Cause at her residence at 1000 Avenue at Port Imperial, Number 706, Weehawken, New Jersey. GX 4 (Declaration of Service of Order to Show Cause) at 1–2.

On April 13, 2018, the Government submitted a Request for Final Agency Action (RFAA) and the evidentiary record to my Office. The Government represented that ''Registrant has not requested a hearing and has not otherwise corresponded or communicated with DEA regarding the Order served on her, including the filing of any written statement in lieu of a hearing.'' RFAA, at 1–2.

Based on the Government's representation that more than 30 days have now passed since the date of service of the Show Cause Order and that Registrant has not submitted a request for a hearing or any other reply, I find that Registrant has waived her right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

Registrant is the holder of two DEA Registrations pursuant to which she is authorized to dispense controlled substances in schedules II–V as a practitioner at the registered address of 49 Veronica Avenue, Somerset, New Jersey (Registration No. BW4026375), and at the registered address of 620 Cranbury Road, Suite #115, East Brunswick, New Jersey (Registration No. BW8636219). GX 1 at 1–2.

On April 12, 2018, the Associate Chief of the DEA Registration and Program Support Section certified that both registrations were due to expire by their terms on May 31, 2018. *Id.* at 1–2. She further stated that ''[Registrant] has no other pending or valid DEA registrations in New Jersey or in any other state.'' *Id.* at 1–2. Pursuant to 5 U.S.C. 556(e), I take official notice of Registrant's registration record with the Agency. *See also* 21 CFR 1316.59(e).[1]

A review of Agency registration records shows that Registrant has not filed any applications for renewal, nor has she filed a new application for a DEA Registration. Accordingly, I find that Registrant's registrations expired on May 31, 2018, and that there is no application to act upon.

Having reviewed the record, I hold that this proceeding is now moot. DEA has long held that ''if a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke.'' *Donald Brooks Reece II, M.D.,* 77 FR 35054 (2012) (quoting *Ronald J. Riegel,* 63 FR 67132, 67133 (1998); *see also Thomas E. Mitchell,* 76 FR 20032, 20033 (2011), *Donald Kenneth Shreves, D.V.M,* 83 FR 22518 (2018). Moreover, in the absence of an application (whether timely filed or not), there is nothing to act upon. Accordingly, because Respondent has allowed her registrations to expire and has not filed either a renewal or a new application, this case is now moot and will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that the Order to Show Cause issued to Sharon C. Worosilo, M.D., be, and it hereby is, dismissed. This Order is effective immediately.

Dated: September 12, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018–20384 Filed 9–18–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 16–22]

Brian Thomas Nichol, M.D., Decision and Order

On March 14, 2016, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Brian Thomas Nichol, M.D. (Respondent), which proposed the revocation of his DEA Certificate of Registration No. BN4578057, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 5106 McLanahan Drive, Suite B, North Little Rock, Arkansas. Administrative Law Judge Exhibit (ALJ Ex.) 1, at 1. As grounds for the proposed action, the Show Cause Order alleged that Respondent's ''registration would be inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f), 824(a)(4)). For the same reason, the Order also proposed the denial of any of Registrant's ''pending applications for renewal or modification of such registration, and . . . any applications for any other DEA registrations.'' *Id.*

More specifically, the Show Cause Order set forth six independent reasons why the Government alleges that Respondent's registration should be revoked. *Id.* at 1–3. The Show Cause Order first charged that Respondent's ''pre-signing of prescriptions for controlled substances violated [21] [1] CFR 1306.05(a).'' *Id.* at 2. The Order states that this charge is based on the allegation that in 2006, the Arkansas State Medical Board found that Respondent violated Arkansas and federal laws when (1) he ''pre-signed controlled substance prescriptions, which [his] staff members, who were not authorized by law to issue such prescriptions, then issued to patients'' and (2) he ''[was] not present and [was] not consulted by [his] staff when such prescriptions were issued.'' *Id.* at 1–2. The Order further alleged that in 2006, as a result of these findings, the Arkansas Board suspended Respondent's medical license for six months. *Id.* at 2.

