ex. 4 at 7. During his criminal proceedings, Respondent did not object to these statements in his PSR. *Id.*

During these administrative proceedings, Respondent's description of the events behind his conviction was unclear and, at times, internally inconsistent and inconsistent with his own exhibits. Respondent stated that he had to help his father with the clinic, so he assisted with signing checks for rent and electrical bills, while also contributing his own money to keep the business solvent. Tr. 60–62; *see also* Resp't Ex. 4 at 10 (''[There] was a shortage of money. I had to give the money to the operating'' expenses) (cleaned up). Despite the record from his criminal trial, however, Respondent maintained that he was not a manager at the clinic. Tr. 60 (denying prosecutor's unopposed claim at sentencing that Kim was a manager—''I had no idea'') and 61–62 (''I was not in payroll on management, so called management''). Respondent explained the discrepancy between his trial documents and his hearing testimony by stating that he ''was not 100 percent truthful on [being a manager],'' when he pleaded guilty. *Id.* at 100. Respondent further stated that he was practicing dentistry outside of the clinic while his wife, E.K., and sister, M.L., were responsible for the management work at the clinic. *Id.* at 61.

While acknowledging his guilty plea, Respondent nonetheless denied any direct role in the conspiracy. Rather, when asked about his culpability, he responded: ''I don't know what conspiracy meant, but I think I was a—you know, I hear it, what's going on. I didn't stop them.'' *Id.* at 70; *see also id.* at 64 (''I was aware what's going on, but I was not actively involved at meetings.''); *but see id.* at 68 (''I'm not an attorney, but I'm assuming that I was a manager, on that indictment, I was a

[5] Specifically, the GS's testimony laid the foundation for Government Exhibits 2 and 4–7. *Id.* at 26–28, 34–36, 36–38, 31–33, 38–40. Prior to the GS's testimony, the Government moved for the admission of Government Exhibits 1 and 3 as self-authenticating documents certifying the accuracy of DEA records regarding Respondent's DEA registration status and history. *Id.* at 17.

[6] Respondent did not object to the admission of any exhibit offered by the Government. Tr. 20–21, 28, 33, 36–37, 40.

[7] Respondent's exhibits 1, 3, and 4–7 were admitted. Tr. 77–93. Respondent's exhibits 2 and 8 were excluded. *Id.* at 82 and 93.

[8] Respondent's Exhibit 3 is the letter submitted by the prosecutor in his criminal case pursuant to § 5K1.1 of the United States Sentencing Guidelines. While Respondent did not sign the letter, he accepted the benefit of the letter, which was a sentence reduction for providing substantial assistance to the government. Moreover, the § 5K1.1 letter is based upon, and repeatedly cites, ¶ 20 of the Presentence Report, to which Respondent did not object during his sentencing proceedings. Resp't. Ex. 4 at 7.

manager.''). He repeatedly denied understanding the Medicare fraud. *Id.* at 53 (''I was not involved in the billing. I don't know what the medical billing was.''); 60 (''And then also the Medicare billing. And that, I have no idea.''); 62–66 (''I don't know completely'' about billing practices of other members at the clinic); 69 (''to this day, I don't know what Medicare, you know, medical billing is about'') (''still I—scratching my head'' about the billing); 101 (''Again, I said, you know, even medical billing, I, to this day I have no idea what, you know, the billing code is, I have no idea.''); 109 (''. . . but Medicare billing, and you know, that part, I have no idea up to this point'').

When asked whether he was ''present during management meetings where the scheme was discussed,'' Respondent answered: ''I have to say no, little bit yes.'' *Id.* at 64. When asked to clarify that answer, Respondent testified that he ''knew what's going on.'' *Id.* at 65. Specifically, he testified that he learned about the fraud from conversations with his wife and sister. *Id.* at 66. Later in his testimony, however, Respondent stated that he had pleaded guilty because at ''the early meeting, I was a participant, fully participant on that.'' *Id.* at 69.

