DATES: Comments are encouraged and will be accepted for an additional 30 days until August 26, 2020.

ADDRESSES: 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;

—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 with change of a currently approved collection.

(2) *The Title of the Form/Collection:* Application for Tax-Exempt Transfer of Firearm and Registration to Special Occupational Taxpayer.

(3) *The agency form number, if any, and the applicable component of the Department* sponsoring the collection:

Form number: ATF Form 3 (5320.3).

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Federal Government.

Abstract: The Application for Tax-Exempt Transfer of Firearm and Registration to Special Occupational Taxpayer—ATF Form 3 (5320.3) form is used by Federal firearms licensees, to apply for the transfer and registration of a National Firearms Act (NFA) firearm that is subject to exemption from transfer tax, as provided by 26 U.S.C. 5852(d).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 130,289 respondents will utilize the form annually, and it will take each respondent approximately 30 minutes to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 65,145 hours, which is equal to 130,289 (# of respondents) * 1 (# of responses per respondent) * .5 (30 minutes or the total time taken to complete each response).

(7) An Explanation of the Change in Estimates: The adjustments to this information collection include a decrease in the total responses by 47,211. Consequently, the annual burden hours has also reduced by 23,605. However, the public cost increased to $ 4,292, because some respondents completed and mailed their applications to ATF for processing, although this collection can be electronically submitted.

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: July 22, 2020.

Melody Braswell,

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

[FR Doc. 2020–16172 Filed 7–24–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–29]

Frank Joseph Stirlacci, M.D.; Decision and Order

I. Introduction

On April 5, 2017, the then-Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Frank Joseph Stirlacci, M.D. (hereinafter, Respondent), of Agawam, Massachusetts and Hammond, Indiana. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposed the revocation of Respondent's DEA certificate of registration (hereinafter, registration) on the ground that he ''materially falsified . . . [his] application for renewal in violation of 21 U.S.C. 823(f) and 824(a)(1).'' *Id.*

The substantive grounds for the proceeding, as more specifically alleged in the OSC, are that Respondent, ''[o]n or about February 7, 2017, . . . submitted a renewal application for . . . [his registration number] BS5000411 seeking to change . . . [his] registered address to . . . Hammond, Indiana . . . [and] made two material false statements in . . . [his] renewal application''—(1) answering ''no'' to whether he had ever been convicted of a crime in connection with controlled substances under state or federal law, or whether any such action is pending, and (2) answering ''no'' to whether he had ever surrendered (for cause) or had a state professional license revoked, suspended, denied, restricted, or placed on probation, or whether any such action is pending. *Id.* at 2. Citing 21 U.S.C. 823(f) and 824(a)(1), the OSC concluded that ''DEA must revoke . . . [Respondent's registration] based upon . . . [his] material falsifications of . . . [his] renewal application.'' *Id.*

The OSC notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2–3 (citing 21 CFR 1301.43). Respondent timely requested a hearing by letter dated April 29, 2017. ALJX 2 (Request for Hearing).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge (hereinafter, ALJ) John J. Mulrooney, II. The parties initially agreed to eight stipulations.[1]

[1] ''1. The Respondent is registered with the DEA as a practitioner to handle controlled substances in Schedules II to V under DEA COR [certificate of registration] No. BS5000411, with a registered address of Regional Health Center, 559 State Street, Hammond, Indiana 46320. The Respondent's DEA COR expires by its own terms on February 29, 2020.

''2. From April 17, 2015 to May 11, 2015, the Respondent was incarcerated in Kentucky.

''3. On February 5, 2016, the Respondent entered into a Voluntary Agreement Not to Practice Medicine in the Commonwealth of Massachusetts with the Board of Registration.

''4. On January 26, 2017, the Respondent was indicted by the Commonwealth of Massachusetts

Continued

ALJX 11 (Prehearing Ruling, dated June 22, 2017), at 1–2.

The hearing in this matter lasted one day and took place in Arlington, Virginia on August 22, 2017. The Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD) is dated September 29, 2017. Respondent filed exceptions to the RD. ALJX 31 (Respondent's Exceptions to the CALJ's Recommended Decision, dated Oct. 19, 2017). The Government sought and received leave to respond to Respondent's Exceptions over Respondent's objection. ALJX 32 (Government's Request for Leave to File Response to Respondent's Exceptions, dated Oct. 19, 2017); ALJX 34 (Order Granting the Government's Request for Leave to File Response to Respondent's Exceptions, dated Oct. 24, 2017). The Government's response to Respondent's Exceptions is dated November 1, 2017. ALJX 35 (Government's Response to Respondent's Exceptions, dated Nov. 1, 2017).

Having considered the record in its entirety, I agree with the RD's conclusion that the record establishes, by clear, unequivocal, and convincing evidence, that Respondent materially falsified his registration renewal application.[2] I find that Respondent did not accept responsibility for the material falsification. Accordingly, I conclude that I can no longer entrust Respondent with a registration, that his registration should be revoked, and that any pending application by Respondent for registration in Indiana should be denied. I make the following findings.

II. Findings of Fact

A. Respondent's Current Registration

Respondent's current registration, BS5000411, is at the Regional Health Center in Hammond, Indiana. GX 1 (Certificate of Registration), at 1; Tr. 13. Its expiration date is February 29, 2020.[3] GX 1, at 1; GX 2 (Certification of Registration Status), at 1.

B. The Investigation of Respondent

A former employee of Respondent contacted DEA stating that Respondent ''authorized the issuing of prescriptions and seeing patients by a medical assistant in his office while he was incarcerated.'' Tr. 20, 23. The case Diversion Investigator (hereinafter, DI) followed up on the allegation by obtaining copies of prescriptions that Respondent issued during his incarceration and requesting recordings of telephone conversations between Respondent and his office staff during the same period. *Id.* at 23–30.

While the hearing testimony's description of the allegation does not specify whether any of the alleged prescriptions were for controlled substances, there is substantial evidence in the record that the allegation did include, at least in part, the prescribing of controlled substances. For example, the DEA employee staffing the DEA tip line referred the allegation to DI. *Id.* at 20–23. If the allegation had no potential connection to controlled substances, the DEA employee initially receiving the tip would not have referred it to DI for investigation based on DEA's jurisdiction. Further, DI's investigation of the allegation included his request for information from prescription monitoring programs (hereinafter, PDMP). *Id.* at 23–24. The Massachusetts PDMP was established to ''maintain an electronic system to monitor the prescribing . . . of all schedule II to V, inclusive, controlled substances and certain additional drugs . . . determined . . . to carry a bona fide potential for abuse.'' Mass. Gen. Laws ch. 94C, § 24A (Current through Chapter 44 of the 2020 2nd Annual Session). Had the tip not included an allegation related to controlled substances, there would not have been any reason for DI to request PDMP information. As such, I find that the allegation by Respondent's staff concerned, at least in part, the unlawful prescribing of controlled substances.

C. The Material Falsification Allegations

As already discussed, the OSC alleges that Respondent submitted a renewal application containing two material falsifications. OSC, at 2. The first alleged material falsification is his negative response to whether he had ever been convicted of a crime in connection with controlled substances under state or federal law, or whether ''any such action [is] pending?'' *Id.* According to the Government, Respondent's negative response to this ''liability question'' was materially false, because the ''Commonwealth of Massachusetts had indicted . . . [him] for crimes in connection with controlled substances less than two weeks earlier.'' *Id.*

The second alleged material falsification is Respondent's negative response to whether he had ''ever surrendered (for cause) or had a state professional license . . . revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.* The OSC alleges, and the Government sufficiently and timely further explicated, that this negative response was materially false, because Respondent ''had just agreed to not practice medicine within the Commonwealth of Massachusetts.'' [4] *Id.;* 5 U.S.C. 554(b)(3); *contra* ALJX 31, at 1.

There is factual agreement among the witnesses on a number of matters. When there is factual disagreement, I apply my credibility determinations and the credibility recommendations of the Chief ALJ in all but a portion of one instance. *Infra* Section D.

D. The Government's Case

The Government's admitted documentary evidence consists primarily of Respondent's renewal application (GX 6), the sixty-eight page Hampden County Superior Court criminal indictment of Respondent (GX 5), and the Voluntary Agreement Not to Practice Medicine that Respondent and his attorney signed and that the Massachusetts Board of Registration in Medicine (hereinafter, MBRM) ''accepted,'' on February 5, 2016 (GX 3) (hereinafter, Mass. Accepted Voluntary No-Practice Agreement).[5] The

for: (1) 26 counts of Improper Prescriptions, in violation of Mass. Gen. Laws ch. 94C § 19(a); (2) 22 counts of False Health Care Claims, in violation of Mass. Gen. Laws ch. 175H § 2; and (3) 20 counts of Uttering False Prescriptions, in violation of Mass. Gen. Laws ch. 94C § 33(b).

''5. On February 7, 2017, at approximately 17:04 Eastern Time, the Respondent submitted a renewal application for his DEA COR.

''6. The Respondent did not disclose the February 5, 2016 Voluntary Agreement Not to Practice Medicine on his February 7, 2017 renewal application.

''7. The Respondent did not disclose the January 26, 2017 indictments outlined above on his February 7, 2017 renewal application.

''8. The Respondent did not supplement his February 7, 2017 renewal application.''

On the hearing day, the parties submitted additional Stipulations. ALJX 26; transcript page number (hereinafter, Tr.) 5–6. According to the ''Joint Notice of Stipulations,'' the parties stipulated to the authenticity of Respondent's registration in GX 1, of Respondent's registration history in GX 2, and of the Affidavit of Daniel Kelly, RX 3.