The Show Cause Order also set forth five charges of recordkeeping violations based on DEA's July 4, 2014 ''on-site inspection of [Respondent's] registered location.'' *Id. First,* the Order charged that Respondent ''failed to maintain an initial inventory of all controlled substances in violation of 21 U.S.C. 827(a)(3) & 842(a)(5) and 21 CFR 1304.11(b).'' *Id. Second,* the Order charged that he ''failed to maintain complete and accurate dispensing records in violation of 21 U.S.C. 827(a)(3) & 842(a)(5) and 21 CFR 1304.21(a).'' *Id.* at 2–3. *Third,* the Order charged that, during the on-site inspection, Respondent ''could not provide a DEA–222 order form dated [January 16, 2014], for an order of oxycodone tablets, in violation of 21 U.S.C. [842](a)(5) and 21 CFR 1305.17(a).'' [2] *Id.* at 3. *Fourth,* the Order

[1] Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

[1] Although the Order erroneously referenced Title 42 of the Code of Federal Regulations for this violation, Government counsel corrected the error during his Opening Statement at the administrative hearing when he made clear that Title 21 was the title that the Government had intended to allege. *See* Transcript (Tr.) 18. Respondent raised no objection based on the erroneous title reference, and I find that this error was merely a scrivener's error and that Respondent had adequate notice of the charged violation.

[2] Although the Order erroneously referenced an August 28, 2013 DEA 222 form for this charge, the Government corrected the date of the allegedly missing DEA 222 form to January 16, 2014 in its

charged that Respondent ''failed to properly annotate two DEA–222 order forms in violation of 21 U.S.C. 842(a)(5) and 21 CFR 1305.13(b).'' *Id. Fifth,* the Order charged that Respondent ''failed to maintain [his] inventory and dispensing records at [his] registered location and these records were not readily retrievable, in violation of 21 U.S.C. 842(a)(5) and 21 CFR 1304.04.'' *Id.* Related to this last charge, the Order alleged that Respondent's ''inventory and dispensing records were located at Moore Clinical Trials,'' which was not located at his registered address, and that he ''had not asked for permission to store controlled substance records at a central location'' in violation of 21 CFR 1304.04(a)(1). *Id.*

Although the pending Show Cause Order discussed a prior September 27, 2011 Show Cause Order that DEA issued to revoke Respondent's DEA registration, as well as the terms of an April 27, 2012 Memorandum of Agreement (MOA) that was intended to resolve the charges in that prior Order, the pending Order did not expressly charge Respondent with violating the MOA. *See id.* at 2. Instead, the Government charged Respondent with violating the MOA in its May 12, 2016 Prehearing Statement, and further alleged that these violations constituted an independent basis to revoke his registration. *See* ALJ Ex. 7, at 10–11, 11 n.4.[3]

After service of the Show Cause Order, Respondent, through his counsel, made a timely request for hearing. *See* ALJ Ex. 2. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ). On May 19, 2016, the parties participated in a telephonic prehearing conference, which was not transcribed, and the ALJ issued a Prehearing Ruling and Protective Order (ALJ Ex. 9) memorializing 12 accepted stipulations of fact (set forth more fully *infra*) as well as the terms of a protective order. Following other pre-hearing procedures, the ALJ conducted an evidentiary hearing in Little Rock, Arkansas on August 16–17, 2016, at which both parties elicited testimony from witnesses and submitted various exhibits.[4]

The parties submitted briefs of their proposed findings of fact, conclusions of law, and argument on October 3, 2016, and the ALJ issued his Recommended Decision (R.D.) on December 5, 2016. The ALJ found that the Government sustained only two of its charges. *First,* the ALJ found that the Government had sustained its first charge that Respondent pre-signed prescriptions in violation of 21 CFR 1306.05(a). R.D., at 30. However, the ALJ also found that Respondent ''has presented sufficient mitigating evidence'' concerning this charge ''to show that he can be entrusted with a DEA registration.'' *Id.* at 42. As a result, the ALJ did not recommend any sanction as a result of this violation. *See id.* at 41–46.

