SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 (''Section 337'') provides that if the Commission finds a violation it shall exclude the articles concerned from the United States unless the public interest factors listed in 19 U.S.C. 1337(d)(1) prevent such action. A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting comments on public interest issues raised by the recommended relief should the Commission find a violation, specifically: (1) A general exclusion order (''GEO'') directed to certain child resistant closures with slider devices having a user actuated insertable torpedo for selectively opening the closures and slider devices therefor imported, sold for importation, and/or sold after importation that infringe one or more of claims 1, 3, 5, and 8–10 of U.S. Patent No. 9,505,531; claims 1, 4, 6–8, 11, 12, 15, and 19 of U.S. Patent No. 9,554,628; and claims 1, 3, 5, and 8 of U.S. Patent No. 10,273,058; and (2) if the Commission declines to issue a GEO, then a limited exclusion order (''LEO'') directed to certain child resistant closures with slider devices having a user actuated insertable torpedo for selectively opening the closures and slider devices therefor imported, sold for importation, and/or sold after importation by defaulting respondents Dalian Takebishi Packing Industry Co., Ltd. of Dalian, China and Dalian Altma Industry Co., Ltd. of Dalian, Liaoning, China that infringe one or more of the above claims.

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4). In addition, members of the public are hereby invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on April 21, 2020. Comments should address whether issuance of the remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended GEO and LEOs are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the recommended GEO and LEOs;

(iii) Identify like or directly competitive articles that complainant, its licensees, and/or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, its licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended GEO and LEOs within a commercially reasonable time; and

(v) Explain how the recommended GEO and LEOs would impact consumers in the United States.

Written submissions from the public must be filed no later than by close of business on May 21, 2020.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1171'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary ((202) 205–2000). Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 23, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–09031 Filed 4–28–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kansky J. Delisma, M.D.; Decision and Order

On May 23, 2019, the Drug Enforcement Administration (hereinafter, DEA or Government) Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ), issued a Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, RD) on the action to deny Kansky J. Delisma, M.D.'s application for a DEA Certification of Registration. The Government filed exceptions to the RD to which Dr. Delisma responded. Having reviewed and considered the entire administrative record before me, including the Government's Exceptions, I adopt the ALJ's RD with minor modifications, where noted herein.*A

Government's Exceptions

The Government filed an exception (hereinafter, Govt Exceptions) to the ALJ's interpretation and application of 21 U.S.C. 824(a)(5) and that provision's interplay with 42 U.S.C. 1320a–7(a). Govt Exceptions, at 2. Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration ''may be suspended or revoked'' upon a finding of one or more of five grounds. 21 U.S.C. 824. The ground in 21 U.S.C. 824(a)(5) requires that the registrant

*A I have made minor modifications to the RD. I have substituted initials for the names of witnesses to protect their privacy, and I have made minor, nonsubstantive grammatical changes. 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.

''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' *Id.* 42 U.S.C. 1320a–7(a) provides a list of four predicate offenses for which exclusion from Medicare, Medicaid and federal health care programs is mandatory and sets out mandatory timeframes for such exclusion. *Id.*[*B]

The Government argues that in cases brought pursuant to 21 U.S.C. 824(a)(5), the statutory language *requires* DEA to ''revoke a respondent's registration (or deny a respondent's application) once the Government has proven that respondent is currently mandatorily excluded from participation in Federal health care programs and that DEA should not permit a respondent to have a DEA registration for as long as the respondent has been excluded.'' Govt Exceptions, at 2. As the Government noted in its brief, the Government advocated for this position in several contemporaneous exclusion cases. *Id.* at n.2. Since the Government filed its brief, I have issued a Decision and Order in one of the other exclusion cases, *Jeffrey Stein, M.D.,* that directly addressed and rejected the Government's argument. 84 FR 46968 (2019).

The clear language of 21 U.S.C. 824(a)—''[a] registration . . . may be suspended or revoked by the Attorney General''—gives the Administrator the *discretion* to revoke the registration of a registrant who has been excluded from participation in Federal health programs. *Stein,* 84 FR at 46970–71 (providing detailed analysis of the language and legislative history of 21 U.S.C. 824(a)(5)). It does not require automatic revocation or denial on that ground. *Id.*

Accordingly, although section 824(a) provides DEA with the authority to revoke a respondent's registration upon a finding of one or more of the five listed grounds, if a respondent presents evidence, either in a written statement or in the context of a hearing, I will review the evidence provided by the respondent to determine whether revocation or suspension is appropriate given the particular facts. *See* 5 U.S.C. 556(d) (''A party is entitled to present his case or defense by oral or documentary evidence.''); 21 CFR 1301.43(c) (permitting a Respondent to file ''a waiver of an opportunity for a hearing . . . together with a written statement regarding such person's position on the matters of fact and law involved in such hearing.''); *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 829 (11th Cir. 2018) (''[W]e may set aside a decision as 'arbitrary and capricious when, among other flaws, the agency has . . . entirely failed to consider an important aspect of the problem.' ''); *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 177 (D.C. Cir. 2005) (''To uphold DEA's decision, . . . we must satisfy ourselves 'that the agency ''examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.' ''). Where, as in the instant case, the Government has made a *prima facie* case to suspend or revoke a registration based on a mandatory exclusion pursuant to section 1320a–7(a) of Title 42, I review any evidence and argument the respondent submitted to determine whether or not respondent has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)).[*C]

As I explained in *Stein,* the Government's proposed reading of the CSA would also ''be a significant departure from past Agency decisions.'' 84 FR at 46970; *see, e.g., Kwan Bo Jin, M.D.,* 77 FR 35021, 35023 (2012); *Dinorah Drug Store, Inc.,* 61 FR 15972, 15974 (1996).

For the above reasons, I reject the Government's exception and issue the Order below adopting the recommendations of the ALJ.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823, I hereby order that the pending application for a Certificate of Registration, Control Number W18071098C, submitted by Kansky J. Delisma, M.D., is approved. This Order is effective May 29, 2020.

Uttam Dhillon,

Acting Administrator.

Paul E. Soeffing, Esq., for the Government.

Laura Perkovic, Esq. and Jeremy L. Belanger, Esq., C.H.C., for the Respondent.

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

On January 17, 2019, the Drug Enforcement Administration served Kansky J. Delisma, M.D. (''Dr. Delisma'' or ''Respondent'') with an Order to Show Cause (''OSC''), proposing to deny his application for a DEA Certificate of Registration (''COR''), Control Number W18071098C. Administrative Law Judge Exhibit (''ALJ–'') 1, at 1. The OSC alleged that denial is warranted under 21 U.S.C. 824(a)(5), because Dr. Delisma is excluded from federal health care programs pursuant to 42 U.S.C. 1320a–7(a). In response to the OSC, Dr. Delisma timely requested a hearing before an Administrative Law Judge. ALJ–2. The hearing that Dr. Delisma requested was held in Pittsburgh, Pennsylvania, on April 18, 2019.

The issue before the Acting Administrator is whether the record as a whole establishes by a preponderance of the evidence that DEA should deny the application for a Certificate of Registration of Kansky J. Delisma, M.D., Control Number W18071098C, and deny any pending application 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 he has been excluded from federal health care programs under 42 U.S.C. 1320a–7(a). ALJ–10, at 1.

This Recommended Decision is based on my consideration of the entire Administrative Record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

The Allegation

1. On May 31, 2016, judgment was entered against Dr. Delisma based on his guilty plea to one count of ''Receipt of Kickbacks in Connection with a Federal Health Care Program,'' in violation of 42 U.S.C. 1320a–7b(b)(1)(A). Based on this conviction for health care fraud, the U.S. Department of Health and Human Services, Office of Inspector General (''HHS/OIG''), by letter dated August 31, 2016, mandatorily excluded Dr. Delisma from participation in Medicare, Medicaid, and all federal health care programs for the minimum statutory period of five years pursuant to 42 U.S.C. 1320a–7(a), effective September 20, 2016. ALJ–1, at 2. Despite the fact that the underlying conduct for which Dr. Delisma was convicted did not involve controlled substances, his mandatory exclusion from Medicare, Medicaid, and all federal health care

[*B] Although the language of 21 U.S.C. 824(a)(5) discusses suspension and revocation of a registration, it may also serve as the basis for the denial of a DEA registration application. *Dinorah Drug Store, Inc.,* 61 FR 15972–03, 15973 (1996).