[2] I reviewed, and agree with, the Chief ALJ's pre-hearing, hearing, and post-hearing rulings and orders.

[3] The current status of Respondent's registration, whether expired or timely renewed, does not impact my adjudication of this matter. *Jeffrey D. Olsen, M.D.,* 84 FR 68,474 (2019); 5 U.S.C. 558(c).

[4] Although the date in the OSC associated with this allegation is February 5, 2017, the parties subsequently agreed that the correct date is February 5, 2016. Joint Stipulation No. 3.

[5] The Hampden County Superior Court criminal indictment charges Respondent with twenty-six counts of ''improper prescription,'' twenty counts of ''uttering false prescription,'' and twenty-two counts of ''false health care claim.'' GX 5 (Massachusetts Superior Court Indictment No. 17 039 (dated Jan. 26, 2017)). The improper prescription allegations concern controlled substances such as hydrocodone (15 counts),

Government called two witnesses: DI and an Investigator for the MBRM (hereinafter, MBRM Investigator).

DI testified about his investigation-related activities of the ''tip'' submitted by Respondent's former employee, including, his interaction with Respondent's attorney, Daniel M. Kelly, on February 6, 2017, about the Hampden County Superior Court criminal indictment of Respondent and his request for the surrender of Respondent's registration, and his acquisition of an official copy of the Mass. Accepted Voluntary No-Practice Agreement (GX 3). Tr. 34–40 and 41–43, respectively.

DI testified during the Government's rebuttal case that he investigated whether DEA had a record of Respondent's notification of the Mass. Accepted Voluntary No-Practice Agreement. Tr. 140. DI stated that he checked DEA's ''permanent and running database of any activity regarding any registrants or any DEA registration.'' *Id.* at 142. He also testified that he asked the registration specialist for Massachusetts, who is responsible for recording any communication from a registrant, whether DEA had received a communication from Respondent. *Id.* at 143. Neither the check of the database nor the check with the registration specialist showed any communication from Respondent about the Mass. Accepted Voluntary No-Practice Agreement. *Id.* at 140–45. DI acknowledged that Respondent could have notified DEA after DI checked the database and spoke with the registration specialist, and that the registration specialist's check may not have been thorough. *Id.* at 146–48.

I agree with the Chief ALJ that DI's testimony was ''sufficiently detailed, internally consistent, and plausible to be granted full credibility'' and that he ''presented as a credible, objective, dispassionate investigator without any discernible incentive to fabricate or exaggerate.'' RD, at 5.

MBRM Investigator testified that he is the lead MBRM investigator assigned to assess the information the MBRM received from DEA about Respondent, that Respondent issued prescriptions when incarcerated in Kentucky, and that the investigation remains open. Tr. 59, 77. MBRM Investigator testified about the multiple oral and written communications he had with Respondent, Respondent's hiring an attorney, Respondent's signing the Mass. Accepted Voluntary No-Practice Agreement, and Respondent's continued lack of permission to practice medicine in Massachusetts due to his signing the Mass. Accepted Voluntary No-Practice Agreement.[6] Tr. 59–75, 74, 74–75, and 75–80, respectively.

MBRM Investigator testified during the Government's rebuttal case that he previously investigated two other cases concerning Respondent. *Id.* at 150–52. In both instances, MBRM Investigator stated, he notified Respondent of the investigation by phone, by letter, or by both phone and letter. *Id.* at 152.

MBRM Investigator also testified during the Government's rebuttal case that Respondent ''would call and leave . . . messages'' about the case, ''continually . . . asking what he could do to speed the case along.'' *Id.* at 152–53. According to the MBRM Investigator, Respondent's calls occurred during the summer of 2016. *Id.* at 153. Respondent did not rebut this aspect of MBRM Investigator's testimony. *Id.* at 154.

I agree with the Chief ALJ that MBRM Investigator's testimony was ''sufficiently detailed, internally consistent, and plausible to be granted full credibility,'' except as to the plausibility of MBRM Investigator's interpretation of the legal effect of the Mass. Accepted Voluntary No-Practice Agreement. RD, at 5. I agree with the Chief ALJ that MBRM Investigator ''presented as a credible, objective, dispassionate investigator without any discernible incentive to fabricate or exaggerate.'' *Id.*

E. Respondent's Case

Respondent testified and called no other witness. Tr. 81–82.

During his testimony, Respondent recounted his pursuit of a career as a physician since his childhood, discussed his medical licenses and primary care physician practices in Indiana and Massachusetts, and explained that the ''immediate cause'' of his moving from Massachusetts to Indiana was his ''enter[ing] into the voluntary agreement not to practice medicine'' on February 5, 2016. *Id.* at 86–87, 88–93, and 93–95, respectively.

Respondent testified that he first found out from MBRM Investigator that Massachusetts was investigating him on or about January 27, 2016, about a week after he submitted a medical license renewal application. *Id.* at 131. Respondent testified he entered into the Mass. Accepted Voluntary No-Practice Agreement because the MBRM ''had concerns regarding what occurred with . . . [his] divorce, incarceration, contempt,'' and because MBRM Investigator asked him to sign it. *Id.* at 95–96. He testified that he signed it with the assistance of Mr. Kelly, ''the attorney who's representing . . . [him] in the indictment in Massachusetts,'' that his Massachusetts medical license had not expired, and that the Mass. Accepted Voluntary No-Practice Agreement ''is non-disciplinary, there's no violation, so I guess it's a tool that Massachusetts has or a remedy until they can further pursue . . . whatever they have concerns about.''[7] *Id.* at 96–97.

Respondent confirmed that there are ''reporting requirements'' associated with the Mass. Accepted Voluntary No-Practice Agreement and certified that he fulfilled them. *Id.* at 97–98, 155–56. He testified that he received a ''return receipt requested'' green card from his notification to DEA, but no actual notification of receipt from DEA. *Id.* at 98–99.[8] He also stated that he did not have a ''direct conversation'' with anyone at DEA about his entering into the Mass. Accepted Voluntary No-Practice Agreement. *Id.* at 99.

During cross-examination, Respondent offered his perspective of the Mass. Accepted Voluntary No-Practice Agreement. He testified that the ''effect'' of the document is ''self-contained in the words of the document itself.'' *Id.* at 110. He stated that, although he did not know whether Massachusetts was still investigating him, he ''assumed'' that its investigation

oxycodone (6 counts), fentanyl (3 counts), and methadone (3 counts).

[6] During cross-examination, MBRM Investigator responded ''no'' when Respondent's counsel asked if the Mass. Accepted Voluntary No-Practice Agreement is a suspension, revocation, resignation, lapsing, or restriction on Respondent's medical license, or if it is a ''probationary agreement.'' Tr. 77–78.

In response to questions posed by the Chief ALJ, MBRM Investigator stated his understanding that ''if you practice [medicine] during a voluntary, we as the Board of Medicine could possibly summarily suspend you.'' Tr. 80; *see also* GX 3, at 2.

[7] Stipulation No. 2, ''From April 17, 2015 to May 11, 2015, the Respondent was incarcerated in Kentucky,'' concerns Respondent's having been held in contempt and incarcerated in Kentucky in connection with a divorce matter. ALJX 11, at 2. During cross-examination, Respondent admitted that he responded in the negative to a question on the Massachusetts medical license renewal application about whether he had been ''charged with any criminal offense during this period?'' Tr. 124–25. He also admitted to responding ''no'' to questions on the same application about whether any criminal offenses or charges against him had been resolved during the time period, and whether any criminal charges were pending against him ''today.'' Tr. 125–26. Respondent explained that he answered ''no'' because the Kentucky matter was about his divorce and not, in his understanding, about a medical or criminal matter. Tr. 129. He stated that ''to think that contempt in my divorce rose to a level of criminal activity, it didn't quite register like that. I mean, I'm sorry. It just didn't.'' *Id.*

[8] According to Respondent, he ''possibly may,'' but does not ''believe'' that he still has the return receipt card from the mailing to DEA. Tr. 115.

was still open, more likely than not. *Id.* In response to a question posed by the Chief ALJ, however, Respondent agreed that his signing the Mass. Accepted Voluntary No-Practice Agreement meant that everything was ''sort of'' held in the status quo. *Id.* at 134. He again ''assumed'' that the hold was so MBRM could finish its investigation. *Id.* at 135. As Respondent continued to say ''I don't know'' and ''I guess'' about the status of the MBRM investigation, the Chief ALJ sought clarification, asking, ''But your belief wasn't that you were just going to stop practicing medicine forever. Your belief was that until they sort this out, you were in this status?'' *Id.* Respondent answered, ''Until, right, right, that they would sort it.'' *Id.* at 135–36.