Second, with respect to the Government's recordkeeping charges, the ALJ only sustained the Government's fourth recordkeeping charge ''that the Respondent failed to properly record the date he returned controlled substances to [his supplier] and the amount he returned.'' *Id.* at 45. The ALJ found that, although this recordkeeping violation also constituted a violation of the MOA, it was not a sufficiently ''significant violation'' of the MOA to warrant revocation. *Id.* at 40 (emphasis omitted). The ALJ also recommended that I find that this failure was ''mitigated by the fact that the Government has presented no evidence that Respondent had been previously cited for this type of recordkeeping failure or that this recordkeeping failure . . . is in any way related to the Respondent's day to day treatment of his normal patients.'' *Id.* at 45. The ALJ concluded that he ''would be exceeding the scope of [his] responsi[bil]ities were [he] to recommend that the Respondent's [registration] be revoked.'' *Id.* The ALJ added that he ''would reach the same conclusion even if the Government had proven all of its allegations in this weak case.'' *Id.* Thus, the ALJ recommended that I not revoke Respondent's registration and that I approve any pending application for renewal. *Id.* The ALJ further recommended that I find that the testimony of the Government's sole witness was not sufficiently credible to support any of the Government's remaining recordkeeping charges. *See, e.g., id.* at 4, 15 n.17, 19 n.25, 21 n.28, 34.

Nonetheless, the ALJ found that this recordkeeping violation ''merits the imposition of a sanction'' and found that ''Respondent's recordkeeping violation to be egregious . . . because it prevented the DEA from being able to use the Respondent's own records to conduct an accurate audit of the

May 12, 2016 Prehearing Statement and during Government counsel's Opening Statement at the administrative hearing. *See* ALJ Ex. 7, at 8; Tr. 15. In addition, although the Order erroneously referenced Section 821 of Title 21 of the United States Code for this charge, the Government corrected the error in its May 12, 2016 Prehearing Statement to Section 842 of Title 21. *See* ALJ Ex. 7, at 8 (''Respondent's failure to provide the DEA–222 form for this shipment was in violation of 21 U.S.C. 842(a)(5) and 21 CFR 1305.17(a).''). I find that these errors were merely scrivener's errors and that Respondent had adequate notice of the charged violation.

[3] ''[P]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.'' *Moore Clinical Trials, L.L.C.,* 79 FR 40145, 40159 n.34 (quoting *Citizens States Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984)) (internal citations and quotations omitted). ''An agency is not required to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront.'' *Id.* (quoting *Boston Carrier, Inc.* v. *ICC,* 746 F.2d 1555, 1560 (D.C. Cir. 1984)) (internal citations and quotations omitted). ''Thus, the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.'' *Id.* (quoting *George Mathew, M.D.,* 75 FR 66138, 66146 n.20 (2010)); *see also Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996) (''the parameters of the hearing are determined by the prehearing statements'').

[4] On August 23, 2016, Respondent filed a Motion to Supplement the Record requesting that the ALJ accept new exhibits. ALJ Ex. 14. Specifically, Respondent requested leave to supplement the administrative record with the back pages of certain DEA 222 forms entered into evidence at the hearing to rebut a Government witness's testimony about the instructions contained on those back pages. *Id.* at 1–2. Respondent also attached to his motion the affidavit of Matilda Buchanan, who identified and copied these DEA 222 form back pages for purposes of the motion and who prepared the proposed exhibits. See Exhibits 1–2 to ALJ Ex. 14.