Respondent pleaded guilty to health care fraud involving luring Medicare beneficiaries to the clinics for massages, facials, lunches, dancing classes, and other services, inducing those beneficiaries to provide their Medicare numbers, and billing Medicare for services that were not provided or medically necessary (Gov. Ex. 4 at 5); however, at the hearing, Respondent defined the fraud as narrowly involving a decision to save money by not hiring enough physical therapists to justify the treatment. Tr. 63–67. He testified that he tried to convince his family members to do the billing correctly but they refused. *Id.* at 66–67 (''I said do it correctly, you know . . . That's what I was trying to tell them, but they did not listen. So I did not stop them.''). Because he was ''very concerned,'' Respondent also spoke to his father about the billing practices and suggested the clinic use a third-party billing company. *Id.* at 67–68. According to Respondent, his wife and sister—the managers of the clinic—''never listened to [his] advice.'' *Id.* at 68.

Respondent repeatedly explained that he pleaded guilty because of his family. *Id.* at 19 (''I had to plead guilty to minimize any trauma.'') (cleaned up); 53 (''I should have stopped the business' so-called rehab. However, you know, I have to admit that I'm part of it, because if I had not done that I would have pointed out my wife, my sister, and would traumatize all the family. So I had to plead guilty.''); 54 (''I pled guilty to minimize the financial and emotional, you know, trauma to my family. And I decided that I, you know, needed to avoid a costly and lengthy trial.''). The only wrongdoing to which Respondent admitted throughout his testimony was that he should have stopped his family, not that he was a manager in the clinic, consistent with his guilty plea. *Id.* at 63 (''I was trying to stop them''); 65 (''I knew what's going on. I couldn't stop them''); 71–72 (''I don't know what conspiracy meant, but I think I was a—you know, I hear it, what's going on. I didn't stop them . . . I should have stopped them, but I didn't—I couldn't stop them, you know. That was my involvement'').

On cross-examination, Respondent admitted that he failed to disclose that the New York State Dental Board placed him on probation in 1993 on two of his DEA applications for registration. *Id.* at 106–108. Respondent confirmed that he submitted an application in 2016 and in 2020 for DEA registration and that he did not disclose his probation in 1993 in response to the following question on both applications: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.;* Gov. Ex. 1 at 1; Gov. Ex. 3 at 2. Respondent acknowledged that he provided false responses on both applications and attempted to excuse his responses by stating that he misunderstood the question. Tr. 107–108.

Additionally, Respondent admitted that he did not object to being classified as a manager in his PSR and during his sentencing hearing. *Id.* at 109–110. Respondent insisted that he was telling the truth now, *i.e.,* that he was not actually a manager at the clinic. *Id.* at 110–111. He explained that he was classified as a manager and given a role enhancement as a part of his sentence because he was ''not 100 percent truthful'' during his sentencing hearing. *Id.;* Resp't Ex. 4 at 9.

According to Respondent, he has been practicing dentistry part-time and seeing many pro-bono patients since his dentistry license was reinstated in March 2020. Tr. 77. While he acknowledged that it is possible to continue practicing without a DEA registration, he compared it to sending a solider to war without any bullets. *Id.* at 104.[9]

As for remedial measures, Respondent testified that his wife and family are not involved in his dental practice since they were ''the biggest issue.'' Tr. 101. He is the sole manager and is ''in total control'' of the finances and billing practices. *Id.* at 101–102. He stated that if it were not for his family at the clinic, he would have done the billing 100 percent correctly,[10] so his sole remedial measure is not working with his family. *Id.*

II. Discussion

The Government opposes Respondent's COR application on the ground that he has been excluded from participating in Medicare, Medicaid, and all federal health care programs. ALJ Ex. 1 at 1. *[C] [In its OSC, the Government relies upon grounds Congress provided to support revocation/suspension, not denial of an application. Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR at 33744–45 (collecting cases); *see also, William Ralph Kincaid.* In *Robert Wayne Locklear, M.D.,* the former Acting Administrator stated his agreement with the results of these past decisions and reaffirmed that a provision of section 824 may be the basis for the denial of a practitioner registration application. 86 FR at 33745. He also clarified that allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *Id.*

Accordingly, when considering an application for a registration, I will

[9] Respondent also suggested that he was being denied a COR because of his race. Respondent's claim was premised on two arguments. First, Respondent offered a motion filed by a co-defendant alleging selective prosecution based on race. Resp't Ex. 8 for identification. That motion—which was not accepted into evidence—did not relate to Respondent and was apparently never ruled upon by the court handling the criminal proceedings. Second, Respondent referenced an unnamed ''Caucasian'' dentist who he claimed was banned for life from participation in Medicare and Medicaid but was able to obtain a new DEA registration number. Tr. 90. This claim had no relationship to Respondent's Exhibit 8 for identification, which did not reference the unnamed dentist, nor was Respondent able to identify the unnamed dentist or provide any documentary evidence to support his claim.

