is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–14210 Filed 7–1–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–22]

Keith A. Jenkins, N.P.; Decision and Order

On February 19, 2020, the Drug Enforcement Administration (hereinafter, DEA or Government) Administrative Law Judge Mark M. Dowd (hereinafter, ALJ), issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD) on the action to revoke the DEA Certificate of Registration Numbers MJ3401609 and MJ4509331 of Keith A. Jenkins, N.P. The ALJ transmitted the record to me on March 10, 2020. Having reviewed and considered the entire administrative record before me, I adopt the ALJ's RD with modifications, where noted herein.*A

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby dismiss the Order to Show Cause issued to Keith A. Jenkins, N.P. I further order that any pending applications for renewal of DEA Certificates of Registration MJ3401609 and MJ4509331 be granted. This Order is effective immediately.

D. Christopher Evans,

Acting Administrator.

Paul Soeffing, Esq., for the Government
Robert W. Liles, Esq. and Meaghan K. McCormick, Esq., for the Respondent

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

The Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause (OSC),[1] dated April 23, 2019, seeking to revoke the Respondent's Certificates of Registration (COR), numbers ''MJ3401609 and MJ4509331, pursuant to 21 U.S.C. 824(a)(5), and deny any applications for renewal or modification of such registration and any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(5),'' because the Respondent has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42. OSC, at 1. The Respondent requested a hearing on May 16, 2019,[2] and prehearing proceedings were initiated.[3] A hearing was conducted in this matter on November 20, 2019, at the DEA Hearing Facility in Arlington, Virginia.

The issue ultimately to be adjudicated by the Acting Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by a preponderance of the evidence that the Respondent's subject registration with the DEA should be revoked pursuant to 21 U.S.C. 824(a)(5).

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.

The Allegations

In the OSC, the Government contends that the DEA should revoke the Respondent's DEA COR because he has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42.

Specifically, the Government alleges the following:

1. Respondent is registered with the DEA as an MLP-nurse practitioner in Schedules II through V under DEA Certificate of Registration MJ3401609, at 105 Vanner Rd., Mt. Juliet, TN 37122. Respondent is also registered with the DEA under DEA Certificate of Registration MJ4509331, at 3909 Woodley Rd., Toledo, OH 43606, with a mailing address of 105 Vanner Rd., Mt. Juliet, TN 37122. Respondent's registrations both expire by their terms on December 31, 2020. *Id.* Prior to the current action, Respondent's DEA Certificates of Registration have not been the subject of disciplinary or other adverse action by the DEA.

2. On August 7, 2017, Respondent entered an ''Alford Plea of Guilty to a Felony'' to the offense of ''False Statement to Medicaid.'' On August 1l, 2017, the Circuit Court of Fairfax County, Virginia entered its sentencing Order for Respondent's offense of ''False Statement for Payment (F)'' in violation of Va. Code Section 32.1–314(F) FRD 3337F9. *See Commonwealth of Virginia* v. *Keith Allen Jenkins,* No. FE–2017–0000711 (Fairfax Cty. Cir. Ct.).

3. Based on Respondent's conviction, the U.S. Department of Health and Human Services, Office of Inspector General (''HHS/OIG''), by letter dated February 28, 2018, mandatorily excluded Respondent from participation in Medicare, Medicaid and all federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a–7(a), effective March 20, 2018. Notwithstanding the fact that the underlying conduct for which the Respondent was convicted had no nexus to controlled substances, the Respondent's mandatory exclusion from Medicare, Medicaid, and all federal health care programs by HHS/OIG warrants revocation of the Respondent's registration pursuant to 21 U.S.C. 824(a)(5). *See, e.g., Richard Hauser, M.D.,* 83 FR 26308 (2018).

The Hearing

Government's Opening Statement

The Government outlined its case in its Opening Statement. The Government seeks the revocation of the Respondent's registrations pursuant to 21 U.S.C. 824(a)(5), as the Respondent has been excluded from a program pursuant to § 1320a–7a of Title 2. Tr. 12. The Government explained that in 2017, the Respondent entered an Alford plea of guilty, to the felony offense of false statement to Medicaid, in the Circuit Court of Fairfax County, Virginia. On the basis of that conviction, in 2018, the Department of Health and Human Resources, Office of Inspector General mandatorily excluded the Respondent from participation in Medicare, Medicaid and all federal health care programs pursuant to 42 U.S.C. 1320a-7(a). The Respondent's exclusion remains in effect. *Id.*

Respondent's Opening Statement

In his Opening Statement, the Respondent noted he has stipulated to all of the operative facts of the case. *Id.* at 13. The Respondent conceded he was convicted as charged, he was excluded from participation from Medicare, Medicaid and all federal health benefit programs, as alleged. Acknowledging the evidentiary burden shift to him, upon the *prima facie* showing of these facts, the Respondent argued that his

*A I have made minor, nonsubstantive, grammatical changes to the RD. Where I have made any substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have bracketed the modified language and explained the edit in a footnote marked with an asterisk and a letter in alphabetical order.