[*C] The Government correctly argues, and Respondent did not rebut, that the underlying conviction forming the basis for a registrant's mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation pursuant to section 824(a)(5). *Stein* at 46971–72; *see also Narciso Reyes, M.D.,* 83 FR 61678, 61681 (2018); *KK Pharmacy,* 64 FR at 49510 (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60727, 60728 (1996).

programs warrants denial of his application for DEA registration pursuant to 21 U.S.C. 824(a)(5). ALJ–1, at 2, paras. 2–3.

Witnesses

I. The Government's Witnesses

Because Respondent stipulated to the admissibility of all of the Government's Exhibits, the Government called no witnesses. Stipulation (''Stip.'') 12. Rather, the Government moved the admission of Government Exhibits 1–4, and upon their admission into the Administrative Record, the Government rested its case. Transcript (''Tr.'') 14–15.

II. Respondent's Witnesses

Respondent presented his case through two witnesses. The Respondent was the first witness. Tr. 17–57. In his testimony, Dr. Delisma provided background information about his education and training. Tr. 17–20. He explained that he decided to go into medicine out of a ''true calling from inside to serve.'' Tr. 20. As such, after completing his medical education, he began his medical practice working at a Veteran's Hospital and a public health hospital in Miami, Florida. *Id.* He first obtained a DEA Certificate of Registration in 2004 and kept it until it expired in 2016. Tr. 28, 43–44.

Dr. Delisma went into a private, internal medicine practice in 2008–09. Tr. 20. While in that private practice, he accepted a kickback of $700. for referring a patient to a home-health provider. Tr. 28–29. Because of that action, following his guilty plea, Dr. Delisma was convicted in Federal Court of a single count of accepting a kickback. *Id.* For that crime, Dr. Delisma was sentenced to eight months confinement, to pay a $5,000. fine, fees of $100., and restitution of $49,000., and following his confinement, he was placed on one year of supervised release. Tr. 29. Dr. Delisma has satisfied all the terms of his sentence. *Id.* Because of his conviction, Dr. Delisma was excluded from participation in federal health care programs. Tr. 33–36.

Although Dr. Delisma allowed his Florida medical license to expire, he later obtained licenses to practice medicine in Pennsylvania, Montana, New York, and Maryland. Tr. 36–39. At the time he applied for a license in each state, he informed the licensing board of his conviction and none placed any restrictions on his medical license. Tr. 38–39. He currently works as the Medical Director at the State Correctional Institution in Somerset, Pennsylvania, and he has requested a Certificate of Registration for that location. Tr. 20–21, 49. He is the only full-time physician who works at that facility. Tr. 50–51. There have been times when his inmate patients have had to wait to obtain prescriptions for controlled substances. Tr. 52–54.

Dr. Delisma has taken three continuing medical education courses, all related to medical ethics. Tr. 39–41, 44–45. He also accepted responsibility for his actions, and expressed his remorse. Tr. 29, 42.

Dr. Delisma presented his testimony in a clear, candid, and convincing manner. He impressed me as sincere in his acceptance of responsibility and his remorse. I find his testimony to be entirely credible.

The Respondent's second witness was Dr. A.D. Tr. 58–70. Dr. A.D. is the Regional Medical Director for the Central Region of the Pennsylvania Department of Corrections. Tr. 59. He has known Dr. Delisma since shortly before Dr. Delisma was hired into his current job. *Id.* Dr. A.D. wanted to meet and interview Dr. Delisma upon reviewing his ''remarkable'' credentials. Tr. 60.

Dr. A.D. testified concerning the fine quality of work Dr. Delisma has performed as the medical director at Somerset. Tr. 60, 64, 68. He considers Dr. Delisma to be ''one of our top physicians.'' Tr. 60. Dr. A.D. also testified that Dr. Delisma's lack of a Certificate of Registration adversely impacts the quality of medical care he is able to provide to the inmates. Tr. 62–64, 67–68. In fact, it was Dr. A.D. who suggested that Dr. Delisma apply for a Certificate of Registration. Tr. 70; RE–10, at 1.

Dr. A.D. presented his testimony in a clear, candid, and convincing manner. His testimony also corroborated substantial portions of Dr. Delisma's testimony. Accordingly, I find his testimony to be entirely credible.

The Facts

I. Stipulations

The Parties agree to 12 stipulations, which are accepted as facts in these proceedings:

1. Respondent applied to DEA for registration as a practitioner in Schedules II through V pursuant to DEA control number W18071098C, with a proposed registered address of 1590 Walters Mill Rd., Somerset, PA 15510 and a proposed mailing address of 600 N 12th Street, Lemoyne, PA 17043. Respondent submitted his online application on or about July 9, 2018.

2. On May 31, 2016, judgment was entered against Respondent in the United States District Court for the Southern District of Florida based on his guilty plea to one count of ''Receipt of Kickbacks in Connection with a Federal Health Care Program,'' in violation of 42 U.S.C. 1320a–7b(b)(l)(A).

3. HHS/OIG, by letter dated August 31, 2016, mandatorily excluded Respondent from participation in Medicare, Medicaid and all federal health care programs for the minimum statutory period of five years pursuant to 42 U.S.C. 1320a–7a. The exclusion was effective September 20, 2016.

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. Since Respondent's criminal conviction, he has satisfied all assessments, fines, and restitution as of August 22, 2017. Tr. 10–11.

7. On April 24, 2018, the Florida Board of Medicine settled its case with Respondent by issuing a Letter of Concern and by requiring Respondent to pay a fine.

8. Respondent was issued a medical license by the Pennsylvania Bureau of Professional and Occupational Affairs as of March 22, 2018.

9. Respondent was issued a medical license by the New York State Education Department on July 2, 2018.

10. Respondent was issued a medical license by the Maryland Board of Physicians on June 19, 2018, with terms and conditions. All of those terms and conditions were satisfied as of November 21, 2018.

11. On January 26, 2018, Respondent was issued a medical license by the Montana Board of Medical Examiners.

12. The Government and Respondent stipulate to the admissibility of Government Exhibits 1–4.

II. Findings of Fact

Dr. Delisma's Background and Training

1. Dr. Delisma was born in Haiti, where he completed high school. Tr. 17.

2. At age 19, Dr. Delisma went to the University of Bordeaux in France, where he studied for six years. Tr. 17. While in France, Dr. Delisma earned four university degrees. Tr. 17–18.

3. Dr. Delisma immigrated to the United States in 1992, moving to South Florida. Tr. 18.

4. Dr. Delisma attended Howard University Medical School in Washington, DC, from 1997 to 2001. Tr. 19.

5. From 2001 to 2004, Dr. Delisma completed an internship and residency

in internal medicine at the Yale University School of Medicine. Tr. 19. Dr. Delisma remained at Yale for another year, as an attending physician. *Id.*

6. Dr. Delisma had a DEA registration from 2004 until it expired in May 2016. Tr. 28, 43–44.

7. Dr. Delisma received a scholarship to Harvard University in 2005, where he completed a master's degree in public health and a fellowship in health policy in 2006. Tr. 19.

Dr. Delisma's Medical Practice in Florida

8. Dr. Delisma returned to South Florida in 2006, where he worked as an emergency room physician at the Veterans Administration hospital in Miami for two years, and for a year at Jackson Hospital, a public health hospital in Miami. Tr. 19–20.