[10] As previously discussed, Respondent testified multiple times that he has no understanding of medical billing. Tr. 60, 69, 101, 109.

*[C] I have substituted the RD's language assessing the application of the revocation grounds to my assessment of an application under 21 U.S.C. 823(f) in accordance with recent decisions.

consider any actionable allegations related to the grounds for denial of an application under 823 and will also consider any allegations that the applicant meets one of the five grounds for revocation or suspension of a registration under section 824. *Id. See also Dinorah Drug Store, Inc.,* 61 FR 15972, 15973–74 (1996).

A. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the Controlled Substances Act (hereinafter, CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

In this case, it is undisputed that Respondent holds a valid state dentistry license and is authorized to dispense controlled substances in the State of New York where he practices.

Because the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823, and although I have considered 823, I will not analyze Respondent's application under the public interest factors. Therefore, in accordance with prior agency decisions, I will move to assess whether the Government has proven by substantial evidence that a ground for revocation exists under 21 U.S.C. 824(a).

Regarding the revocation/suspension grounds alleged in the OSC, the CSA provides, in pertinent part: ''A registration pursuant to section 824 of this title to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant: . . . (5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' 21 U.S.C. 824(a)(5).][11]

B. Exclusion From Participation in a Federal Health Care Program

The CSA grants the Agency discretion to [revoke a respondent's registration] if he ''has been excluded (or directed to be excluded) from participation in a program pursuant to [42 U.S.C. 1320a–7(a)].'' 21 U.S.C. 824(a)(5) (2012). *See supra.* Section 1320a–7 comprises the exclusion of individuals or entities by the Secretary of the U.S. Department of Health and Human Services HHS from participating in federal health care programs. 42 U.S.C. 1320a–7 (2012). A federal health care program is (1) a plan or program providing health benefits and which is funded in some way by the U.S. Government (42 U.S.C. 1320a–7b(f)); or (2) a state health care program or plan receiving certain approval or funding from the U.S. Government (42 U.S.C. 1320a–7(h)). Under clear DEA precedent, Medicare and Medicaid programs qualify as ''federal health care programs,'' exclusion from which can constitute a basis for revocation of a registration. *See, e.g., Daniel Ortiz-Vargas, M.D.,* 69 FR 62095, 62095–96 (2004); *Joseph M. Piacentile, M.D.,* 62 FR 35527, 35527–28 (1997); *Anibal P. Herrera, M.D.,* 61 FR 65075, 65077 (1996); *Suresh Gandotra, M.D.,* 58 FR 64781, 64782 (1993); *George D. Osafo, M.D.,* 58 FR 37508, 37509 (1993).

Specifically, subsection (a) of § 1320a–7, the part of the statute referenced by 21 U.S.C. 824(a)(5), dictates when HHS is required to exclude individuals or entities.[12] *Id.* § 1320a–7(a) (''The Secretary *shall* exclude the following individuals and entities from participation in any [f]ederal health care program . . . .'') (emphasis added). There are four instances requiring mandatory exclusion: (1) Conviction of a criminal offense ''related to the delivery of an item or services under [42 U.S.C. 1395 *et seq.*] or under any [s]tate health care program''; (2) conviction, ''under [f]ederal or [s]tate law,'' related to patient ''neglect or abuse'' connected ''with the delivery of a health care item or service[;] (3) [f]elony conviction related to health care fraud''; and ''(4) [f]elony conviction related to . . . the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.'' *Id.* The unambiguous words of the CSA in 21 U.S.C. 824(a)(5) provide that a practitioner's registration ''may be suspended or revoked'' if the practitioner ''has been excluded'' from participating in a program pursuant to 42 U.S.C. 1320a–7(a). 21 U.S.C. 824(a)(5). DEA has strictly interpreted this provision and acknowledged that the Administrator has discretionary power to suspend or revoke a registration only when the practitioner has been mandatorily excluded from a federal health care program under subsection (a) of 42 U.S.C. 1320a–7. *See, e.g., Terese, Inc., d/b/a Peach Orchard Drugs,* 76 FR 46843, 46847 (2011); *Herrera,* 61 FR at 65077; *Gandotra,* 58 FR at 64782; *Nelson Ramirez-Gonzalez, M.D.,* 58 FR 52787, 52788 (1993). [The Agency has consistently found that] the misconduct mandating exclusion need not relate to controlled substances in order to provide the Administrator with the power to suspend or revoke (or in this case deny an application for) a COR. *Ibrahim Al-Qawaqneh, D.D.S.,* 86 FR 10354, 10356 (2021) (registrant excluded due to a conviction for illegal remuneration); *Jeffrey Stein, M.D.,* 84 FR 46968, 46973 (2019) (registrant excluded due to a conviction for tax evasion); *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998) (registrant excluded due to a conviction for vendor fraud); *Osafo,* 58 FR at 37508 (registrant excluded due to conviction for second degree larceny). Additionally, the Agency is generally unwilling to consider the impact of revocation or suspension on the community when exercising the discretionary authority to grant/deny/revoke/suspend a practitioner COR under the CSA. *Linda Sue Cheek, M.D.,* 76 FR 66972, 66972 (2011); *see also, Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