The Chief ALJ then asked Respondent ''who is Daniel Kelly? Where does he come into it?'' *Id.* at 136. Respondent replied that Mr. Kelly represented him in the federal and local criminal matters ''from the beginning . . . so he was aware of—he knew the entire situation, I guess,'' and that Respondent retained him ''a year prior'' to the indictment. *Id.* at 136–37. During this inquiry, the Chief ALJ suggested, and I agree, that Respondent retained a criminal defense attorney because he knew that a criminal investigation was pending. *Id.*

Respondent stated his understanding that the ''or is any such action pending'' portion of the third liability question did not call for him to answer yes, even though he assumed that Massachusetts was still investigating him. *Id.* at 111–12. When asked if he would have had to answer ''yes'' if he knew about an investigation by Massachusetts, he answered yes, he should have answered ''yes'' if he were aware of a Massachusetts investigation. *Id.* at 114–15. He elaborated by reiterating his view that the Mass. Accepted Voluntary No-Practice Agreement is a ''tool'' of the MBRM. *Id.* at 112. He stated that it is ''non-disciplinary'' and that it is ''not restriction, probation, all of the things that it has in there pertaining to the question, and my understanding is it's to avoid any action.'' *Id.* Further, on re-direct, Respondent testified that he ''answered the question [on the DEA application] honestly at that time . . . to the best of my knowledge.'' *Id.* at 130. On re-cross, Respondent answered ''no'' when asked whether he thought ''putting all those ''No's'' there, it was more likely that they were going to renew your certificate of registration.'' *Id.* at 133. He responded ''not one way or the other. I mean, they're asking questions and then they will make a determination based on the totality of everything. . . . [I]t's up to them.'' *Id.*

Regarding the Hampden County Superior Court criminal indictment, Respondent confirmed that its allegations stem ''from that time . . . [he] was incarcerated.'' *Id.* He testified that Mr. Kelly told him about the indictment on Thursday morning, February 9, 2017, a couple days after Respondent submitted the registration renewal. *Id.* at 100. He stated that he did not know that he had been indicted when he submitted the registration renewal. *Id.; see also id.* at 102–03 (denying he received personal service of the indictment before he submitted the renewal application).

Respondent testified that he never had a problem with his registration since he first received it in ''approximately'' 1996, and that he has had a ''full unrestricted'' medical license since 1996. *Id.* at 100–01. He stated that his registration and medical licenses have ''all been in good standing, unrestricted [in] full with all states that I've ever held licenses in.'' *Id.* at 101. Respondent explained his negative response to the third liability question on the renewal application by testifying that ''my license has not been revoked, my license has not been suspended. They did not deny my license. I have my license. It's currently preserved . . . . There's no restriction on my license. It has not been placed on probation. So the answer is no.'' *Id.* at 104. In addition, Respondent confirmed that he did not ''consider whether the Massachusetts voluntary agreement not to practice medicine, whether that should cause . . . [him] to answer ''Yes'' to that particular question.'' *Id.*

Respondent testified that he ''honestly believed when . . . [he] completed the application that . . . [his] answers were truthful, to the best of . . . [his] ability,'' and that he had ''no intent to deceive the DEA. There would be no purpose in that.'' *Id.* at 104–05; *see also id.* at 109.[9]

I agree with the Chief ALJ's analysis of the credibility of Respondent's testimony.

While the Respondent's testimony was not without some credible aspects, it was also not without some bases for reservation. In addition to the incontrovertible fact that as the subject of these proceedings, the Respondent has the most at stake, his unequivocal assertion that his state licensure has never been the subject of any investigation since the commencement of his medical practice in 1996 was convincingly contradicted by . . . [MBRM Investigator], who credibly testified that he investigated the Respondent regarding a patient complaint and failure to cooperate with that complaint, and that he telephonically informed him about that investigation. . . . Further, . . . [Respondent's] unwillingness to acknowledge that benign responses to the Liability Questions were less likely to raise concern did not enhance his credibility here. The Respondent is an educated professional, and irrespective of his view that his answers in the application were candid, his refusal to accept the proposition that unremarkable responses are generally more likely to result in a favorable outcome in a DEA application was a gratuitous depreciation of his overall credibility.

Moreover, the Respondent's testimony that he forwarded a copy of the . . . [Mass. Accepted Voluntary No-Practice Agreement] to DEA, but failed to keep a shred of paperwork memorializing that act, is implausible. By the Respondent's own account, sending the Agreement to various offices, including DEA, was a term of the Agreement. . . . That he would fail to keep any evidence of his compliance with that term, particularly after he expounded on the importance of such compliance as an integral aspect of his profession, is simply not credible. Although much of the Respondent's testimony is worthy of belief, in instances where that testimony is at variance with other credible testimony, it must be viewed with heightened scrutiny.[10]

RD, at 7–8 [citations and footnotes omitted].

F. Allegation That Respondent Submitted a Materially False Registration Renewal Application

As already discussed, the OSC charged Respondent with submitting a renewal application containing two material false statements. The first alleged material false statement concerns Liability Question No. 1 and Respondent's negative response as to whether he had ever been convicted of a crime in connection with controlled substances under state or federal law, ''or [is] any such action pending.'' OSC, at 2. The second alleged material false

[9] Respondent also testified that he would lose his job if he did not have a registration. Tr. 105.

[10] The RD ''found that Respondent's testimony was 'convincingly contradicted' by a Government witness, thus disputing the credibility of Respondent's testimony.'' ALJX 31, at 9. Respondent took exception to this portion of the RD, arguing that the RD's credibility determination ''is not supported by the cited record as Respondent never made any such assertion.'' *Id.* at 10. I reject Respondent's exception.

First, although Respondent correctly distinguishes between the words ''discipline'' and ''investigations'' in the transcript, he ignores the substance of MBRM Investigator's testimony. Tr. 101, 151. MBRM Investigator clearly testified that he opened a ''second docket'' due to Respondent's ''failure to answer the . . . [MBRM] during that first case.'' *Id.* at 152. I find that Respondent's fully honest response to his counsel's question of ''And before all this started taking place, did you ever have any sort of medical state discipline?'' would have included and disclosed the opening of the second docket due to Respondent's failure to answer the MBRM during the first case. *Id.* at 101. Second, as the Government points out, Respondent inaccurately suggests that the RD makes a ''negative credibility determination based solely on Respondent's failure to disclose two prior state investigations.'' ALJX 35, at 8.

statement concerns Liability Question No. 3 and Respondent's negative response as to whether he had ever surrendered (for cause) or had a state professional license revoked, suspended, denied, restricted, or placed on probation, or whether ''any such action [is] pending.'' *Id.*

G. Liability Question No. 1

I find that Respondent answered ''no'' to the first Liability Question on the registration application. GX 2, at 2; ALJX 11, at 2 (Stipulation Nos. 7 and 8). I find that the Hampden County Superior Court criminal indictment of Respondent is dated January 26, 2017. GX 5. I find that DI informed Respondent's attorney about the Hampden County Superior Court criminal indictment on February 6, 2017. Tr. 34–40. Even if the Hampden County Superior Court criminal indictment is a precursor ''action pending'' to a possible criminal conviction in connection with controlled substances under state or federal law, I find that there is insufficient evidence in the record that Respondent, himself, as opposed to his attorney, knew about the Hampden County Superior Court criminal indictment on or before February 7, 2017. I, thus find that the evidence the Government submitted does not establish that Respondent's ''no'' response to the first Liability Question was false, let alone materially false, when he submitted his renewal application to DEA on February 7, 2017.

H. Liability Question No. 3

I find from clear, unequivocal, and convincing evidence that Respondent answered ''no'' to the third Liability Question on the registration application. ALJX 11, at 2 (Stipulation Nos. 6 and 8); GX 2, at 2. I find from clear, unequivocal, and convincing evidence that Respondent and his attorney signed the Mass. Accepted Voluntary No-Practice Agreement on February 5, 2016. GX 3, at 3. I find from clear, unequivocal, and convincing evidence that the MBRM ''accepted'' and ''ratified'' the Mass. Accepted Voluntary No-Practice Agreement on February 5, 2016 and February 11, 2016, respectively. *Id.*

I find from clear, unequivocal, and convincing evidence that the Mass. Accepted Voluntary No-Practice Agreement resulted from the MBRM investigation of the tip DEA received, that the Mass. Accepted Voluntary No-Practice Agreement is still in effect, and that the MBRM investigation was open at least through the date of the DEA administrative hearing. Tr. 76–77. I find from clear, unequivocal, and convincing evidence that the Mass. Accepted Voluntary No-Practice Agreement is the reason Respondent is not permitted to practice medicine in Massachusetts. ALJX 11, at 2 (Stipulation No. 3); Tr. 94–99. I find from clear, unequivocal, and convincing evidence that the terms of the Mass. Accepted Voluntary No-Practice Agreement include Respondent's ''immediate'' cessation of the practice of medicine in Massachusetts. GX 3, at 2. Based on clear, unequivocal, and convincing evidence, I find that the Mass. Accepted Voluntary No-Practice Agreement is a clear indicator, and is part, of pending action by the MBRM regarding Respondent's Massachusetts medical license. For example, the top of the first page of the Mass. Accepted Voluntary No-Practice Agreement is captioned ''In the Matter of'' Respondent and shows a docket number starting with the year. *Id.* The second paragraph clearly states that the Mass. Accepted Voluntary No-Practice Agreement ''will remain in effect'' until the MBRM modifies it, terminates it, ''takes other action against . . . [Respondent's] license to practice medicine,'' or ''takes final action on the above-referenced matter.'' *Id.* The sixth paragraph of the Mass. Accepted Voluntary No-Practice Agreement warns that ''[a]ny violation of this Agreement shall be *prima facie* evidence for immediate summary suspension of my license to practice medicine.'' *Id.* [italics added]. The last page of the Mass. Accepted Voluntary No-Practice Agreement contains the dates on which the MBRM ''accepted'' and ''ratified,'' by vote of the MBRM, the Agreement. GX 3, at 3. These terms and provisions leave no room for doubt that the Mass. Accepted Voluntary No-Practice Agreement evidences, and is part of, pending action by the MBRM regarding Respondent's medical license. Indeed, I find from clear, unequivocal, and convincing evidence that the Mass. Accepted Voluntary No-Practice Agreement envisions the possibility that it could be used as *prima facie* evidence for the ''immediate summary suspension'' of Respondent's Massachusetts medical license. GX 3, at 2.