9. In 2008–09, Dr. Delisma began private practice in internal medicine in Florida. Tr. 20. He treated about 60% of his patients in hospital settings, and about 40% were in an outpatient clinic. Tr. 20

10. Dr. Delisma let his Florida medical license expire and did not renew it. Tr. 36.

Medicare Exclusion

11. Dr. Delisma's exclusion from federal health care programs is the result of his 2016 conviction in Florida for receiving a $700. kickback for referring a patient to a home health agency. Tr. 28; Government Exhibit (''GE–'') 2, 3. His conviction involved only one patient. Tr. 28–29.

12. Dr. Delisma pled guilty to the offense and took responsibility for his actions. Tr. 29. Dr. Delisma offered his apology, and is deeply sorry for his actions. *Id.*

13. On May 26, 2016, Dr. Delisma was convicted, and sentenced to eight months in Federal detention in Miami, Florida, followed by one year of supervised release. Tr. 29; GE–2, at 2–3. He was also ordered to pay $49,000. in restitution, a $5,000. fine, and $100. in fees. Tr. 29; GE–2, at 5–6.

14. The restitution that Dr. Delisma was required to pay was for the amount of money the home-health care provider had billed Medicare for the patient Dr. Delisma had referred to the home health care provider. Tr. 50.

15. Dr. Delisma satisfied all the conditions of his sentence by January 2018.[1] Tr. 29; RE–1.

16. Concerning Dr. Delisma's conviction, there were no issues regarding the quality of the patient care he rendered to his patients. Tr. 31. In addition, there were no allegations concerning prescribing any medications. *Id.*

17. Because of Dr. Delisma's exclusion from federal health care programs, the Florida Board of Medicine (''Board'') reprimanded him and imposed a $500. fine, but placed no restrictions on his practice.[2] Tr. 35–36; RE–2, at 4–5. In addition, Dr. Delisma was required to reimburse the Board $882.94. to cover the cost of its proceedings against him. RE–2, at 1, 6.

Dr. Delisma's Current Medical Position

18. Dr. Delisma is currently licensed to practice medicine in Pennsylvania, Montana, New York, and Maryland. Tr. 37–39; RE–3, 4, 7, 8. When applying for a medical license in each of the states, Dr. Delisma informed the licensing board of each state of his criminal conviction in Florida. Tr. 38–39. The medical licensing boards of those states have not placed any restrictions on Dr. Delisma's ability to prescribe medications or to practice medicine. Tr. 39.

19. Dr. Delisma currently works as the Medical Director at the State Correctional Institution in Somerset, Pennsylvania. Tr. 20–21. Dr. Delisma is seeking a Certificate of Registration for his work at the Somerset Correctional Institution, located at 1590 Walters Mill Rd., Somerset, Pennsylvania. Tr. 49.

20. Dr. A.D. is the regional medical director for the central region of the Pennsylvania Department of Corrections (''Department of Corrections''). Tr. 59.

21. At the time Dr. Delisma was hired, Dr. A.D. was aware of Dr. Delisma's past legal issues. Tr. 60.

22. Due to Dr. Delisma's remarkable credentials, Dr. A.D. was very interested in seeing and interviewing him. Tr. 60. Although Dr. Delisma had no correctional medicine experience, he took to it amazingly well and quickly picked-up the nuances required in correctional medicine. *Id.*

23. In Dr. A.D.'s opinion, Dr. Delisma is one of the top physicians within his organization. Tr. 60.

24. Dr. A.D. suggested to Dr. Delisma that he apply for a Certificate of Registration for the reasons Dr. A.D. expounded upon in his testimony. Tr. 70.

25. In Dr. A.D.'s opinion, granting a Certificate of Registration to Dr. Delisma ''would vastly improve the quality of care that is given'' at Somerset. Tr. 66. Delaying care to a patient can result in pain and suffering by the patient. Tr. 67–68. The Department of Corrections strives to avoid that. *Id.*

26. The standard of care for inmates is no different than the standard of care for any patient who is not in prison. Tr. 68.

27. The Somerset Correctional Institution is where inmates come from all over the State of Pennsylvania for surgical procedures, oncology care, and end-of-life care. Tr. 22.

28. For many inmates their first interaction with the medical community is when they are in prison. Tr. 68. Many inmates present with years of undiagnosed, untreated medical conditions. *Id.*

29. There are about 2,600 inmates at Somerset, and Dr. Delisma routinely provides medical care to about 300 of them. Tr. 23–24.

30. On a daily basis, Dr. Delisma sees about 15 patients in the correctional facility infirmary, where patients are waiting to go to the hospital or have just returned from the hospital. Tr. 21. In addition, Dr. Delisma sees up to 30 patients a day in the facility's outpatient clinic. *Id.*

31. With the patient population at Somerset, it is necessary to prescribe controlled substances up to five times a week. Tr. 26. Some inmates may require controlled substances to alleviate pain following surgery or due to acute injuries. Tr. 26–27. Other patients may require a benzodiazepine or a chemotherapy drug. Tr. 27. Because many of the inmates have some sort of addiction problem, however, the Department of Corrections is ''extraordinarily careful to limit [their] use of any type of controlled substance . . . .'' Tr. 66.

32. It is consistent with the standard of care in internal medicine to be able to prescribe necessary medications to a patient. Tr. 44.

33. When Dr. Delisma evaluates one of his inmate patients and determines that the patient needs a controlled substance, Dr. Delisma refers the patient to another physician who has a DEA registration. Tr. 47. That physician also works at the Somerset facility, but he is not assigned there full-time. Tr. 47–49. That physician also works at other correctional facilities. Tr. 48–49

34. When Dr. Delisma refers a patient to another doctor for a prescription for a controlled substance that doctor independently evaluates the patient before issuing a prescription for a

[1] The ''Satisfaction of Judgment'' was entered on August 22, 2017. RE–1.

[2] Although Dr. Delisma testified that the Florida Board of Medicine did not impose any restrictions on his medical license, he also testified that his ''license was reinstated after being suspended for one year.'' Tr. 36. Nothing in the Final Order of the Board, or in the Settlement Agreement with the Board, however, indicates that the Board suspended Dr. Delisma's medical license. RE–2, at 1–14.

controlled substance to the patient. Tr. 47.

35. No full-time medical professional works at the Somerset facility who has a DEA Certificate of Registration. Tr. 50–51. In addition to a physician who works at other correctional facilities, the regional director and a physician's assistant will sometimes help at Somerset. *Id.*

36. There are times when no one at the Somerset Correctional Institution has a DEA registration. Tr. 51.

37. If Dr. Delisma determines that an inmate requires a controlled substance, the patient can normally get a prescription for that controlled substance in less than 24 hours. Tr. 52. Over a weekend, however, it has taken up to 72 hours for an inmate to obtain a prescription for a controlled substance. Tr. 53–54.

38. Dr. Delisma is the only full-time physician at Somerset. Tr. 63. Sometimes the inmates, however, need immediate medical attention. Tr. 63. Therefore, it is not in the medical interest of the inmates when their only full-time physician is unable to deliver the expected standard of care because he does not have a Certificate of Registration. Tr. 64, 67.

39. Even though Dr. Delisma does not have a Certificate of Registration, the Department of Corrections wants to keep him because he has ''already demonstrated himself to be reliable, talented, well trained, and always willing to help us out when we need him.'' Tr. 64.

40. According to Dr. A.D., Dr. Delisma is valuable to the Department of Corrections ''because of his experience and training in internal medicine, from some of the best institutions in this world.'' Tr. 68.

41. Respondent's Exhibit 10 is a letter of recommendation that Dr. A.D. drafted on behalf of Dr. Delisma. Tr. 65.

42. The State Medical Director for the Department of Corrections has endorsed Dr. Delisma's application for a Certificate of Registration. Tr. 44–45; RE–11.

No Prior Incidents Concerning Controlled Substances

43. In Dr. Delisma's entire career as a licensed physician he has never received any reprimands for improper or irresponsible prescribing of any medications, to include controlled substances. Tr. 42.

44. Dr. Delisma has never been under investigation by any governmental agency for any inappropriate or irresponsible prescribing practices. Tr. 42.