When DEA alleges that a practitioner has been mandatorily excluded from a federal health care program under 42 U.S.C. 1320a–7a, and thus seeks to impose a COR sanction, the Government bears the burden to prove that such an exclusion occurred. *Jin,* 77 FR at 35023; *see also,* 21 CFR 1301.44(d) (2018) (''At [a] hearing for the denial of a [COR], the [Government] shall have the burden of proving that the requirements for such registration . . . are not satisfied.''). A mandatory exclusion, however, does not mandate revocation/suspension or denial of an application; the Agency

[11] [To avoid repetition, I have omitted the RD's footnote which briefly discussed how, in accordance with prior Agency decisions, analysis of the public interest factors is unnecessary when the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823.]

[12] In contrast to subsection (a), subsection (b) of 42 U.S.C. 1320a–7 provides sixteen discretionary grounds of exclusion from health care programs. 42 U.S.C. 1320a–7(b) (2012).

retains authority to independently weigh the evidence presented and exercise discretion. *Stein,* 84 FR at 46970 [ ]. Accordingly, DEA is not required to deny Respondent's COR application merely because he is subject to a mandatory exclusion. *Id.*

In the instant case, it is undisputed that Respondent was excluded from participation in Medicare, Medicaid, and all federal health care programs under the mandatory authority of 42 U.S.C. 1320a–7a. Stip. 6; Gov. Ex. 6. Consequently, under § 824(a)(5), it is within the discretion of the Agency to determine, based on the entire record, [the consequence of] his exclusion from federal health care programs [on his registration or application for a registration]. *See Narcisco A. Reyes, M.D.,* 83 FR 61678, 61681 (2018) (holding that where the Government has demonstrated the requisite mandatory federal health care program exclusion(s), it has satisfied its *prima facie* case, shifting the burden to the respondent).

Accordingly, in review of the evidence of record, including the stipulations of the parties, OSC Allegations 1, 2, and 3 are *sustained.*[*D]