[1] ALJ Ex. 1.
[2] ALJ Ex. 2.
[3] ALJ Ex. 3.

Registrations should not be revoked as that would be inconsistent with the public interest. The Respondent argued that he has accepted responsibility for his misconduct, and further that this type of conduct can no longer reoccur, as preventive safeguards are now in place.

Referring to the five operative factors under § 823(f), the Respondent noted that the Respondent has the ''backing and support'' of the state nursing boards. *Id.* at 14. He is knowledgeable and experienced with respect to controlled substances. He has never been accused of any violation, state or federal, of controlled substance statutes. He has always complied with these statutes. Finally, there is no evidence that any of his ''other conduct'' could be a threat to the public safety. Thus, in balancing the five factors under § 823(f), the retention of his registrations would not be inconsistent with the public interest. *Id.* at 15.

Government's Case in Chief

Before presenting witnesses, the Government offered the sworn and notarized COR history for the Respondent, which was admitted without objection. *See* GX 1. The Government otherwise presented its case in chief through the testimony of a single witness. The Government presented the testimony of a Diversion Investigator.

Diversion Investigator (DI)

The DI has worked for the Drug Enforcement Administration for five and a half years and holds a Bachelor's Degree in Accounting and a Master's Degree in Business Administration. Tr. 16–17. She has graduated from the 12-week Basic Diversion Investigator School. *Id.* at 17. She has also received advanced diversion investigator training, tactical diversion training, and asset forfeiture training. *Id.* at 18.

The instant investigation commenced when the DEA learned that the Respondent's Tennessee Nursing license had been suspended by the Tennessee Board of Nursing. *Id.* The DI later learned that the Respondent had been excluded from Medicare, Medicaid and all other federal health care programs by HHS/OIG. The DI obtained a copy of the Respondent's Alford plea of guilty to the Virginia felony offense of False Statement to Medicaid, a copy of the sentencing order and a copy of the Respondent's exclusion letter by HHS/OIG. *Id.* at 19–22; GX 3, 4, 5. The DI verified the Respondent's exclusion by accessing the HHS website. Tr. 23; GX 6. The DI confirmed on the HHS website the exclusion remained active as of the day of the hearing. Tr. 24.

On cross-examination, the DI conceded the instant case did not involve the diversion of controlled substance, nor was she aware of any such violations by the Respondent. *Id.* at 24–25.

Respondent's Case in Chief

Keith A. Jenkins, N.P.

The Respondent, Keith A. Jenkins, is a licensed Advanced Practice Registered Nurse in Tennessee and Ohio. *Id.* at 33; RX 1, 7. He holds DEA registrations in Tennessee and Ohio. Tr. 33, 39–40; RX 4. Other than this instant proceeding, the Respondent has never been disciplined or cautioned by the DEA. Tr. 39, 61. The Respondent has never been admonished, reprimanded or disciplined by any of the state nursing boards regarding his prescribing practices. *Id.* at 61. The Respondent has never been convicted of any offense involving controlled substances. *Id.*

His educational background includes an Associate's Degree in Medical Laboratory Technology from Cumberland College in 1997, an Associate's Degree in Nursing in 2002, a Master's Degree in Nursing and Adult Bariatric Nurse Practitioner in 2014, post-Master's Certificate for Family Nurse Practitioner in 2015, and post-Master's Certificate for Psychiatric Nurse Practitioner in 2017. *Id.* at 28. The Respondent is currently working on his Doctorate, which he expects to complete by January 2020.

The Respondent is an adjunct faculty member in a nurse practitioner program. *Id.* at 28–29; RX 1. He teaches various courses, including Pharmacology. Tr. 41. He works part-time at two clinics, a bariatric clinic, and a primary care psychiatric clinic. *Id.* at 29. The Respondent typically prescribed controlled substances, Phentermine and Qsymia. At the psychiatric clinic, controlled substances typically prescribed include benzodiazepines, such as Clonazepam. Other controlled substances prescribed there include Alprazolam, Ritalin, and Adderall. *Id.* at 30. The Respondent also volunteers at a free clinic and may prescribe, on average, one opioid per month. *Id.* at 31, 80.

The Respondent reported taking precautions in prescribing controlled substances, including checking the state database for patient drug use pattern or use history. *Id.* at 32. Additionally, he requires drug screens if warranted by the results of the database inquiry, as well as randomly. To remain current with obligations regarding prescribing controlled substances, the Respondent reported that he attends at least two medical conferences per year, a number of continuing education courses, and receives regulatory updates. *Id.* at 41, 44; RX 9, 10, 11. His adjunct faculty position also requires him to stay current with prescribing protocol.