In sum, I find from clear, unequivocal, and convincing evidence that the third Liability Question on the application Respondent submitted to DEA asks whether the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, ''or is any such action pending?'' [11] GX 2, at 2. As already discussed, I find from clear, unequivocal, and convincing evidence that, at a minimum, the Mass. Accepted Voluntary No-Practice Agreement shows a pending action exists in Massachusetts concerning Respondent by its explicit warning that ''immediate summary suspension'' of Respondent's Massachusetts medical license is a possible result of ''any violation of this Agreement.'' [12] GX 3, at 2. Consequently, I find based on clear, unequivocal, and convincing evidence, that Respondent's ''no'' answer to the third Liability Question was false.[13] For the same reasons, and based on the same clear, unequivocal, and convincing evidence, I also find that Respondent knew, or should have known, that his answer to the third Liability Question was false. Further, for the same reasons and based on the same evidence in conjunction with the credibility determinations I already made, I find that Respondent falsified his answer to the third Liability Question to help ensure DEA's favorable action on his application and, therefore, that Respondent's falsification indicates an intent to deceive.[14]

III. Discussion

A. The Controlled Substances Act and the OSC Allegations

Pursuant to section 303(f) of the Controlled Substances Act (hereinafter, CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . .

[11] I need not address Respondent's argument that his signing the Mass. Accepted Voluntary No-Practice Agreement was not a ''for cause'' surrender because my Decision is not based on that aspect of Liability Question No. 3.

[12] Respondent's argument that he is still subject to an open investigation may also be true. ALJX 30 (Respondent's Proposed Findings of Fact and Conclusions of Law, dated Sept. 21, 2017), at 11. I need not address Respondent's argument that an investigation is not a ''pending action.'' *Id.* at 12–13. As already explained, the Mass. Accepted Voluntary No-Practice Agreement makes clear on its face that the MBRM has a pending action concerning Respondent, and I find unavailing all of Respondent's arguments to the contrary. *See, e.g.,* ALJX 31, at 4–6.

[13] For the same reasons, I conclude that Respondent's arguments that he ''still maintains his license,'' that he did not surrender it, are misplaced and legally irrelevant.

[14] Proof of intent to deceive has never been, and is not, a required element of a material falsification under 21 U.S.C. 824(a)(1). Indeed, at its essence, intent to deceive conflicts with Agency decisions' long-standing material falsification determinations of whether the applicant ''knew or should have known'' that the application was false. Some past Agency material falsification decisions address an intent to deceive in determining the appropriate sanction for a material falsification, as do I. *See infra* note 32.

controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires me to consider the following factors:

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

(2) The applicant's experience in dispensing . . . 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. Id.

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one,'' and I ''can 'give each factor the weight . . . [I] determine[ ] is appropriate.'''' *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009) quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005)). In other words, the public interest determination ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Peter A. Ahles, M.D.,* 71 FR 50,097, 50,098–99 (2006).

Pursuant to section 304(a)(1), the Attorney General is also authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in this section are also properly considered in deciding whether to grant or deny an application under section 303. *See Richard J. Settles, D.O.,* 81 FR 64,940, 64,945 (2016); *Arthur H. Bell, D.O.,* 80 FR 50,035, 50,037 (2015); *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74,334, 74,338 (2007); *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,852 (2007); *Alan R. Schankman, M.D.,* 63 FR 45,260, 45,260 (1998); *Kuen H. Chen, M.D.,* 58 FR 65,401, 65,402 (1993).[15]

The Government has the burden of proof in this proceeding. 21 CFR 1301.44.

As already discussed, Respondent submitted a registration renewal application containing a false answer to the question of whether he ''ever surrendered (for cause) or had a state professional license . . . revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' The Supreme Court explained decades ago that ''the ultimate finding of materiality turns on an interpretation of substantive law.'' *Kungys* v. *United States,* 485 U.S. 759, 772 (1988) (citing a Sixth Circuit case involving 18 U.S.C. 1001 and explaining that, even though the instant case concerned 8 U.S.C. 1451(a), ''we see no reason not to follow what has been done with the materiality requirement under other statutes dealing with misrepresentations to public officers''). The Supreme Court also clarified that a falsity is material if it is ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.'' *Id.* at 771.

In this case, application of the Supreme Court's materiality analysis, in the context of the CSA, means that Respondent's false submission was material. *Id.* Indeed, the falsity Respondent submitted in his renewal application relates to three of section 303(f)'s five factors, which provide the bases for my determination of whether an application is inconsistent with the public interest. 21 U.S.C. 823(f); *see JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28,667, 28,681 (2015) (stating that a falsity must be analyzed in the context of the application requirements sought by DEA and provided by the applicant, and must relate to a ground that could affect the decision); *see also* ALJX 30 (Respondent's Proposed Findings of Fact and Conclusions of Law, dated Sept. 21, 2017), at 14; *Universal Health Servs., Inc.* v. *United States ex rel. Escobar,* 136 S. Ct. 1989, 2003 (2016) (hereinafter, *Escobar*) (stating that ''[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'''); *Maslenjak* v. *United States,* 137 S. Ct. 1918, 1928 (2017) (concluding that when ''there is an obvious causal link between the . . . lie and . . . [the] procurement of citizenship,'' the facts ''misrepresented are themselves disqualifying'' and I ''can make quick work of that inquiry''). Respondent's provision of false information deprived me of the ability to carry out my statutorily mandated five-factor analysis concerning the registration of practitioners. 21 U.S.C. 823(f). In other words, there is no doubt that Respondent's falsity was ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision'' the CSA instructs me to make. *Kungys,* 485 U.S. at 771.

The facts in this case clearly demonstrate the connection between one liability question and three of section 303(f)'s five factors. *Infra* note 30. The first section 303(f) factor is the ''recommendation of the appropriate State licensing board or professional disciplinary authority.'' 21 U.S.C. 823(f)(1). In this case, the MBRM accepted and ratified Respondent's Mass. Accepted Voluntary No-Practice Agreement on February 5 and 11, 2016, respectively. GX 3, at 2. As already discussed, pursuant to Respondent's Mass. Accepted Voluntary No-Practice Agreement, as accepted and ratified by the MBRM, Respondent admits that his Massachusetts medical license no longer permits him to practice medicine; Respondent's state professional license is restricted to a practical nullity. Tr. 89, 93. Further, as already discussed, the second paragraph of the Mass. Accepted Voluntary No-Practice Agreement explicitly states that the ''Matter'' of Respondent's Mass. Accepted Voluntary No-Practice Agreement, Docket No. 16–033, remains pending before the MBRM. GX 3, at 2 (''This Agreement will remain in effect until the . . . [MBRM] determines that this . . . [Mass. Accepted Voluntary No-Practice Agreement] should be modified or terminated; or until the . . . [MBRM] takes other action against . . . [Respondent's] license to practice medicine; or until the . . . [MBRM] takes final action on the above-

[15] Just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *Richard J. Settles, D.O.,* 81 FR at 64,945; *Arthur H. Bell, D.O.,* 80 FR at 50,037; *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR at 74,338; *Bobby Watts, M.D.,* 58 FR 46,995, 46,995 (1993); *Shannon L. Gallentine, D.P.M.,* 76 FR 45,864, 45,865 (2011).

referenced matter.''). In addition, also already discussed, a clear indication of the significance of the Mass. Accepted Voluntary No-Practice Agreement is the document's sixth paragraph that ''[a]ny violation . . . shall be *prima facie* evidence for immediate summary suspension'' of Respondent's medical license. *Id.* [italics added]. Thus, Respondent's false submission implicates the first factor that I am statutorily mandated to consider. *John O. Dimowo, M.D.,* 85 FR 15,800, 15,809–10 (2020).

The second section 303(f) factor is the ''applicant's experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). I already found that DEA and Massachusetts law enforcement were investigating an allegation that Respondent unlawfully issued controlled substance prescriptions when he was incarcerated in Kentucky. Tr. 20–40. Further, the unrefuted record testimony is that Respondent entered into the Mass. Accepted Voluntary No-Practice Agreement after multiple interactions with the MBRM Investigator regarding this allegation. *Id.* at 93–97, 155–56; GX 5. The fact that this unrefuted record evidence includes unproven allegations does not change the salient point. The CSA requires me to consider Respondent's experience in dispensing controlled substances. Respondent's alleged controlled substance dispensing while incarcerated in Kentucky, which irrefutably led to the Mass. Accepted Voluntary No-Practice Agreement, implicates this CSA-mandated factor regardless of the weight, if any, I give it. The falsity Respondent submitted in his application deprived me of information potentially relevant to factor two, and, therefore, I was unable to carry out my CSA-mandated responsibilities.

The analysis of the same unrefuted record evidence under factor four (compliance with applicable state, federal, and local laws relating to controlled substances) leads to the same conclusion. Respondent's submission of a falsified application deprived me of information potentially relevant to factor four, and, therefore, I was unable to carry out my CSA-mandated responsibilities.

In sum, the falsity Respondent submitted relates to three of section 303(f)'s five factors. Based on an analysis of the CSA, Respondent's falsity directly implicates my statutorily mandated analysis and decision by depriving me of legally relevant facts. *Escobar,* 136 S. Ct. at 2002 (''Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'''). Consequently, I must find, based on the CSA and the analysis underlying multiple Supreme Court decisions involving materiality, that the falsity Respondent submitted was material.[16]

B. Respondent's Arguments and Exceptions

Respondent posited many arguments during the administrative hearing and in exceptions to the RD. Some have already been addressed. Others are addressed below.