Continuing Education

45. In March 2017, Dr. Delisma completed a continuing education course in ''Legal and Ethical Issues in Healthcare,'' and in September 2017 he completed a course in ''Medical Ethics for Physicians.'' Tr. 40–41; RE–5, at 44–45.

46. On November 17, 2018, Dr. Delisma attended the ''Medical Ethics and Professionalism'' course in Atlanta, Georgia, presented by the University of California, Irvine School of Medicine. Tr. 39–40; RE–6.

Analysis

To deny an application for DEA registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for denial are satisfied. *Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981); 21 CFR 1301.44(e). The sole basis for sanction in this case is the mandatory exclusion provision of 21 U.S.C. 824(a)(5). DEA has held that section 824(a)(5) authorizes the denial of applications as well as revocation of existing registrations. *Dinorah Drug Store, Inc.,* 61 FR 15972, 15973 (1996); *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993).

Under 21 U.S.C. 824(a)(5), DEA may deny an application for registration if the applicant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' The Government can meet its burden under section 824(a)(5) simply by advancing evidence that the applicant has been excluded from a federal health care program under 42 U.S.C. 1320a–7(a). *Johnnie Melvin Turner, M.D.,* 67 FR 71203, 71203–04 (2002); *Dinorah Drug Store, Inc.,* 61 FR at 15973. The Administrator has issued sanctions where the Government introduced evidence of the applicant's plea agreement and judgment for health care fraud, and the resulting letter from the U.S. Department of Health and Human Services imposing mandatory exclusion. *Richard Hauser, M.D.,* 83 FR 26308, 26310 (2018); *Johnnie Melvin Turner, M.D.,* 67 FR at 71203–04.

Section 1320a–7(a) of Title 42, United States Code, establishes four bases for mandatory exclusion that authorize the Secretary of the Department of Health and Human Services to exclude individuals or entities from Federal health care programs. Those bases include conviction of program-related crimes, patient abuse, health care fraud, or a felony related to controlled substances. 42 U.S.C. 1320a–7(a)(1)–(4). These 4 bases are different from the 16 bases that authorize permissive exclusion under 42 U.S.C. 1320–7(b). The distinction is important because section 824(a)(5) specifically references 42 U.S.C. 1320a–7(a), the section establishing four bases for mandatory exclusion. Thus, to carry its burden under section 824(a)(5), the Government must prove that the applicant's exclusion was mandatory (42 U.S.C. 1320a–7(a)) and not permissive (42 U.S.C. 1320–7(b)). Exclusion under one of the 16 permissive grounds listed in section 1320a–7(b) does not provide a basis for sanction. *Hoi Y. Kam, M.D.,* 78 FR 62694, 62697 (2013); *Terese, Inc., d/b/a Peach Orchard Drugs,* 76 FR 46843, 46846–47 (2011); *James Henry Holmes, M.D.,* 59 FR 6300, 6301 (1994).

In addition, DEA has reiterated in numerous final orders that the underlying conviction that led to mandatory exclusion does not need to involve controlled substances to support sanction.[3] This long held and consistent precedent makes it undisputed that the Government does not need to advance any evidence related to controlled substances to meet its burden under section 824(a)(5). The absence of evidence related to controlled substances, however, can be considered as mitigation evidence [to show why the applicant can be entrusted with a registration].*[D] *See Mohammed Asgar, M.D.,* 83 FR 29569, 29573 (2018) (noting respondent's conviction ''did not involve the misuse of his registration to handle controlled substances''); *Kwan Bo Jin, M.D.,* 77 FR 35021, 35027 (2012) (highlighting the lack of evidence concerning respondent's ''prescribing practices''); *Dinorah Drug Store, Inc.,* 61 FR at 15944 (''[B]alanced against this basis for denial is . . . the lack of any adverse action or allegations pertaining to [respondent's] conduct related to controlled substances.''). In the absence of evidence involving controlled substances, however, sanction is warranted where the Administrative Record presents ''serious questions as to the'' registrant's integrity. *Anibal P.*

[3] [*Jeffrey Stein,* 84 FR at 46971–72 (2019)] * (citation added); *Mohammed Asgar, M.D.,* 83 FR 29569, 29571 (2018); *Narciso A. Reyes, M.D.,* 83 FR 61678, 61681 (2018); *Richard Hauser, M.D.,* 83 FR 26308, 26310 (2018); *Orlando Ortega-Ortiz, M.D.,* 70 FR 15122, 15123 (2005); *Juan Pillot-Costas, M.D.,* 69 FR 62084, 62085 (2004); *Daniel Ortiz-Vargas, M.D.,* 69 FR 62095, 62095–96 (2004); *KK Pharmacy,* 64 FR 49507, 49510 (1999); *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998); *Anibal P. Herrera, M.D.,* 61 FR 65075, 65078 (1996); *Stanley Dubin, D.D.S.,* 61 FR 60727, 60728 (1996); *Richard M. Koenig, M.D.,* 60 FR 65069, 65071 (1995); *George D. Osafo, M.D.,* 58 FR 37508, 37509 (1993); *Nelson Ramirez-Gonzalez, M.D.,* 58 FR 52787, 52788 (1993); *Gilbert L. Franklin, D.D.S.,* 57 FR 3441, 3441 (1992).

*[D] Language added.

Herrera, M.D., 61 FR 65075, 65078 (1996).

I. The Government's Position

The Government submitted its ''Proposed Findings of Fact and Conclusions of Law'' (''Government's Brief'') on May 17, 2019.[4] I have read and considered the Government's Brief in preparing this Recommended Decision.

In its Brief, the Government's proposed findings of fact are essentially the same as the findings of fact set forth in this Recommended Decision. ALJ–12, at 1–5. The Government also acknowledges that it is appropriate to analyze this case under the public interest factors of 21 U.S.C. 823(f).[*E] *Id.* at 6. The Government also acknowledges that Factors 1–4 of 21 U.S.C. 823(f) are not applicable in this case, but argues that the Respondent's conviction for accepting a kickback and his exclusion from federal health care programs is a Factor 5 consideration. *Id.* at 9.

Relying on *Richard Hauser, M.D.,* 83 FR 26308, 26310 (2018), and cases cited therein, the Government argues that ''notwithstanding the fact that the underlying conduct for which Respondent was convicted had no nexus to controlled substances'' his exclusion ''warrants revocation (sic) of his registration.'' [5] ALJ–12, at 7.

Continuing, the Government argues that ''[i]t would be incongruous and contrary to the public interest for DEA to grant Respondent a registration when he has not completed the period of his health care exclusion . . . .'' [6] *Id.* at 10.

Finally, the Government notes that Dr. Delisma did not need a Certificate of Registration to be hired into his current position, or to keep it. ALJ–12, at 10. Without citation to any authority, the Government argues that Dr. Delisma's application should be denied because ''there is no compelling public interest purpose for Respondent to be granted a DEA registration where the public interest is currently being served . . . .'' *Id.*

II. The Respondent's Position

Respondent submitted his ''Closing Argument & Proposed Findings of Fact and Conclusions of Law'' (''Respondent's Brief'') on May 17, 2019.[7] I have read and considered the Respondent's Brief in preparing this Recommended Decision.

In his Brief, the Respondent's proposed findings of fact are essentially the same as the findings of fact set forth in this Recommended Decision. ALJ–13, at 1–8. While the Respondent notes that the Government established a *prima facie* case, the Respondent also argues that the Government failed to prove ''by a preponderance of the evidence that the Respondent's application should be denied solely based off of the Respondent's exclusion from participation in federal health care programs.'' *Id.* at 9. The Respondent notes that the licensing authorities in four states ''do not perceive Dr. Delisma as a threat to public safety and believe that [] his unfettered licensure is consistent with public interest.'' *Id.* Like the Government, the Respondent acknowledges that it is appropriate to analyze this case under the five factors contained in 21 U.S.C. 823(f). *Id.* In reviewing those factors, the Respondent argues that all five factors weigh in his favor. *Id.* at 10–12.