The Respondent's Ohio APRN includes the authority to prescribe controlled substances. Tr. 34; RX 7. At the time of the hearing, the Respondent's authority to prescribe in Ohio was unrestricted. However, the Respondent's Tennessee license reflected the disciplinary action of probation, requiring some continuing education as a result of the Virginia state court conviction. Tr. 36; RX 8. The Respondent has completed the required continuing education. Tr. 42–43; RX 9, 10, 11. His Tennessee prescribing authority remained unrestricted. Tr. 36, 60. In September 2019, despite disclosing the circumstances surrounding his Virginia conviction, the Respondent obtained South Carolina nursing licensure. *Id.* at 37–38; RX 12. He retains unrestricted prescribing authority in South Carolina. Tr. 38.

As relates to the Respondent's underlying misconduct, the Respondent worked for Actera Home Health from 2008–2015, as Administrator. *Id.* at 45. He did not generally provide any clinical support or prescribe medication. *Id.*

His employment there ended as a result of an audit by state authorities. The mother of a child patient of the home health service was found to be abusing medication. *Id.* at 46. In response to actions by the service, the mother filed a complaint with state regulators against the home health service, resulting in an investigation and audit. *Id.* Although the investigation revealed no wrongdoing by the service, the audit disclosed a billing discrepancy. A different child patient was signed up for ''personal care'' services. *Id.* at 47, 71, 73–74. The service used an Electronic Medical Record system (EMR) to maintain treatment records and to bill for services. The Respondent explained that the service's EMR system could not directly bill Medicaid, so the service used a secondary billing system to bill Medicaid, which auto billed weekly. *Id.* at 48, 70. The secondary billing system would automatically ''pull claims over'' to it from the EMR. *Id.* at 48, 70–71. Services for this child were initiated and reported in the EMR system, which automatically initiated the Medicaid billing through the secondary billing system. *Id.* at 48, 71, 78. The normal checks and balances within the home

health service involved squaring the care-giver service reports with the billing. *Id.* at 49, 72. If the caregiver reported a cessation of care or change in care, the billing would be ceased or adjusted to reflect that. *Id.* at 78–79. However, in this case, the grandmother/custodian refused to allow care-givers to provide any care at all. As there were no care-giver reports generated, the billing to Medicaid continued automatically. There were no care-giver reports to prompt the review of that patient's billing to Medicaid, [so the audit safeguards never caught the error.] *Id.* at 49, 74–76, 78. The overpayment from Medicaid was approximately $80,000. *Id.* at 48. When the audit revealed this overpayment, Medicaid audited every patient the service billed Medicaid. No other discrepancies were discovered. *Id.* at 53, 78.

The Respondent entered an Alford plea of guilty to false statement to Medicaid. *Id.* at 50, 52. The Respondent understood at the time of his plea that, as Administrator of the home health service, he was ''responsible'' for the improper claims to Medicaid, despite that he did not personally enter the claims. *Id.* at 50, 69. His sentence was three years suspended, three years inactive probation, and $83,027.56 in restitution. *Id.* at 51–52, 63. I asked the Respondent if he realized, at the time he plead guilty, the criminal offense of false statement to Medicaid required the intent of intentional or willful. The Respondent reported that his criminal attorney handled the plea negotiation and recommended the Respondent view the guilty plea as a ''business decision.'' *Id.* at 68–69. [Respondent stated, ''Since they never got a record on him, it never got caught. In hindsight, it was a huge gap on our end or my end, really, that let that slip through.'' *Id.* at 49. His attorney asked, ''So whose fault was it?'' *Id.* ''Well, mine.'' *Id.*]

Conceding the Government proved its *prima facie* case, the Respondent argued that he should be permitted to keep his CORs. *Id.* at 57. He explained that the incident that gave rise to the felony conviction and the resultant HHS exclusion was [''an isolated incident, it wasn't intentional but [he does] realize that in [his] acting role as administrator, ultimately, it is [his] responsibility.''] *Id.* at 58, 67. The Respondent did not have clinical duties at the service. He did not supervise the line care providers. They were supervised by the nursing director. *Id.* at 77–78. Although he had access to the billing records in the form of an electronic report, his duties did not include reviewing the accuracy of the billing report. *Id.* at 78. The accuracy of the billing was insured by periodic audits, which failed them in this case. *Id.* The Respondent did not benefit from the overpayment,[*B] other than his salary.

For his Tennessee APRN, a physician supervisor is required. *Id.* at 59. The Respondent has a physician supervisor at each clinic where he works. *Id.* at 63–64. Although supervision is required once a month, he works closely with his physician supervisor and sees him weekly. The supervisor critically reviews patient charts and must sign off on each controlled substance prescription. *Id.* at 59. The Respondent reported that his supervisors have yet to reject any of the Respondent's prescriptions. *Id.* at 65.