III. Sanction

Because the Government has met its *prima facie* burden, the Respondent now has the burden to show that registration should be granted as a matter of discretion, *i.e.,* he must show that he can be entrusted with a registration due to his unequivocal acceptance of responsibility and remedial measures to ensure the misconduct will not recur. *See, e.g., Salvatore Cavaliere, D.O.,* 85 FR 45657, 45666 (2020); *Al-Qawaqneh,* 86 FR at 10356; *George Pursley, M.D.,* 85 FR 80162, 80187 (2020); *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018); *Heavenly Care Pharmacy,* 85 FR 53402, 53420 (2020); *Suntree Pharmacy and Suntree Medical Equipment, LLC,* 85 FR 73753, 73776 (2020); *Stein,* 84 FR at 49972; *Fred Samimi, M.D.,* 79 FR 18698, 18713 (2014). He must do so by unequivocally acknowledging his misconduct and accepting responsibility. *Al-Qawaqneh,* 86 FR at 10356 (collecting cases); *Stein,* 84 FR at 49972–73; *Mohammed Asgar, M.D.,* 83 FR 29569, 29572 (2018); *Lon F. Alexander, M.D.,* 82 FR 49704, 49728 (2017) (collecting cases); *Jeffery M. Freesemann, M.D.,* 76 FR 60873, 60888 (2011) (collecting cases); *Ronald Lynch, M.D.,* 75 FR 78745, 78749 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Stein,* 84 FR at 49973. Mere stipulation to facts without admitting to misconduct does not amount to an acceptance of responsibility. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.32 (2019); *see also Kaniz F. Khan-Jaffery, M.D.,* FR 45667, 45690 (2020) (holding that it was not enough for the respondent to simply acknowledge that she ''should have written more''). Minimization of misconduct undermines any acceptance of responsibility. *See Pursley,* 85 FR at 80188 (registrant acknowledged his unfamiliarity with governing regulations, but stated ''I don't think I left a lot of dead bodies laying around.''); *Arvinder Singh, M.D.,* 81 FR 8247, 8249–51 (2016) (registrant minimized conduct when he claimed he overbilled patients only 15 to 20 times, but District Court ordered him to pay more than $227,000 in restitution to approximately 250 payees); *Stein,* 84 FR at 46972–73 (respondent's assertion that his misdeeds had no effect on his patients held to indicate a minimization of his acceptance of responsibility rendering it less than unequivocal); *Lynch,* 75 FR at 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *Rose Mary Jacinta Lewis, M.D.,* 72 FR 4035, 4042 (2007) (registrant's dishonesty under oath undermined registrant's acceptance of responsibility). Blaming others for misconduct does not constitute acceptance of responsibility. *The Pharmacy Place,* 86 FR 21008, 21016 (2021) (no acceptance when registrant blamed computer software for her inability to have ''readily retrievable documents'' and failed to correct her conduct ''by providing DEA with accurate and complete log within a reasonable time following the inspection''); *Michael W. Carlton, M.D.,* 86 FR 10337, 10353 (2021) (no acceptance of responsibility when registrant blamed another member of the practice); *Hamada Makarita, D.D.S.,* 85 FR 45691, 45699 (2020) (no acceptance of responsibility when registrant blamed his conviction on false testimony of his former office manager and denied he ever wrote a prescription without a valid dental purpose). *But see Michele L. Martinho, M.D.,* 86 FR 24012, 24014, 24019–20 (2021) (Respondent met burden when she testified she accepted responsibility 100%, always referred to herself as a felon, repaid the bribes, amended her tax returns, paid the taxes on the money she took, and embarked upon an effort of ''restorative justice'' by engaging in 69 speaking engagements focused on real-world ethical decisions).

A. Acceptance of Responsibility

In the instant case, Respondent's testimony was not candid on the key issue of culpability.[13] His testimony was, at times, non-responsive, internally inconsistent, and inconsistent with his own exhibits. Importantly, this tribunal cannot ignore that Respondent pleaded guilty to conspiracy to commit health fraud that included a scheme to submit false and fraudulent claims to Medicare. In his criminal proceedings, Respondent did not object to his PSR's description of the fraudulent scheme, which was broader than merely hiring insufficient physical therapists. Resp't Ex. 3 at 3–4 (no physical therapy provided at the clinic; rather, patients were ''lured'' to the clinic and would ''receive medically unnecessary chiropractic services,'' facial treatments, free lunches, and classes). In these proceedings, however, he cast the scheme as merely a desire to save money by not hiring physical therapists. *See* Tr. 63 (''they were not doing all the fraud, but I think for the rehab, I think it was some of them were doing—bypassing—you know, trying to save money.''); *id.* (''I said to do it correctly, . . . you have to hire more physical therapists to justify the treatment.''). I may treat Respondent's failure to dispute these facts at a sentencing hearing as an admission of those specific facts. *See Uvienome Linda Sakor, N.P.,* 86 FR 50173, 50176 (2021).

Nor, in his criminal proceedings, did Respondent object to the assertion in the PSR that he was a manager who *actively* participated in the scheme, which resulted in the application of a

[*D] Moved conclusion and added headings.