The Respondent notes that he has accepted responsibility for his actions. ALJ–13, at 12. The Respondent also notes that patients at the correctional facility where he works have had to wait, at times up to 72 hours, to obtain needed medication. *Id.* The Respondent argues that by granting him a registration the inmate patients at Somerset will not have to ''suffer needlessly while the facility locates a provider that (sic) can write a prescription for a controlled substance.'' *Id.* at 13.

III. 21 U.S.C. 824(a)(5): Mandatory Exclusion From Federal Health Care Programs Pursuant to 42 U.S.C. 1320a–7(a)

Mandatory exclusion from a federal health care program under 42 U.S.C. 1320a–7(a) serves as an independent basis for denying an application for DEA registration. 21 U.S.C. 824(a)(5). The OSC's sole allegation is that Dr. Delisma's mandatory exclusion from all federal health care programs warrants denying his application under 21 U.S.C. 824(a)(5). Specifically, the Government alleges that on May 31, 2016, judgment was entered against Dr. Delisma based on his guilty plea to one count of ''Receipt of Kickbacks in Connection with a Federal Health Care Program,'' in violation of 42 U.S.C. 1320a–7b(b)(1)(A). ALJ–1, at 2. Based on this conviction, the HHS/OIG, by letter dated August 31, 2016, mandatorily excluded Dr. Delisma from participation in Medicare, Medicaid, and all federal health care programs for the minimum statutory period of five years pursuant to 42 U.S.C. 1320a–7(a), effective September 20, 2016. *Id.* The Government further alleged that although the underlying conduct for which Dr. Delisma was convicted did not involve controlled substances, his mandatory exclusion from Medicare, Medicaid, and all federal health care programs warrants denial of his application for DEA registration pursuant to 21 U.S.C. 824(a)(5). *Id.*

Neither party disputes that Dr. Delisma was mandatorily excluded from federal health care programs under 42 U.S.C. 1320a–7(a) for the minimum period of five years based on Dr. Delisma's guilty plea to one count of receiving a kickback in connection with a federal health care program. Stips. 2–

[4] The Government's Brief has been marked as ALJ–12.

[*E] In its Motion for Summary Judgment, which the ALJ properly denied, the Government argued that the five public interest factors were inapplicable to this case because the Government was seeking to deny the application based on section 824(a)(5) (exclusion from federal health care programs) and had not alleged grounds under section 824(a)(4) (registrant has committed acts that would render his registration inconsistent with the public interest) in its Order to Show Cause. Govt MSJ at 5, n. 2. In reviewing an application for a registration, however, section 823(f) instructs the Agency to consider the public interest when determining whether to grant a petitioner's application to dispense controlled substances. 21 U.S.C. 823(f). Accordingly, the Respondent appropriately raised, and the ALJ appropriately considered, the public interest in determining whether to grant the Respondent's application in this case.

[5] It is accurate to state that *Hauser,* and the cases cited therein, state that where a registrant is excluded from Federal health care programs, DEA may revoke a Certificate of Registration even if the exclusion is unrelated to controlled substances. Having read *Hauser* and the cases the Government cited, however, all are inapposite to the case before me. For example, in four of the cases cited by the Government no hearing was held and the underlying criminal conviction involved fraud (solicitation) and there is no mention of acceptance of responsibility: *Orlando Ortega-Ortiz, M.D.,* 70 FR 15122 (2005); *Juan Pillot-Costas, M.D.,* 69 FR 62084 (2004); *Daniel Ortiz-Vargas, M.D.,* 69 FR 62095 (2004); and *KK Pharmacy,* 64 FR 49507 (1999), which also involved controlled substances and a materially false application. In *Stanley Dubin, D.D.S.,* 61 FR 60727 (1996), the respondent had been convicted of Medicare fraud, criminal conspiracy, forgery, and tampering with or fabricating evidence. In addition, the Administrative Law Judge did not credit a portion of Dubin's testimony and there is no discussion of acceptance of responsibility. Finally, in *Nelson Ramirez-Gonzalez, M.D.,* 58 FR 52787 (1993), the Administrative Law Judge found that the registrant had been convicted of nine felony counts, to include mail fraud, false claims, and making false statements. There is no mention of acceptance of responsibility in the decision.

[6] In my view, this argument is contrary to the discretion the Administrator has in determining whether to grant an application for a registration, or to revoke one. *Dan E. Hale, D.O.,* 69 FR 69402, 69406 (2004). It also fails to account for the Administrator's decisions in *Kwan Bo Jin, M.D.,* 77 FR 35021, 35023 (2012) and *Mohammed Asgar, M.D.,* 83 FR 29569, 29572 (2018). In addition, for the reasons explained in my ''Order Denying Government's Motion for Summary Disposition,'' the Government's reliance on *Narciso A. Reyes, M.D.,* 83 FR 61678 (2018) is also misplaced. ALJ–12, at 8; ALJ–9, at 4–5.

[7] The Respondent's Brief has been marked as ALJ–13.

3, 5. The parties also stipulated to the admissibility of the Government's four exhibits. Stip. 12.

The Government's evidence shows that the United States District Court for the Southern District of Florida (''District Court'') entered judgment against Dr. Delisma on May 31, 2016, on one count of ''Receipt of Kickbacks in Connection with a Federal Health Care Program,'' in violation of 42 U.S.C. 1320a–7b(b)(l)(A). GE–2, at 1; Stip. 2. The evidence further shows that Dr. Delisma pled guilty to the offense. *Id.* The judgment form indicates that the District Court sentenced Dr. Delisma to 8 months imprisonment and 1 year of supervised release. GE–2, at 2–3. The District Court also ordered Dr. Delisma to pay fines of $100. and $5,000., and to pay $49,000. in restitution. *Id.* at 5–6.

The Government's evidence also shows that on August 31, 2016, HHS/OIG issued a letter to Dr. Delisma informing him that HHS was excluding him from participation in Medicare, Medicaid, and all federal health care programs under section 1128(a)(1) of the Social Security Act (codified at 42 U.S.C. 1320a–7(a)). GE–3, at 1; Stip. 3. The letter states that HHS excluded Dr. Delisma based on his conviction for ''a criminal offense related to the delivery of an item or service under the Medicare or a State health care program.'' GE–3, at 1; *see* 42 U.S.C. 1320a–7(a)(1) (establishing mandatory exclusion based on conviction ''of a criminal offense related to the delivery of an item or service under subchapter XVIII or under any State health care program''). The letter further states that HHS excluded Dr. Delisma for the statutory minimum of five years and the exclusion was effective September 20, 2016. GE–3, at 1; Stip. 3. The letter also explains that reinstatement in federal health care programs is not automatic. *Id.* at 2; Stip. 4.

The Government's evidence also includes a printout from the HHS/OIG website showing that Dr. Delisma was excluded under Section 1128(a)(1) (42 U.S.C. 1320a–7(a)(1)) for a program-related conviction effective September 20, 2016. GE–4. Lastly, the Government's evidence includes a notarized document titled, Certification of Registration Non-Registration (''Certification''), signed by the Associate Chief of the Registration and Program Support Section. GE–1. The Certification states that Dr. Delisma submitted an application for DEA registration on or about July 9, 2018, and that the Registration and Support Section assigned his application Control Number W18071098C. *Id.;* Stip. 1. The Certification further indicates that when Dr. Delisma submitted his application, he disclosed his conviction and exclusion from federal health care programs. *Id.*

Evidence of Dr. Delisma's plea agreement, judgment, and the HHS exclusion letter are sufficient to sustain an allegation under 21 U.S.C. 824(a)(5). *Kwan Bo Jin, M.D.,* 77 FR at 35023; *Linda Sue Cheek, M.D.,* 76 FR 66972, 66982 (2011). Based on the Government's documentary exhibits, and the parties' joint stipulations, I find that the Administrative Record shows by a preponderance of the evidence that Dr. Delisma was convicted of receiving a kickback in connection with a federal health care program. I also find that based on this conviction, he was mandatorily excluded from participation in Medicare, Medicaid, and all federal health care programs for five years under 42 U.S.C. 1320a–7(a). Thus, the Government's allegation that Dr. Delisma's application for DEA registration should be denied under 21 U.S.C. 824(a)(5) because he was mandatorily excluded from Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a) is SUSTAINED. ALJ–1, at 2, paras. 2–3. This allegation weighs in favor of denying Dr. Delisma's application for DEA registration.