The Respondent reported that he has not used his Ohio nursing license. He has not worked in Ohio. *Id.* at 66.

The Respondent stated he remains fully compliant with state and federal controlled substance laws and regulations. *Id.* at 61. The Respondent noted he was an infrequent prescriber of controlled substances. *Id.* The Respondent believed it is in the public interest for him to retain his registrations.

The Facts

Stipulations of Fact

The Government and the Respondent have agreed to each of the following stipulations, which I recommend be accepted as fact in these proceedings:

1. Respondent is registered with the DEA as a MLP-nurse practitioner in Schedules II through V under DEA Certificate of Registration MJ3401609 at 105 Vanner Rd., Mt. Juliet, TN 37122. Respondent is also registered with the DEA under DEA Certificate of Registration MJ4509331 at 3909 Woodley Rd., Toledo, OH 43606, with a mailing address of 105 Vanner Rd., Mt. Juliet, TN 37122. Respondent's registrations both expire by their terms on December 31, 2020. Prior to the current action, Respondent's DEA Certificates of Registration have not been the subject to disciplinary or other adverse action by the DEA.

2. From 2006 to 2013, Respondent worked in an administrative, non-clinical, capacity for a Virginia-based home health agency. While employed at the home health agency, the agency was audited by state Medicaid authorities and Respondent's role in the billing of claims for a specific patient were investigated by the state. On August 7, 2017, Respondent entered an ''Alford Plea of Guilty to a Felony'' to the offense of ''False Statement to Medicaid.'' On August 11, 2017, the Circuit Court of Fairfax County, Virginia, entered its sentencing Order for Respondent's offense of ''False Statement of Payment(F)'' in violation of Va. Code Section 32.1–314(F) FRD3337F9. *Commonwealth of Virginia* v. *Keith Allen Jenkins,* No. FE–2017–0000711 (Fairfax Cty. Cir. Ct.). Mr. Jenkins was sentenced to ''3 years w/all 3 years suspended.'' Furthermore, the Court Ordered that all ''3 years [were subject to] inactive probation.'' Simply put, Mr. Jenkins was not incarcerated, nor is he required to report to a Probation Officer during the period of his 3-year suspended sentence.

3. Based on Respondent's conviction, the U.S. Department of Health and Human Services, Office of Inspector General (''HHS/OIG''), by letter dated February 28, 2018, mandatorily excluded Respondent from participation in Medicare, Medicaid and all federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a–7(a), effective March 20, 2018.

4. Reinstatement of eligibility to participate in Medicare, Medicaid and all federal health care programs after exclusion by HHS/OIG is not automatic.

5. Respondent is currently excluded from participation in Medicare, Medicaid and all federal health care programs.

6. Restitution in the amount of $83,027.56 to the Medicaid program was ordered by the Court. The restitution was paid in full by the time of Respondent's Alford Plea filing.

7. On April 23, 2019, the Assistant Administrator, Diversion Control Division, DEA, issued an Order to Show Cause to Respondent, giving Respondent notice of an opportunity to show cause why the DEA should not revoke Respondent's DEA Certificates of Registration Nos. MJ3401609 (Tennessee) and MJ4509331 (Ohio), pursuant to 21 U.S.C. 824(a)(5), and deny any pending application(s) as a practitioner for registration in Schedules II through V, alleging that Respondent has been excluded from participation in all federal health care programs as defined in 21 U.S.C. 824(a)(5).

8. On May 16, 2019, Respondent, through his legal counsel, filed a timely request for administrative hearing in the Matter of Keith A. Jenkins, N.P.

9. On May 17, 2019, the Administrative Law Judge (ALJ) assigned to this case issued the Court's Order for Prehearing Statements to the DEA and Respondent.

10. On May 29, 2019, counsel for the Government filed the Government's

[*B] This fact seems to be reasonably inferred from the record. The clinic paid restitution ''immediately once it was identified.'' Tr. 52.

Prehearing Statement. Concurrent with this filing, counsel also filed the Government's Motion for Summary Disposition.

11. On May 30, 2019, Respondent filed an Unopposed Motion for Extension of Time to Submit Respondent's Prehearing Statement and Respondent's Response to the Government's Motion for Summary Disposition.

12. On May 31, 2019, the Court issued its Order Granting Respondent's Unopposed Motion for Extension of Time until June 21, 2019 at 2:00 p.m. EST.

13. Respondent is currently licensed by the Ohio Board of Nursing to practice as an Advanced Practice Registered Nurse (APRN), license number APRN.CNP.021771. The Respondent's Ohio APRN license includes the authority to prescribe.