[13] During his testimony, Respondent also acknowledged that he had twice failed to disclose a 1993 disciplinary action in New York that resulted in his license being placed on probation. Specifically, Respondent failed to answer the question on the application form which asks: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' Tr. 106; Gov. Ex. 2 at 1. Respondent claimed that he did not understand the question (Tr. 106), although he did correctly answer that same question on his 2020 application. Gov. Ex. 2 at 1. While Respondent's false answers are not the focus of this inquiry, his failure to disclose the 1993 disciplinary proceeding [by his own admission] certainly gives this tribunal pause when evaluating whether he can be entrusted with a DEA registration.

sentencing enhancement based on that managerial role. *See* Resp't Ex. 3 at 4; Resp't Ex. 4 at 7–8; *see also* Tr. 96 (stating this assertion was inaccurate). According to the PSR, that active participation included a meeting with other managers ''where they discussed how to bill Medicare for lesion removals, when, in fact, they would only provide cosmetic facial services that would entice beneficiaries to come to the clinic.'' Resp't Ex. 3 at 4 (citing PSR ¶ 20); *see also* Resp't Ex. 4 at 7 (sentencing transcript, noting Respondent had not objected to nor did he object to PSR ¶ 20). But in these proceedings, Respondent repeatedly denied being in any meetings (Tr. 64–66; 98–99), although he subsequently admitted, at least obliquely, that he had participated in the ''early meeting.'' Tr. 69. On this point, Respondent testified that he was ''not 100 percent truthful'' in his criminal proceedings about his managerial role. *Id.* at 100 and 110–111. That admission alone—that he lied under oath in his criminal proceedings—strongly supports the conclusion that the Agency cannot entrust Respondent with a DEA COR.

More generally, it is worth noting that, by pleading guilty, Respondent obtained a benefit of acceptance of responsibility and, ultimately, a sentence of one year of home confinement despite facing a Guideline Sentence of 63 to 78 months. Tr. 71; Resp't Ex. 4 at 9. His guilty plea in federal court saved him from significant prison time. In these proceedings, however, Respondent has attempted to distance himself from some of his admissions in the criminal proceedings—in particular, his failure to object to the PSR's description of him as a manager and active participant in the scheme. Tr. 110. Respondent's approach is inconsistent with acceptance of responsibility.

Indeed, throughout his testimony, Respondent had ample opportunity to take full and unequivocal responsibility for his misconduct. Yet repeatedly, when pressed on the details of his conviction, Respondent failed to do so and, instead, made excuses and blamed others. He portrayed himself as simply a good son who was only trying to help his family run the clinic and so he began signing checks. Tr. 52. He claimed that he tried to stop his family when he realized they were defrauding federal health care programs, but did little more than have a few conversations with his family members and then gave up when they failed to listen. *Id.* at 67. Finally, he pleaded guilty to spare his family the emotional and financial trauma of a trial. *Id.* at 108–109. Overall, Respondent has seriously minimized his role in the conspiracy, portrayed himself as an innocent party who was protecting his family, and blamed others, including his wife. Thus, Respondent's statements fall far short of unequivocal acceptance of responsibility. *See Pursley,* 85 FR at 80188; *Singh,* 81 FR at 8249–51; *Stein,* 84 FR at 46972–73; *Lynch,* 75 FR at 78749; *Jacinta Lewis,* 72 FR at 4042.[14]

Thus, based on the evidence as detailed *supra,* I find that, in the face of the Government's *prima facie* case, Respondent has failed to unequivocally accept responsibility for his past misconduct; therefore, he cannot be trusted with a DEA COR. *See Singh,* 81 FR at 8250.

Having concluded that Respondent has failed to prove an unequivocal acceptance of responsibility, I need not address remedial measures. *Ahuja,* 84 FR at 5498 n.33; *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801 (2015); *Perry County Food & Drug,* 80 FR 70084, 70090–91 (2015); *Jones Total Health Care Pharmacy, LLC* v. *DEA,* 881 F.3d 823, 833 (2018). Nevertheless, even if remedial measures were considered, they would not change the result.

The burden is on Respondent to present sufficient evidence of his remedial measures. *See Scott D. Fedosky, M.D.,* 76 FR 71375, 71378 (2011) (declining to give weight to remedial measures where the respondent testified about them but did not present any corroborating evidence to support his claim). And even if Respondent does introduce specific evidence of remedial measures, registration will not be granted unless such measures demonstrate that he can be entrusted with a COR. *Jeri Hassman. M.D.,* 75 FR 8194, 8237 (2010) (denying a COR where the Agency found that the respondent had learned nothing from the remedial steps she had taken).