Discussion and Conclusions of Law

I sustained the Government's allegation that HHS mandatorily excluded Dr. Delisma from federal health care programs based on a program-related conviction. This allegation is supported by a preponderance of the evidence and the parties' joint stipulations.

Once the Government makes a *prima facie* case under 21 U.S.C. 824(a)(5), the burden shifts to respondent to '' 'present[] sufficient mitigating evidence to show why he can be entrusted with a registration.'' *Mohammed Asgar, M.D.,* 83 FR at 29572; *Kwan Bo Jin, M.D.,* 77 FR at 35023; *Linda Sue Cheek, M.D.,* 76 FR at 66982. Stated differently, where the Government advances substantial evidence to prove that exclusion from a federal health care program justifies sanction under section 824(a)(5), the case is not over, but instead shifts to respondent to argue that a lesser sanction, or no sanction, is appropriate in light of mitigating evidence. *Id.; see KK Pharmacy,* 64 FR 49507, 49510 (1999) (revoking where Government carried its burden and respondent introduced ''[n]o evidence of explanation or mitigating circumstances''); *Joseph M. Piacentile, M.D.,* 62 FR 35527, 35528–29 (1997) (revoking registration because Government met its burden and respondent failed to offer ''any evidence of [his] rehabilitation or remorse''). Once the burden shifts to Respondent, Respondent may present evidence showing that despite his conviction, he does not pose a threat to the public interest. *Linda Sue Cheek, M.D.,* 76 FR at 66982. Respondent may rebut the Government's *prima facie* case by accepting responsibility, showing remorse, introducing evidence of rehabilitation, and satisfying all terms and conditions of his sentence. *Kwan Bo Jin, M.D.,* 77 FR at 35026.

Even in cases involving the exclusion from federal health care programs, DEA analyzes the five public interest factors in 21 U.S.C. 823(f) in determining whether [granting a respondent's application for] [*F] registration would be inconsistent with the public interest. *See Dinorah Drug Store, Inc.,* 61 FR 15972, 15973–74 (1996) (considering all five public interest factors); [].[*G] Those factors are:

(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).

DEA considers these public interest factors separately. *Ajay S. Ahuja, M.D.,* 84 Fed Reg. 5479, 5488 (2019); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76–77 (4th Cir. 1988). When deciding whether registration is in the public interest, DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95

[*F] Language modified.

[*G] Citations omitted for relevance.

(2009) (basing sanction on all evidence of record).

With respect to Factors 1 and 3, it is undisputed that Dr. Delisma holds valid state medical licenses in Pennsylvania, New York, Maryland, and Montana. FF 18. [].*H However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.,* 76 FR 20011, 20018 (2011). It is well established that a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 FR at 15230. The ultimate responsibility to determine whether a DEA registration is consistent with the public interest resides exclusively with the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd Chien* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008).

[In determining the public interest under Factor 1, the ''recommendation of the appropriate State licensing board or professional disciplinary authority . . . shall be considered.'' 21 U.S.C. 823(f)(1). ''Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.'' *John O. Dimowo,* 85 FR 15800, 15809 (2020). *See, also, Vincent J. Scolaro, D.O.,* 67 FR 42060, 42065 (2002) (''While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, [the ALJ] found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances.''). Here, Pennsylvania, where Respondent seeks registration, acted to grant Respondent a medical license after he apprised the licensing authority of his conviction, and the state did not place any restrictions on Respondent's ability to prescribe medications or practice medicine. FF 18. As the ''appropriate State licensing board'' for the purpose of Public Interest Factor One determined that Respondent should be licensed with full knowledge of his conviction, Factor 1 weighs against denial of his application in this matter. *See, e.g., Tyson D. Quy, M.D.,* 78 FR 47412, 47417 (2013); *Vincent J. Scolaro, D.O.,* 67 FR 42060, 42064–65 (2002); *Kwan Bo Jin, M.D.,* 77 FR at 35023–24 (noting that a state medical board's determination that a registrant could maintain his license after his Federal conviction for health care fraud ''does weigh against a finding that [r]espondent's continued registration would be inconsistent with . . . Factor One.'')*I].

As to Factor 3, there is no evidence that Dr. Delisma has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 822 (10th Cir. 2011). Therefore, DEA has held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is not dispositive. *Id.* Accordingly, Factor 3 weighs neither for nor against revocation in this case.

DEA often analyzes Factors 2 and 4 together. *See, e.g., Fred Samimi, M.D.,* 79 FR 18698, 18709 (2014); *John V. Scalera, M.D.,* 78 FR 12092, 12098 (2013). Under Factor 2, DEA analyzes a registrant's ''experience in dispensing controlled substances.'' 21 U.S.C. 823(f)(2). Factor 2 analysis focuses on a registrant's acts that are inconsistent with the public interest, rather than on a registrant's neutral or positive acts and experience. *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012) (explaining that ''every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant's] professional career'' (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009))). Similarly, under Factor 4, DEA analyzes an applicant's compliance with Federal and state controlled substance laws. 21 U.S.C. 823(f)(4). The Factor 4 analysis focuses on violations of state and Federal laws and regulations concerning controlled substances. *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 223–24 (6th Cir. 2009) (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 272, 274 (2006)); *Gaudio,* 74 FR at 10090–91. In this case, however, there are no allegations suggesting that Dr. Delisma has any negative experience in dispensing controlled substances, or that he has failed to comply with any state or federal laws concerning controlled substances. In my view, the absence of such allegations weigh in Dr. Delisma's favor. *Kwan Bo Jin, M.D.,* 77 FR at 35024; *see also Dinorah Drug Store, Inc.,* 61 FR at 15973–74 (noting consideration of the fact that the underlying misconduct that led to the exclusion did not involve controlled substances).

Factor 5 allows for consideration of other conduct a registrant may have engaged in that may threaten the public health and safety. In this case, the Government has not alleged any conduct other than Dr. Delisma's conviction of receiving a kickback and his resulting exclusion from federal health care programs as a basis to deny his application. Thus, in my view, the absence of allegations of any other conduct that may threaten the public health and safety weighs in Dr. Delisma's favor. *Kwan Bo Jin, M.D.,* 77 FR at 35025.

Finally, Dr. Delisma has not presented any evidence to rebut the underlying misconduct, or his exclusion from participation in Federal health care programs. Rather, he stipulated to the accuracy of those allegations. In addition, he accepted responsibility for his actions. FF 12. He initially did so by pleading guilty to the charge in Federal Court (Stip. 2; FF 12), by stipulating to all the elements of the Government's *prima facie* case in these proceedings, and by candidly accepting responsibility on the record. *Id.* Based upon my review of the entire Administrative Record and my evaluation of Dr. Delisma's candor and demeanor under oath, I find that Dr. Delisma's acceptance of responsibility was sincere and unequivocal.

Sanction

Imposing sanctions under 21 U.S.C. 824(a)(5) is a matter of discretion. [*Stein,* 84 FR at 46971;] *J *Kwan Bo Jin, M.D.,* 77 FR at 35023. Even when the Government meets its burden, the CSA provides that issuing a sanction is ''discretionary.'' *Dan E. Hale, D.O.,* 69 FR 69402, 69406 (2004). In exercising that discretion, DEA ''should consider

*H Sentence omitted.

*I I have replaced the ALJ's Factor One analysis in this case to reflect the Factor One legal analysis in *John O. Dimowo,* 85 FR 15800 (2020), which was published after the ALJ issued this RD. As noted in *Dimowo,* a state entity's actions are distinct from its inactions. 85 FR at 15810, n. M. Where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation under Factor 1. *See Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019) (finding that ''where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.''); *see also MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 817–819 (10th Cir. 2011) (noting that the Agency decision found that the lack of action from an appropriate state entity was not a recommendation under Factor One and holding that the Deputy Administrator did not misweigh the public interest factors).