14. Respondent is currently licensed by the Tennessee Board of Nursing to practice as an Advanced Practice Registered Nurse, license no. 19606. Respondent's Tennessee APRN license is currently on probation but is unrestricted.

15. At this time, Respondent's DEA Certificates of Registration in Ohio and Tennessee are active and he is authorized to prescribe controlled substances in Schedules II through V.

Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

1. Respondent is registered with the DEA as a MLP-nurse practitioner in Schedules II through V under DEA Certificate of Registration MJ3401609 at 105 Vanner Rd., Mt. Juliet, TN 37122. Respondent is also registered with the DEA under DEA Certificate of Registration MJ4509331 at 3909 Woodley Rd., Toledo, OH 43606, with a mailing address of 105 Vanner Rd., Mt. Juliet, TN 37122. Stipulation (''Stip.'') l; ALJ Ex. 13 at 10. Respondent's registrations both expire by their terms on December 31, 2020. *Id.* Prior to the current action, Respondent's DEA Certificates of Registration have not been the subject of disciplinary or other adverse action by the DEA. *Id.*

2. On August 7, 2017, Respondent entered an ''Alford Plea of Guilty to a Felony'' to the offense of ''False Statement to Medicaid.'' Stip. 2; ALJ Ex. 13 at 10. On August 11, 2017, the Circuit Court of Fairfax County, Virginia, entered its sentencing Order for Respondent's offense of ''False Statement for Payment (F)'' in violation of Va. Code Section 32.1–314(F) FRD3337F9. *See Commonwealth of Virginia* v. *Keith Allen Jenkins,* No. FE–2017–0000711 (Fairfax Cty. Cir. Ct.).

3. Based on Respondent's conviction, the U.S. Department of Health and Human Services, Office of Inspector General (''HHS/OIG''), by letter dated February 28, 2018, mandatorily excluded Respondent from participation in Medicare, Medicaid and all federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a–7(a), effective March 20, 2018. Stip. 3; ALJ Ex. 13 at 10–11.

4. Reinstatement of eligibility to participate in Medicare, Medicaid and all federal health care programs after exclusion by HHS/OIG is not automatic. Stip. 4; ALJ Ex. 13 at 11.

5. Respondent is currently excluded from participation in Medicare, Medicaid and all federal health care programs. Stip. 5; ALJ Ex. 13 at 11.

6. Restitution in the amount of $83,027.56 to the Medicaid program was ordered by the Court. Stip. 6; ALJ Ex. 13, at 11.

7. On April 23, 2019, the Assistant Administrator, Diversion Control Division, DEA issued an Order to Show Cause to Respondent, giving Respondent notice of an opportunity to show cause why the DEA should not revoke Respondent's DEA Certificates of Registration Nos. MJ3401609 (Tennessee) and MJ4509331 (Ohio), pursuant to 21 U.S.C. 824(a)(5), and deny any pending application(s) as a practitioner for registration in Schedules II through V, alleging that Respondent has been excluded from participation in all federal health care programs as defined in 21 U.S.C. 824(a)(5). Stip. 7; ALJ Ex. 13 at 11.

8. On May 16, 2019, Respondent, through his legal counsel, filed a timely request for administrative hearing in the Matter of Keith A. Jenkins, N.P. Stip. 8; ALJ Ex. 13 at 11.

9. On May 17, 2019, the Administrative Law Judge (ALJ) assigned to this case issued the Court's Order for Prehearing Statements to the DEA and Respondent. Stip. 9; ALJ Ex. 13 at 11.

10. On May 29, 2019, counsel for the Government filed the Government's Prehearing Statement. Stip. 10; ALJ Ex. 13 at 11. Concurrent with this filing, counsel also filed the Government's Motion for Summary Disposition. *Id.*

11. Respondent is currently licensed by the Ohio Board of Nursing to practice as an Advanced Practice Nurse (APRN), license number APRN.CNP.021771. Stip. 13; ALJ Ex. 13 at 12.

12. The Respondent's Ohio APRN license includes authority to prescribe. *Id.*

13. Respondent is currently licensed by the Tennessee Board of Nursing to practice as an Advanced Practice Registered Nurse, license no. 19606. Stip. 14; ALJ Ex. 13 at 12. Respondent's Tennessee APRN license is currently on probation but is unrestricted. *Id.*

14. At this time, Respondent's DEA Certificates of Registration in Ohio and Tennessee are active and he is authorized to prescribe controlled substances in Schedules II through V. Stip. 15; ALJ Ex. 13 at 12.

15. Respondent testified that he works at a bariatric clinic where he predominately treats morbid obesity and typically prescribes Phentermine and Qsymia to those patients. Tr. 29.

16. He also works at a primary behavioral health clinic where he treats depression, anxiety, schizophrenia, bipolar disorder, personality disorders, and substance abuse disorders and prescribes benzodiazepines such as Clonazepam and Alprazolam, as well as stimulants such as Ritalin and Adderall. *Id.* at 30.