Here, Respondent's only claimed remedial measure is that he no longer works with his family and he will handle his own billing as he practices dentistry. But this is not a remedial measure; it is a promise that Respondent will not work with his family. It is not a particularly persuasive promise given Respondent's emphasis that his wife and sister never listened to him and his past history—by his own admission—that he simply acquiesces to them. *See, e.g.,* Tr. 67. Notably absent is any true remedial measure, such as hiring a third-party billing company or taking courses to improve his understanding of Medicare billing, to ensure he does not defraud federal health care programs again. Tr. 101–103. Thus, his promise to not work with his family again is unpersuasive and insufficient. Simply put, Respondent has not made an adequate showing that he can be trusted with a COR.

B. Specific and General Deterrence

*[E] In determining whether and to what extent imposing a sanction is appropriate, the Agency considers specific and general deterrence as well as the egregiousness of the offenses established by the Government's evidence. *David A. Ruben,* 78 FR 38363, 38384, 38385 (2013). The Agency has previously found [based on specific circumstances] that criminal convictions and sanctions by state licensing authorities can sufficiently deter physicians from engaging in misconduct, making the denial or of an application for, or revocation of, a COR unnecessary to achieve the goal of general deterrence. *Kansky J. Delisma, M.D.,* 85 FR 23845, 23854 (2020). Likewise, such punitive measures can suffice to deter the registrant or applicant from future misconduct, making revocation or denial of an application unnecessary to achieve specific deterrence. *Id.*

With respect to specific deterrence, Respondent failed in these proceedings to accept responsibility for his role in a four-year health care fraud conspiracy. He has minimized his responsibility,

[14] At the hearing, Respondent—for the first time and with no prior notice—suggested that DEA had an improper racial motive for denying his application for a COR. Tr. 90–92. Notably, Respondent provided no evidence to support his accusation. Respondent's Exhibit 8 for Identification (which was not admitted), was simply a motion filed by a co-defendant in Respondent's criminal case, alleging that non-Asian clinic practitioners were not prosecuted while Asian clinic practitioners were prosecuted. There is no court order granting this motion. Thus, this exhibit, at best, is an unproven allegation about the criminal case. Respondent's second claim—unrelated to Respondent's Exhibit 8 for Identification—alleged that there was a ''Caucasian'' registrant—whose name and specific circumstances are unknown—who received a COR. This is not admissible evidence. In any event, even if Respondent had presented evidence that he was selectively prosecuted by the Government, which he has not done, selective prosecution is not a defense on the merits. *See, e.g., United States* v. *Armstrong,* 517 U.S. 456, 463 (1996) (''Our cases delineating the necessary elements to prove a claim of selective prosecution have taken great pains to explain that the standard is a demanding one.''); *Wayte* v. *United States,* 470 U.S. 598, 607 (1985) (''In our criminal justice system, the Government retains 'broad discretion' as to whom to prosecute.''); *Martex Farms, SE* v. *EPA,* 559 F.3d 29, 32–33 (1st Cir. 2009) (applying criminal law principles to reject selective prosecution arguments in EPA enforcement action). Because I find that the Agency met its *prima facie* case, and because Respondent has failed to unequivocally accept responsibility, his unsupported claim cannot alter the outcome here.

*[E] Language omitted.

blamed others, and has no concrete remedial plan. Given these facts, the tribunal can only conclude that granting Respondent a COR would put the public at risk of Respondent's previous fraudulent behavior. Moreover, with respect to general deterrence, the Agency bears the responsibility to deter conduct similar to Respondent's past misconduct. *Ruben,* 78 FR at 38385. Granting a COR to an applicant who has neither unequivocally taken responsibility for his misconduct, nor demonstrated sufficient remedial measures to ensure such conduct will not happen again, would send a message to all that there will be few consequences to defrauding federal health care programs.