Respondent argues that a recent Supreme Court decision's treatment of ''materiality'' in a False Claims Act case is ''particularly unfavorable to the Government's attempt to prove materiality in light of DEA's informed inaction.'' ALJX 30, at 16 (citing *Escobar*). According to Respondent, ''[i]n terms of . . . [False Claims Act] liability, the [Supreme] Court held that evidence that the government knew about an alleged regulatory violation that caused a claim submitted to the government to be false yet continued to pay those claims was 'very strong evidence' that the underlying conduct was not material.'' *Id.* at 17. Since the Supreme Court ''utilized the same definition of 'material' set forth by the [Supreme] Court in *Kungys,*'' Respondent argues, the Government ''cannot prevail in light of its inaction despite knowledge of the alleged past conduct underlying the indictment.'' *Id.*

The RD rejects this argument, as do I. RD, at 16–17.

First, Respondent's reasoning, based on the appearance of the same root word, ''material,'' for applying *Escobar's* False Claims Act analysis to the CSA is not convincing. The Supreme Court in *Escobar* ties its analysis to ''other federal fraud statutes'' and to the common law.[17] It connects its discussion of federal fraud statutes with the common law by stating that the ''common law could not have conceived of 'fraud' without proof of materiality.'' *Escobar,* 136 S. Ct. at 2002 (citing *Neder* v. *United States,* 527 U.S. 1, 22 (1999). It emphasizes the similarity of the definitions of ''materiality'' in the False Claims Act and in the common law by stating that ''[w]e need not decide'' whether the False Claims Act's ''materiality requirement is governed by . . . [the False Claims Act] or derived directly from the common law.'' *Escobar,* 136 S. Ct. at 2002. Thus, Respondent's invitation that I apply the Supreme Court's *Escobar* analysis of the False Claims Act to the CSA more broadly than only to the definition of ''materiality'' goes beyond the clear boundaries of *Escobar* and is without merit.[18] As the RD states, ''Whether the

[16] As the parties stipulated, Respondent's false submission to DEA appeared in the registration renewal application he submitted on February 7, 2017. ALJX 11, at 2 (Joint Stipulation No. 5), *supra* note 1. That renewal application was granted. Subsequently, DEA identified the falsity and issued the OSC seeking revocation based of 21 U.S.C. 824(a)(1).

The liability questions implicate the public interest factors of 21 U.S.C. 823(f). *Infra* note 30. A false response to a liability question is, by definition, therefore, always ''material'' and always a reason why I may deny an initial or subsequent application under section 303(f). According to the terms of section 303(f), my ultimate decision of whether to deny such a materially false application shall be based on my determination of whether ''issuance of such registration or modification would be consistent with the public interest'' as determined by my consideration of that section's five factors.

When, however, as here, the Agency does not identify the material falsity until after the registration or modification is granted, the determination of the appropriate sanction, if any, is based on the relevant facts and circumstances. 21 U.S.C. 824(a)(1).

[17] It explicitly mentions mail, bank, and wire fraud statutes, *Neder* v. *United States,* 527 U.S. 1 (1999), and fraudulent statements to immigration officials, *Kungys* v. *United States,* 485 U.S. 759 (1988). *Escobar,* 136 S. Ct. at 2002.

[18] Likewise, in conjunction with the Court's statement in *Maslenjak,* the Court's more recent naturalization decision, that the naturalization process ''is set up to provide little or no room for subjective preferences,'' I note that the CSA differs from the naturalization process in that respect. *Maslenjak,* 137 S. Ct. at 1928 (concluding that ''the question of what any individual decisionmaker might have done with accurate information is beside the point'' because the ''entire system . . . is set up to provide little or no room for subjective preferences''). While the CSA establishes parameters for issuing and terminating registrations, the final registration-related decision, such as granting or denying a registration, and continuing, suspending, or revoking a registration, is left to the reviewable discretion of the Attorney General. 21 U.S.C. 823 and 824 (using the word ''may'' in provisions to confer discretion on the Attorney General regarding the granting, denying, continuing, suspending, and revoking of practitioner registrations). The difference between the objective naturalization process and the discretionary CSA process, however, does not detract from the usefulness of the Supreme Court's decisions on the meaning of ''materially falsified'' under section 304(a)(1).

Although the existence of a factor in 823(f) is not, in and of itself, disqualifying as a fact could be in the naturalization process, the CSA states clearly that ''in determining the public interest, the following factors *shall* be considered.'' 21 U.S.C. 823(f) (emphasis added). Depriving me of accurate information that I am statutorily required to consider interferes with my responsibility to consider the public interest factors. The clear intent of the CSA is that applicants and registrants shall provide me with accurate information for my analysis under section 303, and that a falsification of any information concerning a section 303 factor thwarts my ability to assess the public interest as the CSA requires me to do, and is therefore necessarily material to my decision on the application. In light of the discretion afforded me in the CSA, it would make little sense to impose a ''but for'' test or even a ''more likely than not'' test on the effect of a false statement. After all, I cannot analyze the five factors without accurate information.

Government decides to pay a [contract] claim despite knowledge that certain conditions of payment are not satisfied simply does not implicate the same considerations as the decision of the Government to delay (or even to forgo) bringing . . . [a CSA] action against a . . . [registrant] despite knowledge of alleged conduct which could support a sanction.'' RD, at 16–17. I reject Respondent's invitation to equate the CSA with the False Claims Act. I agree with the RD that these two statutes share no commonality that would legally support, let alone require, such a correlation.

Second, Respondent's argument takes *Escobar* beyond the parameters of the Supreme Court's opinion. Respondent argues that the Government ''*cannot prevail* in light of its inaction, despite knowledge of the alleged past conduct underlying the indictment.'' ALJX 30, at 17 [emphasis added]. The Supreme Court, however, merely warned that ''if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that *is very strong evidence* that those requirements are not material.'' *Escobar,* 136 S. Ct. at 2003 [emphasis added]. Respondent's argument that the Government ''cannot prevail in light of its [prior] inaction'' against Respondent, is not only inapposite, it also carries the *Escobar* decision beyond the Court's clear terms that inaction is ''very strong evidence,'' but not dispositive.

Third, Respondent's argument incorrectly assumes that no crime or violation has occurred unless law enforcement has initiated a criminal prosecution or a civil or administrative enforcement action. According to Respondent, ''[i]f [Respondent's] alleged past conduct were material, DEA could have brought an order to show cause against . . . [him] based on this conduct at some point over the last two years. Instead, DEA has allowed . . . [Respondent] to maintain his COR.'' ALJX 30, at 17. Respondent's position is untenable.

Section 304 of the CSA states that the Attorney General ''may'' revoke or suspend a registration. 21 U.S.C. 824(a). The discretion the CSA affords the Attorney General regarding his initiation of a revocation or suspension enforcement action is unfettered.[19] According to the Supreme Court, in situations such as the one presented by the CSA, ''an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion.'' *Heckler* v. *Chaney,* 470 U.S. 821, 831 (1985); *see also* 5 U.S.C. 701(a) and *Heckler* v. *Chaney,* 470 U.S. at 831–32 (discussing reasons why there is generally no judicial review of agency decisions not to enforce).

Fourth, Agency decisions have addressed section 304(a)(1), including the meaning of ''materially,'' on multiple past occasions. Relying on those interpretations of the CSA, as opposed to taking the novel approach that Respondent proposes, is important to the Agency's mission.[20]

An Agency decision from 1986 noted that the Agency ''processes thousands of practitioner registrations each year'' and that there is ''no feasible method . . . [for the Agency] to make an investigation into the accuracy of each application submitted.'' *William M. Knarr, D.O.,* 51 FR 2772, 2773 (1986) (noting that the falsifications were discovered by accident). This decision and others interpreting section 304(a)(1) concluded that the submission of falsified applications is a serious offense that cannot be tolerated because it renders the Agency ''unable to meaningfully pass on the fitness of the applicant.'' *Id.; see also Carl E. Darby, M.D.,* 53 FR 51,330, 51,331 (1988); *Ronald H. Futch, M.D.,* 53 FR 38,990, 38,991 (1988). The questions on the registration application ''serve a purpose which cannot be overlooked by the Administrator'' and, had the applicant submitted accurate responses, ''an investigation could have taken place.'' *Ezzat E. Majd Pour, M.D.,* 55 FR 47,547, 47,548 (1990) (finding finalized or pending medical license revocation/suspension proceedings in three states even though applicant provided a ''no'' answer to the relevant liability question on the application). In carrying out its statutory mission to authorize the dispensing of controlled substances in the public interest, the Agency must be able to rely on the truthfulness of applicants' submissions. *Anne D. DeBlanco, M.D.,* 62 FR 36,844, 36,845 (1997) (''Since DEA must rely on the truthfulness of information supplied by applicants in registering them to handle controlled substances, falsification cannot be tolerated.''); *Leonel Tano, M.D.,* 62 FR 22,968, 22,972 (1997) (same); *Linwood T. Townsend, D.D.S.,* 59 FR 32,224, 32,225 (1994) (same); *Bobby Watts, M.D.,* 58 FR 46,995, 46,995 (1993) (same); *Carl E. Darby, M.D.,* 53 FR at 51,331 (same); *Ronald H. Futch, M.D.,* 53 FR at 38,991 (same); *William M. Knarr, D.O.,* 51 FR at 2773 (concluding that the Agency ''must rely on the truthfulness of every applicant'').