17. Respondent testified that at both the bariatric clinic and the behavioral health practice where he works, drug screens are performed to ensure that diversion doesn't occur. *Id.* at 32.

18. Respondent testified that although he holds two DEA Certificates of Registration, he does not use his registration for Ohio. *Id.* at 39.

19. Respondent testified that to remain current in his knowledge of, and obligations with respect to, controlled substances and prescribing he attends conferences and takes continuing education. *Id.* at 41–42; RX 9; RX 11.

20. Respondent testified that from 2008 to 2015 he worked at Actera Home Health, which was a home health agency that provided skilled care, private duty and personal care. Tr. 45.

21. Respondent testified that he did not generally provide clinical support at Actera Home Health, nor did he write prescriptions there. *Id.*

22. Respondent testified that the mother of a child receiving services at Actera Home Health lodged a complaint against Actera Home Health. *Id.* at 46.

23. Respondent testified that the complaint was not substantiated. *Id.*

24. During investigation of the complaint by the state of Virginia a billing error was discovered for a different patient. *Id.* at 46, 71.

25. Respondent testified that the billing error was an overpayment of approximately $80,000. *Id.* at 48.

26. Respondent testified that the service's billing checks-and-balance

system failed to disclose an improper billing to Medicaid. Once the initiation of a patient's treatment is entered into the Electronic Medical Record (EMR), which triggers automatic billing, in this case to Medicaid, that billing continues until a treatment report noting cessation of treatment triggers the termination of billing. Here, the patient's guardian refused treatment for the patient. So, no treatment reports were ever generated and automatic billing to Medicaid continued, despite no treatment being provided. *Id.* at 48, 71, 74.

27. Respondent testified that ''it was a huge gap on our end or my end, really, that let that slip through.'' *Id.* at 49.

28. Respondent testified that the fault was ''mine'' and that it was ''my responsibility.'' *Id.*

29. Respondent testified that he entered an Alford plea regarding this incident. *Id.* at 29; GX 3.

30. Respondent testified that he entered the Alford plea because ''I did not personally go enter these claims, but I am responsible for it as the administrator.'' Tr. 50.

31. Respondent testified that he was sentenced to three years, but it was suspended and he served no time in jail. *Id.* at 51.

32. Respondent testified that he was put on probation for three years, which remains in effect for another year. *Id.* at 51–52.

33. Respondent testified that the clinic paid restitution of $83,027.67. *Id.* at 42; GX 3.

34. Respondent testified that his Alford plea resulted in his conviction of a felony for a ''false statement to Medicaid.'' Tr. 52.

35. Respondent testified that he was excluded by the HHS/OIG from Medicare and Medicaid. *Id.* at 54, 57; GX 5.

36. Respondent testified that his false statement to Medicaid ''was an isolated incident,'' ''wasn't intentional'' but that as administrator ''it is my responsibility.'' Tr. 58.

37. Respondent testified that ''[t]he Board of Nursing did not deem me a threat to public welfare and safety'' and that he has ''no criminal background at all with substances.'' *Id.*

38. Respondent testified that he ''absolutely'' accepts responsibility for the misconduct. *Id.* at 58, 67.

39. Respondent testified that he considers his criminal conviction to be a serious violation. *Id.* at 67.

40. Respondent testified that he is remorseful for his violation. *Id.* at 58, 67.

41. Respondent testified that this violation will not happen again because he no longer works in administrative roles, but instead provides direct patient care and does no billing. *Id.* at 58.

42. Respondent testified that he also has a physician supervisor who provides oversight. *Id.* at 58–59. Respondent testified that, under Tennessee law, his physician supervisor must sign off on every controlled substance prescription that he writes. *Id.* at 59, 65.

43. Respondent testified that his Tennessee nursing license is on probation, but that he has no restrictions on his practice or on prescribing. *Id.* at 60.

44. Respondent testified that none of the allegations against him from the home health agency involved controlled substances. *Id.*

45. Respondent testified that his probation is scheduled to end in August 2020. *Id.* at 64; GX 4.

Analysis

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked and any pending applications be denied because the Respondent has been excluded from all federal health care programs, pursuant to 21 U.S.C. 824(a)(5). The Agency has held that section 824(a)(5) authorizes the revocation of existing registrations, as well as the denial of applications. *Dinorah Drug Store, Inc.,* 61 FR 15,972 (1996); *Kuen H. Chen, M.D.,* 58 FR 65,401 (1993).