*J Citation added.

all the facts and circumstances of the case.'' *Id.; see also Linda Sue Cheek, M.D.,* 76 FR at 66982 (''[D]enial of an application for registration [under section 824(a)(5)] is a matter of discretion.''); *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998) (turning to the issue of whether DEA should exercise its discretion to revoke respondent's COR after the Government carried its burden); *Anibal P. Herrera, M.D.,* 61 FR at 65077 (same).

The Government bears the initial burden of proof, and must justify a sanction by a preponderance of the evidence. *Steadman,* 450 U.S. at 100–03. If the Government makes a *prima facie* case for a sanction, the burden of proof shifts to the registrant to show that a sanction would be inappropriate. *Med. Shoppe—Jonesborough,* 73 FR 364, 387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for a sanction by accepting responsibility for wrongful behavior and by taking remedial measures to ''prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010) (citations omitted). In addition, when assessing the appropriateness and extent of sanctioning, DEA considers the egregiousness of the offenses and its interest in specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38363, 38385 (2013).

Prima Facie Showing and Balancing

The Government can meet its burden in a case involving a registrant who has been excluded from federal health care programs simply by showing evidence of the exclusion and the underlying conviction. Further, DEA has long held that the underlying conviction forming the basis of a registrant's mandatory exclusion from participation in Federal health care programs need not involve controlled substances for DEA to issue a sanction pursuant to 21 U.S.C. 824(a)(5). [*Stein,* 84 FR at 46971–71;] [*K] *Hauser,* 83 FR at 26310.

The Government based its case on Dr. Delisma's conviction of his receipt of kickbacks in connection with a federal health care program, and his subsequent exclusion from federal health care programs by the Department of Health and Human Services. ALJ–1, at 2, paras. 2–3. Citing *Hauser,* 83 FR at 26308, the Government asserted that even though Dr. Delisma's underlying conduct ''had no nexus to controlled substances,'' his exclusion warranted the denial of his application for a Certificate of Registration. ALJ–1, at 2, para. 3. The Government has not advanced any evidence under Factors 1–5 of 21 U.S.C. 823(f), other than the exclusion.

After the Government presents a *prima facie* case for a sanction, the Respondent has the burden of production to present ''sufficient mitigating evidence'' to show why he can be entrusted with a DEA registration. *Med. Shoppe—Jonesborough,* 73 FR at 387 (quoting *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007)). To rebut the Government's *prima facie* case, the 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 20727, 20734–35 (2009).

The Respondent may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct. *Robert A. Leslie, M.D.,* 68 FR at 15228. To accept responsibility, a respondent must show ''true remorse'' for wrongful conduct. *Michael S. Moore, M.D.,* 76 FR 45867, 45877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *Wesley G. Harline, M.D.,* 65 FR 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct. *Jeffrey Patrick Gunderson, M.D.,* 61 FR 26208, 26211 (1996). 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 at 38364. In this case, I have found that Dr. Delisma's acceptance of responsibility was both sincere and unequivocal.

The mere acceptance of responsibility, however, does not end the analysis of whether to issue a sanction. ''[T]here are cases in which, notwithstanding a finding that a registrant has credibly accepted responsibility, the misconduct is so egregious and extensive that the protection of the public interest nonetheless warrants the revocation of a registration or the denial of an application.'' *William J. O'Brien, III, D.O.,* 82 FR 46527, 46527 (2017) (quoting *Hatem Ataya, M.D.,* 81 FR 8221, 8244 (2016)) (citation omitted).

In addition, consideration must be given to both specific and general deterrence. *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Id.*

With respect to egregiousness, I do not find the Respondent's conduct to be particularly egregious. Furthermore, the Government's reliance on *Hauser* in the Order to Show Cause is misplaced. Dr. Hauser was convicted of two counts of health care fraud for overbilling a state Medicaid program. *Hauser,* 83 FR at 26309. Dr. Hauser's fraud involved ''executing a scheme with the intent to defraud'' a state Medicaid program for payment of ''services that he did not actually perform,'' a far more egregious offense than that of Dr. Delisma. *Id.* In addition, Dr. Hauser failed to come forward with any evidence explaining or mitigating his overbilling conduct or otherwise explaining why his registration should not be revoked, and the record reflected no such evidence. *Id.* at 26,310. Furthermore, Dr. Hauser's fraud conviction is significant because a fraud conviction suggests that a registrant cannot be trusted to tell the truth except in cases where the registrant credibly accepts responsibility. *Kwan Bo Jin, M.D.,* 77 FR at 35027. In contrast, Dr. Delisma was convicted of a single count of receiving a kickback involving only one patient. In addition, Dr. Delisma was not convicted of fraudulent activities,[8] he accepted responsibility, he submitted credible evidence as to why his application should be approved, and he submitted some evidence of remediation. Further, his misconduct was not related to controlled substances.

The Administrator has also considered various circumstances as mitigating factors in past exclusion cases. Examples of such circumstances include: The fact that misconduct did not involve controlled substances; [9] no evidence that respondent's registration

[*K] Citation added.

[8] There are four bases for mandatory exclusion under 42 U.S.C. 1320a–7(a). They are convictions for: Program-related crimes, patient abuse, health care fraud, or a felony related to controlled substances. The Government's evidence shows that the Respondent's exclusion was for a ''program-related conviction.'' GE–4. Further, unlike several of the registrants in cases cited by the Government, Dr. Delisma was not convicted of ''soliciting'' a kickback.

[9] *See Mohammed Asgar, M.D.,* 83 FR at 29573 (declaring it significant ''that Respondent's criminality did not directly involve his registration or controlled substances''); *Dinorah Drug Store, Inc.,* 61 FR at 15974 (weighing in mitigation ''the lack of any adverse action or allegations pertaining to [respondent's] conduct related to controlled substances'').

threatens the public interest;[10] respondent accepted responsibility;[11] respondent submitted letters and testimony concerning his good character;[12] HHS found no aggravating factors and therefore excluded respondent for the minimum period;[13] respondent was candid about his background with his employer;[14] and respondent satisfied all terms and conditions of his sentence.[15] All of these circumstances are relevant mitigating factors in the case before me. Stip. 3, 6; FF 12, 16, 18, 21, 31, 33–34, 41–44.

It is frequently noted that proceedings concerning an Order to Show Cause are non-punitive in nature. *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988). ''The purpose of this proceeding is not to impose punishment . . . .'' *Jackson,* 72 FR at 23853. Rather, these proceedings are intended to be '' 'a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration.' '' *Id.* (quoting *Miller,* 53 FR at 21932) (citing *Robert M. Golden, M.D.,* 61 FR 24808, 24812 (1996)).

I have also considered the issue of deterrence, both general and specific. With regard to specific deterrence, Dr. Delisma has already been held accountable for accepting a kickback, having been sentenced to prison, as well as having to pay substantial financial penalties. He has fully satisfied all of those imposed requirements by both the Federal courts and licensing authorities. FF 15, 17–18. He has also completed three continuing education courses concerning medical ethics. FF 45–46. In addition, [and importantly,] [*L] he has demonstrated sincere remorse. FF 12. Concerning general deterrence, other practitioners would be sufficiently deterred based upon Dr. Delisma's criminal conviction and punishment, as well as the fees imposed by state licensing authorities. [].[*M] In this case, where there is no allegation or evidence that Dr. Delisma has ever improperly handled controlled substances [or engaged in other behaviors that negatively implicate his potential future compliance with the CSA and where he has been held accountable and expressed sincere remorse],[*N] denying his application would not be remedial in nature, it would simply be added punishment.