In the late 1990s, the Agency elaborated on its earlier decisions and distinguished between finding the existence of a material falsification and determining the appropriate sanction. *Martha Hernandez, M.D.* (hereinafter, *Hernandez*) repeated the observation from earlier Agency decisions that ''the Respondent knew, or should have known, that his DEA registration had been revoked.'' 62 FR 61,145, 61,146 (1997) (citing *Bobby Watts, M.D.,* 58 FR at 46,995 and *Herbert J. Robinson, M.D.,* 59 FR 6304, 6304 (1994)). *Hernandez,* though, characterized this observation as a necessary part of the analysis of the existence of a material falsification. According to *Hernandez,* again referencing *Bobby Watts, M.D.* and *Herbert J. Robinson, M.D.,* ''DEA has previously held that in finding that there has been a material falsification of an application, it must be determined that the applicant knew or should have

[19] Section 304(a)(1–5) lists grounds for suspension or revocation of a registration.

[20] To the extent that Agency decisions contain differences in their interpretations or applications of 21 U.S.C. 824(a)(1), I note *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502 (2009). In that case, the Supreme Court acknowledged that administrative agency adjudications change course and addressed how an agency may do so and continue to pass muster on appellate review under the Administrative Procedure Act (hereinafter, APA). First, the Supreme Court pointed out that the APA does not mention a heightened standard of review for agency adjudication course adjustments. *Id.* at 514. Instead, it stated that the narrow and deferential standard of review of agency adjudications set out in 5 U.S.C. 706 continues to apply. *Id.* at 513–14 (concluding that ''our opinion in *State Farm* neither held nor implied that every agency action representing a policy change must be justified by reasons more substantial than those required to adopt a policy in the first instance.'').

Second, according to the Supreme Court, an agency would ''ordinarily display awareness that it *is* changing position'' and it may not ''depart from a prior policy *sub silentio* or simply disregard rules that are still on the books.'' *Id.* at 515. Further, an agency must ''show that there are good reasons for the new policy'' but need not ''demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better.'' *Id.* (emphases in original). Finally, the Supreme Court had warned in an earlier decision that an ''irrational departure'' from agency policy, ''as opposed to an avowed alteration of it,'' could be overturned as arbitrary and capricious, or an abuse of discretion. *I.N.S.* v. *Yueh-Shaio Yang,* 519 U.S. 26, 32 (1996).

Thus, while my analysis of Agency decisions' legal interpretations over time of ''materially falsified'' shows substantial uniformity, I note a few instances of an arguable degree of departure. The departure may be attributable to particular or unusual facts, to my predecessor's perspective on the degree of transparency or candor required in the specific interaction with the Agency at issue, or the like. While my legal analysis of the CSA's provision addressing material falsification may not be the agency adjudication course adjustment the Supreme Court contemplated in *Fox Television,* I am following the Court's *Fox Television* parameters as I carry out my CSA-related responsibilities. The ramifications of my doing so include increasing transparency and facilitating any appellate review.

known that the response given to the liability question was false.'' 62 FR at 61,146. The Agency then ''conclude[d] that there is no question that . . . [respondent] materially falsified two of her applications for DEA registration'' and stated that this was ''extremely troubling since DEA relies on accurate information being submitted by its applicants.'' [21] *Id.* at 61,148.

Admitting to the inaccuracy of the answers on her DEA application, the *Hernandez* respondent argued that she submitted no ''materially'' false statement, that she had no intent to deceive or mislead DEA, that her underlying misconduct was not related to controlled substances, and that she responded correctly to similar questions on a state application after someone explained the proper way to interpret the application question. *Id.* at 61,146. The Agency did not fully embrace her arguments. In addition to concluding that the falsifications were material, *Hernandez* made clear that a misinterpretation of the application does ''not relieve [respondent] . . . of her responsibility to carefully read the question and to honestly answer all parts of the question.'' *Id.* at 61,147. While the decision may be interpreted to agree with the *Hernandez* respondent that she did not intend to deceive DEA, the decision states that ''negligence and carelessness in completing an application could be a sufficient reason to revoke a registration.'' *Id.* Regarding the *Hernandez* respondent's argument that the falsification did not involve controlled substances, the Agency agreed with the Government that it had ''in fact revoked registrations in the past based upon the material falsification of an application that was not related to the mishandling of controlled substances.'' *Id.* at 61,148 (citing *Ezzat E. Majd Pour, M.D.*).

Hernandez, then, drew the distinction between finding a material falsification and the next inquiry—whether ''revocation is the appropriate sanction in light of the facts and circumstances of this case.'' *Id.* The decision appears to credit as ''credible,'' while also stating it is ''clearly an incorrect interpretation,'' the *Hernandez* respondent's explanation for the falsity. *Id.* Further, the decision calls ''troubl[ing]'' the *Hernandez* respondent's ''carelessness in failing to carefully read the question on the applications.'' *Id.* Nevertheless, the decision finds ''significant'' that, prior to the issuance of the OSC, the *Hernandez* respondent ''answered a similar liability question correctly on her . . . Illinois application . . . after discussing the matter with an Illinois official.'' *Id.* The decision notes that the Illinois Department of Professional Regulation ''has seen fit to allow . . . [her] to continue to practice medicine as long as she continues to repay her loan.'' *Id.* Thus, the decision concludes, the state medical boards' handling of the *Hernandez* respondent's student loan repayment challenges was ''relevant, although not dispositive, in determining the appropriate sanction.'' *Id.* After considering all of the facts and circumstances, the decision concludes that ''revocation would be too severe a sanction given the facts and circumstances of this case.'' *Id.* at 61,148. Instead, it reprimands the *Hernandez* respondent ''for her failure to properly complete her applications for registration,'' and required her, for three years, ''to submit to the DEA . . . , on an annual basis, documentation from . . . [the] medical licensing authorities certifying that her medical licenses remain in good standing . . . and that there is no impediment to her handling controlled substances at the state level.'' *Id.*

Some Agency decisions incorporate both pre-*Hernandez* and *Hernandez* analyses.[22] Other Agency decisions apply the material falsification elaborations and distinctions articulated in *Hernandez,* and continue developing the application of 21 U.S.C. 824(a)(1).[23] For example, in 2005, the Agency confirmed the ''knew or should have known'' determination for whether there had been a ''material falsification'' and the consideration of all the facts and circumstances in determining the appropriate sanction. *Felix K. Prakasam, M.D.,* 70 FR 33,203, 33,205–06 (2005). When faced with a respondent whose ''explanations for the misstatements and his continued insistence that his answers were correct are disingenuous at best,'' the Agency bluntly stated that respondent's answers were not accurate. *Id.* The Agency then stated clearly what it had introduced in a 1993 decision—its ''concern regarding Respondent's on-going refusal or inability to acknowledge a registrant's responsibility to provide forthright and complete information to DEA, when required to do so as a matter of law or regulation. This attitude . . . does not auger well for his future compliance with the responsibilities of a registrant.'' [24] *Id.* Thus, the Agency revoked respondent's registrations based on a finding of a violation of 21 U.S.C. 824(a)(1) and respondent's lack of legally mandated forthrightness and transparency. *Id.*

The Agency continued to develop the *Felix K. Prakasam, M.D.* forthrightness

[21] The falsifications in that case related to the doctor's inability to repay her student loan. The repayment issue had ramifications for her medical licenses in Illinois and Indiana. The *Hernandez* respondent admitted that her responses to the application's liability questions were incorrect. 62 FR at 61,146.

[22] *See, e.g., VI Pharmacy, Rushdi Z. Salem,* 69 FR 5584 (2004) (invoking the ''knew or should have known'' determination, stating that falsification cannot be tolerated since DEA must rely on the truthfulness of the information supplied by applicants in registering them, and evaluating the ''totality of the circumstances'' in determining the appropriate sanction); *Thomas G. Easter II, M.D.,* 69 FR 5579 (2004) (citing *Barry H. Brooks, M.D.* concerning the ''knew or should have known'' determination, reiterating that answers to liability questions are always material because DEA relies on them to determine whether it is necessary to investigate the application, stating that falsification cannot be tolerated since DEA must rely on the truthfulness of the information supplied by applicants in registering them, and evaluating the ''totality of the circumstances'' in determining the appropriate sanction); *Barry H. Brooks, M.D.,* 66 FR 18,305 (2001) (recounting testimony explaining how DEA uses the liability questions to evaluate applications, noting the ''knew or should have known'' determination, rejecting the argument that the omission of relevant information from an application is not material if DEA already knows it, reiterating that answers to liability questions are always material because DEA relies on them to determine whether it is necessary to investigate the application, asserting that falsification cannot be tolerated, and evaluating the ''totality of the circumstances'' in determining the appropriate sanction).

[23] *See, e.g., Theodore Neujahr, D.V.M.,* 64 FR 72,362 (1999) (noting *Hernandez* and the ''knew or should have known'' test to determine materiality); *KK Pharmacy,* 64 FR 49,507 (1999) (same); *Saihb S. Halil, M.D.,* 64 FR 33,319 (1999) (reiterating that the application signatory is responsible for the truthfulness of the application's contents, even if he did not personally complete it, and relying on the ''knew or should have known'' determination, no state authority, and admitted lack of knowledge of controlled substance regulations to revoke the registration); *Anthony D. Funches,* 64 FR 14,267 (1999) (finding a material falsification not based on intentional or negligent behavior, and granting the distributor registration subject to applicant's acceptance of inspection concessions); *John J. Cienki, M.D.,* 63 FR 52,293 (1998) (reiterating that the applicant ''knew or should have known'' about the falsity of the response for a material falsification to exist); *Samuel Arnold, D.D.S.,* 63 FR 8687 (1998) (stating that the applicant ''knew or should have known'' about the falsity of the response for there to be a material falsification, and that a consideration of all the facts and circumstances of the case determines the appropriate remedy when a material falsification exists); *Richard S. Wagner, M.D.,* 63 FR 6771 (1998) (applying the ''knew or should have known'' determination, concluding that intent to deceive does not limit the sanction of revocation, and highlighting the extreme importance of truthful answers since they alert DEA as to whether further investigation is necessary).