In the adjudication of a revocation or suspension of a DEA COR, DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 CFR 1301.44(e) (2010). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). Where the Government has sustained its burden, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he/she can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Acting Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie* v. *DEA,* 419 F.3d 477, 481 (6th Cir. 2005). The Supreme Court has defined 'substantial evidence' as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consolidated Edison Co. of New York* v. *National Labor Relations Board,* 305 U.S. 197, 229 (1938). While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Acting Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989); *Trawick* v. *DEA,* 861 F.2d 72, 77 (4th Cir. 1988*),* all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys* v. *DEA,* 96 F.3d 658, 663 (3rd Cir. 1996). The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall* v. *DEA,* 412 F.3d 165, 183 (D.C. Cir. 2005), but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Acting Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Acting Administrator and do not limit the

exercise of that discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 1947).

Exclusion Under 42 U.S.C. 1320a–7(a)

The Government has alleged that the Respondent has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42. The Government can meet its burden under § 824(a)(5) simply by advancing evidence that the registrant has been excluded from a federal health care program under 42 U.S.C. 1320a–7(a). *Johnnie Melvin Turner, M.D.,* 67 FR 71,203 (2002); *Dinorah Drug Store, Inc.,* 61 FR at 15,973. The Administrator has sanctioned registrants where the Government introduced evidence of a registrant/applicant's plea agreement and judgment, and the resulting letter of exclusion from the U.S. Department of Health and Human Services, Office of Inspector General, imposing mandatory exclusion under section 1320a–7(a). *See Richard Hauser, M.D.,* 83 FR 26,308 (2018).

Additionally, the Agency has consistently held that the underlying conviction that led to mandatory exclusion does not need to involve controlled substances to support a revocation or denial. *See, e.g., Mohammed Asgar, M.D.,* 83 FR 29,569 (2018); *Narciso A. Reyes, M.D.,* 83 FR 61,678 (2018); *Richard Hauser, M.D.,* 83 FR at 26,308; *Orlando Ortega-Ortiz, M.D.,* 70 FR 15,122 (2005); *Juan Pillot-Costas, M.D.,* 69 FR 62,804 (2004). However, evidence that the underlying conviction does not relate to controlled substances can be used in mitigation. *Mohammed Asgar, M.D.,* 83 FR at 29,573 (noting respondent's conviction ''did not involve the misuse of his registration to handle controlled substances''); *Kwan Bo Jin, M.D.,* 77 FR 35,021, 35,027 (2012) (showing a lack of evidence concerning respondent's ''prescribing practices'').[ ] *C

Government's Burden of Proof and Establishment of a Prima Facie Case

Based upon my review of the allegation by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a).

It is clear from the stipulations, the Government's evidence, and the Respondent's position in this matter that there is no controversy between the parties that the Respondent was convicted of the underlying criminal charge in Virginia State court, and was subsequently mandatorily excluded from all federal health care programs by HHS/OIG, pursuant to 42 U.S.C. 1320a–7(a). The Government's evidence clearly demonstrates the necessary elements of proof under 21 U.S.C. 824(a)(5) and I find that the Government has established a *prima facie* case for revocation of the Respondent's COR and denial of any pending applications.

Therefore, the remaining issue, and the central focus for determination in this matter, is whether the Respondent has sufficiently demonstrated that he has accepted responsibility for his actions, has demonstrated remorse and taken sufficient rehabilitative and remedial steps, to demonstrate to the Acting Administrator that he can be entrusted to maintain his COR. *Kwan Bo Jin, M.D.,* 77 FR at 35,021. The Agency must determine whether revocation is the appropriate sanction ''to protect the public from individuals who have misused controlled substances or their DEA Certificate of Registration and who have not presented sufficient mitigating evidence to assure the Administrative that they can be trusted with the responsibility carried by such a registration.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,973 (2019) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). ''The Agency also looks to the nature of the crime in determining the likelihood of recidivism and the need for deterrence.'' *Id.* In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offenses established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38,363, 38,364, 38,385 (2013).[ ] *D

Acceptance of Responsibility and Rehabilitative Measures

The Government's *prima facie* burden having been met, [ ] *E the Respondent must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007).[ ] *F

The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a prima facie case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30,630, 30,644 (2008); *Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009).

Since the discovery of the overpayment, the Respondent has maintained a consistent posture of acknowledging the impropriety and illegality of his actions, and of cooperation with the Government in resolving the matter.*G He has fully accepted responsibility for his conduct, which led to the underlying criminal conviction, both in his criminal prosecution, as well as in the instant proceeding. Tr. 58, 67; FoF 37. The Respondent testified credibly during the hearing when asked if he accepted responsibility for his misconduct: ''Absolutely. If I could go back and fix it, I would.'' Tr. 58. When directly asked by Government counsel during cross-examination if he accepted responsibility, he stated, ''absolutely.'' *Id.* at 67; FoF 37. The Respondent has further demonstrated remorse for his crime. Tr. 67; FoF 39.