C. Egregiousness

Finally, this tribunal finds that Respondent's behavior was egregious. While Respondent did not divert controlled substances, defrauding federal health care programs is egregious. *See Stein,* 84 FR at 46973 (finding that the respondent's actions were egregious because he defrauded the government of taxes and misused his position of trust); *Ramirez-Gonzalez,* 58 FR at 52788 (''fraud perpetrated by the respondent casts doubt upon his integrity, and as such supports an action against his registration''); *Osafo,* 58 FR at 37509 (''Respondent's submission of fraudulent medical claims and subsequent convictions of larceny indicated that Respondent placed monetary gain above the welfare of his patients, and in so doing, endangered the public health and safety.''). Respondent engaged in a four-year conspiracy to defraud federal health care programs and the cost of that fraud, as reflected in the restitution amount imposed at his sentencing, was $5,991,417.13. Tr. 71–73; Gov. Ex. 5 at 2–5.

Moreover, the Agency ''relies heavily on a registrant's honesty and integrity 'to complete its mission of preventing diversion within such a large regulated population.' '' *Michael Jones, M.D.,* 86 FR 20728, 20731 (2021) (quoting *Stein,* 84 FR at 46974). ''Because DEA depends on the integrity of those it entrusts with controlled substance privileges, it takes a close look at a registrant's fraudulent activity.'' *Jones,* 86 FR at 20731 (citing *Ramirez-Gonzalez,* 58 FR at 52788). Even if the fraud does not involve controlled substances, ''fraudulent activity indicates that a registrant places monetary gain above the welfare of his patients, and in so doing, endangers the public health and safety.'' *Jones,* 86 FR at 20731–32 (internal quotations omitted); *see also Osafo,* 58 FR at 37509. Respondent's behavior demonstrates that he lacks integrity and cannot be trusted. In particular, his admission that he ''was not 100 percent truthful on [being a manager]'' when he pleaded guilty under oath (Tr. 100) is stark proof that the Agency cannot rely on Respondent's honesty as a registrant. His lack of remorse and acceptance of responsibility further shows that he does not recognize the seriousness of his actions, so he should not be entrusted with a COR.

Accordingly, it is herein respectfully recommended that Respondent's application for a DEA registration be *denied.*

Dated: October 12, 2021.

Teresa A. Wallbaum,
Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824 and 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W20055916C, submitted by Gilbert Y. Kim, D.D.S. as well as any other pending application of Gilbert Y. Kim, D.D.S. for additional registration in New York. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07717 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

George Pharmacy, Inc.; Decision and Order

On August 1, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to George Pharmacy, Inc. (hereinafter, Registrant) of Dayton Beach, Florida. Government's Request for Final Agency Action (hereinafter, RFAA) Exhibit 1 (OSC). The OSC informed Registrant of the immediate suspension of its DEA Certificate of Registration Number FG5612127 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Registrant's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

The OSC notified Registrant of its right to request a hearing on the allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. *Id.* at 10–11 (citing 21 CFR 1301.43).

In response to the OSC, Registrant filed a timely request for an administrative hearing. RFAAX 3 (Request for Hearing). After both parties filed prehearing statements, and Registrant moved to continue the hearing, the Chief Administrative Law Judge (hereinafter, Chief ALJ), set a hearing date of December 17, 2019, in Arlington, Virginia. RFAAX 4. On December 12, 2019, Registrant filed a motion to terminate proceedings, stating that Registrant ''respectfully withdraws its prior request for hearing and desires that the administrative hearing presently scheduled be cancelled, and the proceedings terminated.'' RFAAX 5. On the same day, the Chief ALJ granted Registrant's motion and cancelled the hearing. RFAAX 6.

On March 12, 2020, the Government forwarded an RFAA, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering its continued registration inconsistent with the public interest. I further find that Registrant's conduct was egregious, and that Registrant's failure to respond to the Government's allegations weighs strongly against continuation of its registration. Accordingly, I conclude that the appropriate sanction is the revocation of Registrant's DEA registration.

I. Findings of Fact

A. Registrant's DEA Registration

Registrant was registered with DEA as a retail pharmacy in Schedules II through V under DEA registration number FG5612127, at the registered address of 948 Orange Avenue, Dayton Beach, Florida 32114–0000. RFAAX 8 (DEA Certificate of Registration). According to Agency records, this registration expired on February 28, 2019. *Id.*[1]

[1] Although Registrant's COR has expired, the Agency has discretion to adjudicate this Order to Show Cause to finality. *See Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68479 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the subject registration to expire before final adjudication). As my predecessor identified in *Olsen,* ''[b]ecause nothing in the CSA

Continued