[24] In *Kuen H. Chen, M.D.,* the Agency characterized, and adopted in its entirety, the Administrative Law Judge's recommendation. 58 FR 65,401 (1993). It did not attach the recommendation. The recommendation, as described in the Agency decision, found that respondent's ''cavalier attitude toward the importance of accurately executing the application suggests a lack of concern for the responsibilities inherent in a DEA registration.'' *Id.* at 65,402.

and transparency analysis for 21 U.S.C. 824(a)(1) in *Peter A. Ahles, M.D.* According to that decision, ''it is clear'' and ''indisputable'' that respondent materially falsified his application by not disclosing that California placed his medical license on probation three times. 71 FR at 50,098. After finding that respondent materially falsified his application, the decision, citing the Sixth Circuit, stated that the Agency considers candor to be an ''important factor when assessing whether a physician's registration is consistent with the public interest'' and, therefore, ''falsification cannot be tolerated.'' *Id.* at 50,099 (citing *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d at 483).

My analysis shows that the approach to section 304(a)(1) taken by most past Agency decisions aligns with the instruction *Kungys* and its progeny provide concerning the meaning of ''material'' absent a definition in the relevant statute.[25] As already discussed, the approach of *Kungys* and its progeny to materiality is consistent with the CSA.[26] The Supreme Court's interpretation and analysis rest on the ''most common formulation . . . that a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed.'' 485 U.S. at 770. The Court emphasized that the test for materiality ''has never been'' that the ''misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation.'' [27] *Id.* at 771 [emphases in original]. According to the Court, the materiality test ''must be met, of course, by evidence that is clear, unequivocal, and convincing.'' *Id.* at 772.

Thus, following the Supreme Court, I conclude that the falsification of any of the liability questions is ''material'' under 21 U.S.C. 824(a)(1). My conclusion flows directly from the fact that each of the liability questions is connected to at least one of section 303(f) factors that, according to the CSA, I ''shall'' consider as I analyze whether issuing a registration ''would be inconsistent with the public interest.'' [28] 21 U.S.C. 823(f). I am unable to discharge the responsibilities of the CSA every time I am given false information in response to a liability question. Thus, each falsification of a liability question has a natural tendency to influence, or is capable of influencing my decision and is therefore material.

After finding the existence of a material falsification, I then determine the appropriate sanction. My determination involves considering all the facts and circumstances before me.

This *Kungys/Maslenjak*–based two-step analysis is consistent with the provisions of the CSA. It is consistent with the statutory requirements under section 303 (''the following factors *shall* be considered'' emphasis added), and the discretion afforded under section 303(f) (''*may* deny an application'' emphasis added) regarding whether to deny a registration application or modification. In addition, my analysis and conclusion that this Respondent submitted a materially false renewal application are in line with the weight of past Agency decisions.[29] Some of the

[25] Indeed, in 2007, an Agency decision relied on *Kungys* for the meaning of ''material.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848 (2007). In that Decision, the Agency determined that the Government's evidence was insufficient to establish a violation of 21 U.S.C. 824(a)(1).

[26] Regarding the different substantive legal contexts in which ''material'' appears, the Supreme Court stated that a statute revoking citizenship and a criminal statute whose penalties are a fine or imprisonment are not ''so different as to justify adoption of a different standard.'' *Kungys,* 485 U.S. at 770. According to the Court, ''[w]here Congress uses terms that have accumulated settled meaning under either equity or the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms.'' *Id.* My review of Supreme Court cases citing *Kungys* shows that decision cited in a variety of cases, including the False Claims Act (*Escobar,* 136 S. Ct. 1989 (2016)), a false statement in conjunction with a firearm sale (*Abramski* v. *United States,* 573 U.S. 169 (2014)), mail and tax fraud (*Neder* v. *United States,* 527 U.S. 1 (1999)), and a false statement to federally insured financial institutions (*United States* v. *Wells,* 519 U.S. 482 (1997)). Thus, the Supreme Court instructs on the meaning of ''material'' in situations when ''material'' is not defined in the statute at issue.

[27] Citing this portion of *Kungys,* some Agency decisions explicitly step away from pre-*Kungys* Agency decisions that found a false answer to a liability question ''always material'' due to DEA's reliance on the answers to those questions. *See, e.g., Mark William Andrew Holder, M.D.,* 80 FR 71,618 n.19 (2015). I, however, see no inevitable conflict between these pre-*Kungys* Agency decisions and *Kungys* and its progeny.

[28] The liability questions on the DEA–225 (04–12), ''Application for Registration,'' (Approved OMB NO 1117–0012, Form Expires: 9/30/2021) are (1) ''Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or is any such action pending?'' (*see* 21 U.S.C. 823(f)(2–4); *see also* § 824(a)(2) and (5)); (2) ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending?'' (*see* 21 U.S.C. 823(f)(2–5); *see also* § 824); (3) ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' (*see* 21 U.S.C. 823(f)(1), (3), and (4); *see also* § 824(a)(3)); and (4) ''If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a federal controlled substance registration revoked, suspended, restricted, denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending?'' (*see* 21 U.S.C. 823(f)(1 through 5); *see also* §§ 824 and 824(a)(2) and (3)) [emphases in original].

[29] *See, e.g., Zelideh I. Cordova-Velazco, M.D.,* 83 FR 62,902 (2018) (citing both the ''knew or should have known'' determination and *Kungys* regarding material falsification allegations, and concluding that applicant's now-current state license is ''simply not relevant in terms of resolving'' the material falsification allegation); *Richard Jay Blackburn, D.O.,* 82 FR 18,669 (2017) (citing *Kungys* and denying the application without a sanction analysis because the applicant had not opposed the Government's motion for summary disposition, let alone offered an explanation for the falsification or mitigating evidence); *Wesley Pope, M.D.,* 82 FR 14,944 (2017) (emphasizing an Agency decision that had applied the ''knew or should have known'' determination); *Daniel A. Glick, D.D.S.,* 80 FR 74,800 (2015) (citing *Kungys,* stating that the ''correct analysis depends on whether the registrant knew or should have known that he or she submitted a false application,'' and considering the ''totality of the circumstances'' in determining the sanction); *Mark William Andrew Holder, M.D.,* 80 FR 71,618 (2015) (finding a clear, intentional, and material falsification because applicant did not want DEA to discover that he was a drug abuser); *Arthur H. Bell, D.O.,* 80 FR 50,035 (2015) (citing *Kungys,* concluding that applicant's failure to disclose his surrender of his DEA registration ''for cause'' was materially false and intentional, and finding that applicant failed to produce sufficient evidence showing why he should be entrusted with a new registration); *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28,667 (2015) (citing both the ''knew or should have known'' determination and *Kungys* regarding material falsification allegations, and concluding that applicant ''clearly knew'' that he ''(1) [h]ad surrendered his registrations, (2) had done so in response to allegations that his pharmacies had committed violations of the CSA, and (3) did so to avoid proceedings to revoke the registrations, [meaning] he also clearly knew that he had surrendered ''for cause''); *Jose G. Zavaleta, M.D.,* 78 FR 27,431 (2013) (citing both the ''knew or should have known'' determination and *Kungys* regarding material falsification allegations); *Richard A. Herbert, M.D.,* 76 FR 53,942 (2011) (citing both the ''knew or should have known'' determination and *Kungys* regarding material falsification allegations, citing *Hoxie* about the importance of candor in the assessment of whether a registration is in the public interest, and explicitly tying the falsification to two 21 U.S.C. 823(f) factors); *Shannon L. Gallentine, D.P.M.,* 76 FR 45,864 (2011) (citing *Kungys* regarding material falsification allegations and explaining that ''[g]iven the circumstances of the surrender, during which . . . [applicant] was confronted with questions by the Investigators about his prescribing practices and lack of documentation to justify his prescriptions, . . . [applicant] cannot claim that he did not surrender his registration for cause''); *Mark De La Lama, P.A.,* 76 FR 20,011 (2011) (citing *Kungys* regarding material falsification allegations); *Gilbert Eugene Johnson, M.D.,* 75 FR 65,663 (2010) (finding that registrant knew his answers were false, citing *Kungys,* and stating that the false answers were material because the CSA requires consideration of the matters registrant falsified); *Alvin Darby, M.D.,* 75 FR 26,993 (2010) (citing both ''knew or should have known'' and *Kungys* regarding material falsification allegations); *Craig H. Bammer, D.O.,* 73 FR 34,327 (2008) (citing *Kungys* on the meaning of

cases that Respondent urges me to follow are not.[30]

In sum, I carefully considered all of Respondent's arguments and conclude, based on

clear, unequivocal, and convincing record evidence, that Respondent materially falsified his registration renewal application.