[Moreover, it is noted that Respondent's crime did not directly benefit Respondent and appears to have been a mistake that Respondent was not aware was occurring. Even so, Respondent did not at any point attempt to shift the blame to anyone, he never tried to cover up his offense or lie, and he credibly maintained that even though his actions were unintentional and indirect, he was still fully responsible in his role as the Administrator for a mistake that happened under his watch. Respondent credibly demonstrated remorse, and I find that he unequivocally accepted responsibility. When asked how much restitution he

*C Language omitted for clarity.

*D Analysis of public interest factors omitted for relevance.

*E Omitted text for clarity.

*F Omitted additional public interest analysis.

*G At the advice of his attorney, Respondent entered an Alford plea of guilty to the felony offense of false statement to Medicaid. Although entering this type of plea could be viewed as mitigating his actions, I do not find this to diminish Respondent's acceptance of responsibility in this case. When asked if he had realized that the offense involved knowing or willful intent, Respondent replied that his attorney had handled the plea negotiation and had recommended that he view the Alford plea as a ''business decision.'' Tr. at 68–69. With regard to his Alford plea specifically, he stated, ''my interpretation of it was essentially that I did not personally go enter these claims, but I am responsible for it as the administrator.'' *Id.* at 50. As such, I find that Respondent made it clear that he was following the legal advice that his lawyer had given him regarding a particular legal element of his offense and that his understanding was that he was still taking responsibility. Therefore, in spite of Respondent's Alford plea, I find that he consistently and completely accepted responsibility.

paid as a result of his criminal sentence, he answered precisely to the cent. Tr. 51. When he talked about the mistake in the billing, he corrected himself when he initially said ''we,'' and stated unequivocally that it was ''really'' him. *Id.* 49. In a situation such as this one that involved a mistake, it would have been very easy for Respondent to have shifted the blame or mitigated the circumstances surrounding his crime, but he unfalteringly maintained that it was his responsibility.] [*H]

Additionally, Respondent has consistently demonstrated that he has taken the necessary steps to correct the error. The Respondent has returned to clinical care, and is not involved in billing or any other administrative responsibility. [Respondent recognized that he should not hold a management or administrative position and Respondent changed his practice area. By doing so, Respondent has made the effort to ensure that there is no recurrence of his mistake in the future. I find this to be further evidence of his acceptance of responsibility that demonstrates that he has taken active steps to prevent future mistakes. He also attends a few conferences a year, receives regulatory update mailings, and stated that his role as adjunct faculty ''forces [him] to stay current.'' *Id.* at 41.] [*I]

Although correcting improper behavior and practices is very important to establish acceptance of responsibility, conceding wrongdoing is critical to reestablishing trust with the Agency. *Holiday CVS, L.L.C.,* 77 FR 62,316, 62,346 (2012); *Daniel A. Glick, D.D.S.,* 80 FR at 74,801. Based upon the evidence presented, I find that the Respondent has demonstrated the full measure of acceptance of responsibility, and has fully demonstrated that he is remorseful for his actions and has taken considerable steps to ensure that this conduct will not be repeated.

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe,* 73 FR at 387.

As demonstrated by the evidence presented in this matter, it is clear to me that the Respondent has unequivocally accepted responsibility for his conduct. His underlying criminal conduct did not relate to his handling of controlled substances and the Government has not alleged or demonstrated any deficiencies by the Respondent related to controlled substance. [] [*J]

There is no indication that the Respondent has ever improperly handled controlled substances or that he represents a danger to the public. Based upon the evidence presented, and consistent with *Jackson, Miller,* and *Stein,* the Respondent has clearly demonstrated that he can be entrusted to properly maintain his COR.

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. However, [] [*K] the evidence suggests that the Respondent has unequivocally accepted responsibility, is remorseful for his conduct, has withdrawn from any responsibilities related to billing or other administrative duties, and has presented convincing evidence demonstrating that the Agency can entrust him to maintain his COR.

Therefore, I recommend the Respondent's DEA Certificates of Registration MJ3401609 and MJ4509331 should *not be revoked* and any pending applications for renewal or modification of such registration, or for additional DEA registrations, be *granted*.

Signed: February 19, 2020.

Mark M. Dowd,
U.S. Administrative Law Judge

[FR Doc. 2021–14163 Filed 7–1–21; 8:45 am]

BILLING CODE 4410–09–P

[*H] Language added.

[*I] Language added.

[*J] Language omitted for clarity.

[*K] Omitted text for clarity.

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0045]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection; Customer Satisfaction Assessment Survey

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Laboratory Division (LD) has submitted the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the established review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

DATES: The Department of Justice encourages public comment and will accept input until August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Customer Satisfaction Assessment.

3. *The agency form number:* FD–1000.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents primarily include federal, state, and local law enforcement. Respondents also include the intelligence community, Department