The Administrator has also frequently noted that ''past performance is the best predictor of future performance.'' *Mohammed Asgar, M.D.,* 83 FR at 29572 (internal citations and quotations omitted). In this case, there is absolutely no evidence that there has ever been any concern about the manner in which Dr. Delisma handled controlled substances. While a respondent's past poor performance in handling controlled substances is often times cited in decisions revoking a Certificate of Registration or denying an application for a Certificate of Registration, the reverse should also be true. In this case, I consider Dr. Delisma's past performance to be the best predictor of continued performance consistent with public health and safety.

Finally, I note that the Government has argued that Dr. Delisma's application should be denied because he did not need a registration to secure his position at Somerset, and does not need it to retain the position. ALJ–12, at 10. The Government cites no authority for this novel proposition. Countering that argument, Dr. Delisma argues that he needs a registration to provide the inmates at Somerset the quality of care they deserve. ALJ–13, at 12–13. The Respondent cites no DEA authority for this novel proposition.[16] I reject both arguments because the analysis of 21 U.S.C. 823(f) focuses on whether granting an application for a registration or revoking a registration is in the public interest. *Jackson,* 72 FR at 23853. Nowhere is there a suggestion that an application should be approved or denied based upon an evaluation, or consideration, of whether the applicant needs the registration.[17] Similarly, while it is commendable that Dr. Delisma is using his medical talents in a public service environment, an environment cannot entitle a practitioner to a registration, where consideration of the five factors of 21 U.S.C. 823(f) might otherwise result in denial of that practitioner's application.

Recommendation

I have considered the entire Administrative Record in this case. Other than Dr. Delisma's exclusion from participation in federal health care programs and his underlying conviction, which prompted that mandatory exclusion, I find absolutely no evidence that Dr. Delisma poses any threat to our public health and safety. To the contrary, the evidence suggests that granting Dr. Delisma a Certificate of Registration would be in the public interest. Accordingly, I recommend that

[10] *See Kwan Bo Jin, M.D.,* 77 FR at 35027 (stressing the lack of any evidence that the practitioner's ''registration would be inconsistent with the public interest, to include issues with his prescribing practices'').

[11] *See Mohammed Asgar, M.D.,* 83 FR at 29573 (finding respondent accepted responsibility and the Government ''put forward no evidence challenging the sincerity of Respondent's acceptance of responsibility''); *Kwan Bo Jin, M.D.,* 77 FR at 35026 (highlighting the practitioner's ''full acceptance of responsibility''); *Melvin N. Seglin, M.D.,* 63 FR at 70433 (holding respondent's attempt to explain why he overbilled did not negate his acceptance of responsibility).

[12] *See Anibal P. Herrera, M.D.,* 61 FR at 65077 (considering ''letters of support from patients and other doctors''); *Suresh Gandotra, M.D.,* 58 FR 64781, 64782 (1993) (considering character testimony).

[13] *See Dinorah Drug Store, Inc.,* 61 FR at 15974 (considering the fact that HHS found no aggravating factors ''to justify imposing more than the mandatory minimum period of exclusion'').

[14] *See Melvin N. Seglin, M.D.,* 63 FR at 70432–33 (stressing that respondent ''was honest and forthcoming regarding his background with his current employer'').

[15] *See Kwan Bo Jin, M.D.,* 77 FR at 35026 (finding it relevant for purposes of mitigation that respondent ''met all terms and conditions of his sentence'').

[*L] Language added.

[*M] Sentence omitted.

[*N] Language added. Although Dr. Delisma's past history with controlled substances weighs in favor of granting his application, certain behaviors that do not directly involve controlled substances may still weigh against an application if the behaviors are relevant to the applicant's potential future compliance with the CSA. *See Stein,* 84 FR 469 (finding a sanction appropriate for deterrence where there were no allegations respondent had improperly handled controlled substances but respondent had impeded a government investigation). Dr. Delisma's single act of accepting a kickback does demonstrate a past failure to comply with federal law, which I factor into my determination of trust, but his actions since his criminal act have been fully compliant and transparent and have given me no further reason to doubt his future compliance with the CSA.

[16] It would seem the decision in *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018) undercuts the Respondent's suggestion. There, the Acting Administrator held that testimony about a registrant's excellent work performance at a medical facility other than where he held his registration and that he was ''providing a valuable service to the community'' is not ''relevant in the public interest determination.'' *Id.* at 18897 n.23.

[17] However, in *Melvin N. Seglin, M.D.,* 63 FR at 70433, the Deputy Administrator found ''it significant that Respondent . . . need[ed] to be able to handle controlled substances in order to continue treating inmates in the local jail.'' The Deputy Administrator decided *Seglin* in 1998. In the more recent case of *Gregory D. Owens, D.D.S.,* 74 FR 36751 (2009), however, the Deputy Administrator reasoned ''[w]hether a practitioner treats patients who come from a medically underserved community or who have limited incomes has no bearing on whether he has accepted responsibility and undertaken adequate corrective measures.'' In 2011, the Administrator upheld this reasoning in *Linda Sue Cheek, M.D.,* 76 FR at 66972. If there ever was a suggestion that DEA should consider whether, and to what extent, an applicant needed a registration, as DEA considered in *Seglin,* DEA has since changed course, as illustrated by *Owens* and *Cheek.* Thus, I find no support for the proposition that I should recommend denying Dr. Delisma's application because he does not need a COR, or that I should recommend granting his application because he might need one.

the Acting Administrator GRANT the application for a Certificate of Registration, Control Number W18071098C, submitted by Dr. Kansky J. Delisma, M.D., without further delay.

Dated: May 23, 2019.

Charles Wm. Dorman,
U.S. Administrative Law Judge.

[FR Doc. 2020–09057 Filed 4–28–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0055]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Currently Approved Collection; The National Instant Criminal Background Check System (NICS) Checks by Criminal Justice Agencies

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until June 29, 2020.

FOR FURTHER INFORMATION CONTACT: All comments, suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to the Federal Bureau of Investigation, Criminal Justice Information Services Division, National Instant Criminal Background Check System Section, Module A–3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, or email *NICS@fbi.gov.* Attention: OMB PRA 1110–0055

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;

—Evaluate whether and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—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:* The National Instant Criminal Background Check System (NICS) Checks by Criminal Justice Agencies (CJA).

3 *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is unnumbered. The applicable component within the Department of Justice is the Criminal Justice Information Services Division, in the Federal Bureau of Investigation.

4 *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal, State, County, City, Tribal law enforcement agencies.

Abstract: In November 1993, the Brady Handgun Violence Prevention Act of 1993 (Brady Act), Public Law 103–159, was signed into law and required federal firearms licensees (FFL) to request background checks on individuals attempting to purchase or receive a firearm. The permanent provisions of the Brady Act, which went into effect on November 30, 1998, required the United States Attorney General to establish a NICS that FFLs may contact by telephone, or other electronic means in addition to the telephone, for information to be supplied immediately as to whether the receipt of a firearm by a prospective transferee would violate Section 922 (g) or (n) of Title 18, United States Code, or state law. There are additional authorized uses of the NICS found at Title 28, Code of Federal Regulations (CFR), Section 25.6(j). The FBI authorized the CJAs to initiate a NICS check to assist their transfer of firearms to private individuals as a change to 28 CFR 25.6(j) in the **Federal Register**, Volume 78, Number 18 pages 5757–5760.

5 *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated the time burden associated with this collection is 3 minutes per transaction, depending on the individual circumstance. The total annual respondent entities taking advantage of this disposition process is 21,156 CJAs.

6 *An estimate of the total public burden (in hours) associated with the collection:* It is estimated the burden associated with this collection is 3 minutes per transaction depending on the individual circumstance. If each of the 21,156 respondents conducted 3 dispositions with this authority per year at 3 minutes per check, then it is anticipated the business burden would be 3,173.4 hours per year.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: April 24, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–09088 Filed 4–28–20; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0039]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Federal Firearms Licensee Firearms Inventory Theft/Loss Report—ATF Form 3310.11

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 1140–0039 (Federal Firearms Licensee Firearms Inventory Theft/Loss Report—ATF Form 3310.11) is being renamed the Federal Firearms Licensee Firearms Inventory/Firearms In Transit Theft/