IV. Sanction

Where, as here, the Government has established by clear, unequivocal, and convincing evidence that a respondent materially falsified his registration renewal application, the respondent must then ''present[ ] sufficient mitigating evidence'' to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018). Further, as past performance is the best predictor of future performance, Agency decisions require the respondent unequivocally to accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (collecting cases); *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972–73 (2019). In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases). The Agency has also considered the need to deter similar acts by the respondent and by the community of registrants. *Id.* Consistent with past Agency decisions, I consider the totality of the facts and circumstances before me to determine the appropriate sanction. *See, e.g., Hernandez,* 62 FR at 61,147–48 (finding material falsification, but denying the Government's request for revocation as ''too severe'' given the facts and circumstances of the case).

Respondent's misconduct proven by the record evidence is one falsity on one application. However, the falsity was not the result of confusion or inadvertence, but a deliberate attempt to hide the existence of the Mass. Accepted Voluntary No-Practice Agreement. RD, at 20. The record evidence regarding that falsity clearly demonstrates to me that Respondent does not take his responsibility of candor to the Agency seriously. *Id.* Accomplishing the scope of DEA's law enforcement responsibilities would be extraordinarily difficult if the Agency could not rely on the candor of applicants and those in the regulated community. *Id.*

I agree with the Chief ALJ that Respondent, through counsel, explicitly stated that Respondent did not accept responsibility and did not offer any remedial measures during his testimony.[31] *Id.* at 18; Tr. 179. In his Posthearing Brief, Respondent reiterated that he does not prescribe controlled substances in his current position, yet needs a registration to continue to qualify for that position. ALJX 30, at 23; Tr. 92, 105. The Posthearing Brief argues that revoking Respondent's registration would deprive the low-income and homeless patients he currently serves of his medical services.[32] ALJX 30, at 23. This argument is not consistent with recent Agency decisions concerning community impact evidence. I decline to accept Respondent's community impact argument.

As the Chief ALJ concluded, Respondent acknowledged no deficiency and offered no plan to conform his future conduct. RD, at 19. ''In his view,'' the RD observes, Respondent ''did nothing wrong and would presumably enter the same false response on a future renewal application if faced with like circumstances.'' *Id.* In this situation, revocation is appropriate to avoid another proceeding charging material falsification ''because the Respondent believes his conduct to have been appropriate.'' *Id.*

a ''material'' false statement and *Hoxie* on ''candor''); *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74,334 (2007) (citing both the ''knew or should have known'' determination and *Kungys* regarding material falsification allegations, and citing *Hoxie* about the importance of candor in the assessment of a registration application); *but see Michel P. Toret, M.D.,* 82 FR 60,041 (2017) (ruling that a Voluntary Surrender Form alone, indicating nothing about applicant's failure to comply with any controlled substance requirement, is an insufficient basis to find a material falsification); *Richard D. Vitalis, D.O.,* 79 FR 68,701 (2014) (citing *Kungys,* finding three ''clearly false, and knowingly so'' answers regarding the suspension of his state medical license based on his history of alcohol dependency, and concluding that those false answers were not material because alcohol dependency is not actionable misconduct under the CSA); *Hoi Y. Kam, M.D.,* 78 FR 62,694 (2013) (citing *Kungys,* finding a false statement, stating that the ''relevant decision for assessing whether a false statement is material is the Agency's decision as to whether an applicant is entitled to be registered,'' and concluding the falsity was not material because the state license was no longer revoked and ''the Government offers no argument, let alone any evidence, that the truthful disclosure of the State's action against his medical license would have led it to evidence in the exclusion proceeding that Respondent violated any state rules or regulations regarding controlled substances and thus would have supported the denial of his application''); *Scott C. Bickman, M.D.,* 76 FR 17,694, 17,701 (2011) (citing both the ''knew or should have known'' determination and *Kungys* regarding material falsification allegations, citing *Hoxie* about the importance of candor in the assessment of a registration application and, citing *Gonzales* v. *Oregon,* granting the renewal application because the Government's evidence did not establish that ''Respondent's failure to disclose that the State Board had placed him on probation was capable of influencing the decision to grant his renewal application,'' because the probation was for medical malpractice and the CSA does not state that medical malpractice is a disqualification for a registration).

[30] *See, e.g.,* Respondent's citation to, and reliance on, the results in *Hoi Y. Kam, M.D.,* 78 FR 62,694 (2013) and *Scott C. Bickman, M.D.,* 76 FR 17,694, 17,701 (2011). ALJX 30, at 14.

Respondent also argues that ''the Government must prove that the overall intent of the application was to deceive DEA.'' ALJX 30, at 9 (citing *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,808 (2015) and *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,852–53 (2007)).

According to *Daniel A. Glick, D.D.S.,* 80 FR at 74,808, ''the correct analysis depends on whether the registrant knew or should have known that he or she submitted a false application,'' and ''[a]lthough even an unintentional falsification can serve as a basis for adverse action regarding a registration, lack of intent to deceive and evidence that the falsification was not intentional or negligent are all relevant considerations.'' Similarly, according to *Samuel S. Jackson, D.D.S.,* 63 FR at 23,852, citing the ''knew or should have known'' determination, Agency decisions ''make clear that culpability short of intentional falsification is actionable.''

Thus, both Decisions Respondent cites, *Daniel A. Glick, D.D.S.* and *Samuel S. Jackson, D.D.S.,* to support his argument state that a falsification need not be intentional to be actionable. I reject Respondent's argument that the Government must prove an ''overall intent to deceive DEA.'' An intent to deceive, however, has been considered as part of the totality of the circumstances when determining the appropriate sanction in the face of a material falsification. *See, e.g., Daniel A. Glick, D.D.S.,* 80 FR at 74,808; *Anthony D. Funches,* 64 FR at 14,268–69.

[31] Respondent's proposed Corrective Action Plan would have ''counsel review all registration applications [for the next five years] prior to submission to DEA to ensure accuracy and compliance with DEA's application disclosure requirements,'' and to take two, specified continuing medical education courses concerning opioids.

[32] Respondent also argued that ''the sanction of revocation . . . would deviate from the Agency's decisions in *Funches* and *Hernandez.*'' ALJX 30, at 23. Both *Funches* and *Hernandez,* however, are inapposite.

In *Funches,* the application was for a registration as a retail distributor of list I chemicals. 64 FR at 14,267. The applicant indisputably operated his business in a ''responsible manner'' and credibly testified that the falsification was neither intentional nor negligent. *Id.* at 14,268. The falsification concerned a guilty plea twenty years before to a misdemeanor whose sentence was subsequently suspended, and ''involvement'' in a cocaine transaction over twenty years before. *Id.* at 14,267–69.

Hernandez, already discussed in detail, concerned a respondent's student loan repayment challenges and the state licensing authority's decision to allow the respondent to retain her medical license as long as she continued to repay her student loans. 62 FR at 61,147. The decision appeared to credit as ''credible,'' while also calling it ''clearly an erroneous interpretation,'' the respondent's explanation for the falsity. *Id.*

I agree with the Chief ALJ that ''[c]onsiderations of specific and general deterrence militate in favor of revocation.'' *Id.* Failing to sanction Respondent in this case would send a message to Respondent and others in the registrant community that Respondent is vindicated, and that his false answer to Liability Question No. 3 is the ''benchmark of exactly how candid . . . [one] ever needs to be in providing information to DEA.'' *Id.* at 19–20. I decline to create a ''perverse incentive on registrants and applicants to withhold requested application information any time where the withheld information may lead to an adverse decision on a DEA registration or renewal application.'' *Id.* at 20.

I agree with the former Acting Assistant Administrator of the Diversion Control Division, that Respondent's proposed Corrective Action Plan provides no basis for me to discontinue or defer this proceeding. Its insufficiencies include Respondent's failure to accept responsibility, to institute remedial measures, and to convince me to entrust him with a registration. 21 U.S.C. 824(c)(3).

Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificates of Registration BS5000411 issued to Frank Joseph Stirlacci, M.D. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I further hereby deny any pending application of Frank Joseph Stirlacci, M.D., to renew or modify this registration, as well as any other pending application of Frank Joseph Stirlacci, M.D. for registration in Indiana. This Order is effective August 26, 2020.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–16193 Filed 7–24–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0057]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection; Uniform Crime Reporting Data Collection Instrument Pretesting and Burden Estimation Generic Clearance

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 September 25, 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 Mrs. Amy C. Blasher, Unit Chief, Federal Bureau of Investigation, CJIS Division, Module E–3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; telephone number (304) 625–3566.

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 Federal Bureau of Investigation, 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:* UCR Data Collection Instrument Pretesting and Burden Estimation Generic Clearance

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is 1110–0057. The applicable component within the DOJ is the CJIS Division, in the FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

5. *Primary:* Federal, state, county, local, and tribal law enforcement agencies

Abstract: This clearance provides the UCR Program the ability to conduct pretests which evaluate the validity and reliability of information collection instruments and determine the level of burden state and local agencies have in reporting crime data to the FBI. The Paperwork Reduction Act only allows for nine or fewer respondents in the collection of information, such as pretesting activities. This clearance request expands the pretesting sample to 350 people for each of the twelve information collections administered by the UCR Program. Further, the clearance will allow for a brief 5-minute cost and burden assessment for the 18,000 law enforcement agencies participating in the UCR Program.

An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: UCR Participation Burden Estimation: There are approximately 18,000 law enforcement respondents; calculated estimates indicate five minutes per submission. UCR Form Pretesting: There are approximately 350 respondents; calculated estimates indicate one hour per pretest.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are approximately 1,850 hours, annual burden, associated with this information collection.

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.