On August 29, 2016, the Government filed its ''Opposition to Respondent's Motion to Supplement the Record and Government's Motion for Leave to File Responding Affidavit.'' ALJ Ex. 16. As a threshold matter, the Government contended that Respondent failed to establish that he had good cause for failing to identify the back pages of the DEA 222 forms as exhibits by July 26, 2016, when supplemental prehearing statements were due—even though Respondent knew that the DEA 222 forms would be introduced and discussed at the hearing. *Id.* at 1–2 (citing 21 CFR 1316.57), 5. The Government argued that Respondent's post-hearing motion was an attempt ''to rectify his perceived oversights made at the hearing'' for failing to introduce these back pages as part of his case, during cross-examination of the Government's witness, or in a rebuttal case. *Id.* at 3. The Government also argued that, in any event, Respondent had failed to establish a proper foundation for these supplemental exhibits, and that the Government can no longer cross-examine Respondent's affiant, whose affidavit was submitted in support of these exhibits. *Id.* at 3–4. Finally, the Government requested leave to file its own affidavit in response to Respondent's affidavit in the event the ALJ granted Respondent's motion. *Id.* at 5.

On the same day, the ALJ issued an order denying Respondent's Motion. ALJ Ex. 17. The ALJ found that Respondent did ''not set forth any reasons in his Motion for failing to submit these additional exhibits by the July 26, 2016 deadline.'' *Id.* at 2. The ALJ also found that ''Respondent had the originals of these exhibits at the hearing and made no attempt to offer the back side of the 222 Forms into evidence at that time. Therefore, the Respondent has not established the requisite good cause for failing to submit these exhibits in a timely manner.'' *Id.* Finally, the ALJ found that admitting ''Respondent's proposed exhibits would be unfairly prejudicial to the Government'' because it ''no longer ha[d] the opportunity to cross-examine Buchanan on the production of the Respondent's additional exhibits, or to introduce additional rebuttal testimony or evidence.'' *Id.* I agree with the ALJ's ruling.

controlled substances for which the Respondent was accountable.'' *Id.* at 45. As a result, the ALJ recommended that I place the following five restrictions on Respondent's registration:

1. That he may not participate in any drug studies in which he is required to order, maintain, store, or dispense controlled substances for a period of four years.

2. That he may not order, maintain, store, or dispense any controlled substances at his registered location for a period of four years.

3. That restrictions one and two, above, will not be lifted, even after four years, until the Respondent has completed a course in controlled substance recordkeeping, a course in controlled substance storage, and a course in the administration of controlled substances, and provides the DEA with evidence of completion of these courses. These courses may not be used to meet any continuing medical education requirement.

4. That prior to renewal of the Respondent's [DEA registration], he sign a document consenting to inspections by DEA personnel of his medical practice without the need for DEA personnel to obtain an administrative inspection warrant prior to conducting an inspection. By the terms contained in the consent form, the consent shall be valid for four years from the date his current renewal application for a [DEA registration] is approved. This consent form is to be delivered to the Respondent's local DEA Field Office.

5. That prior to renewal of the Respondent's [DEA registration], he sign a document consenting to the conditions set forth in Paragraphs one and two above and acknowledging his understanding that his failure to comply with the terms of those conditions will constitute an independent basis for administrative enforcement proceedings by the DEA. This consent and acknowledgement document shall be delivered to the Respondent's local DEA Field Office.

Id. at 46.

On December 19, 2016, Respondent's counsel filed a ''Notice of Respondent's Intent to Comply with Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision'' in which he stated that Respondent ''intends to immediately comply with the Court's Recommended Disposition.'' ALJ Ex. 23, at 1. Respondent also stated that he executed a document attached as Exhibit A to his Notice entitled ''Consent to Conditions and Acknowledgment.'' *See id.*

On December 23, 2016, the Government filed Exceptions to the Recommended Decision. ALJ Ex. 24. In its Exceptions, the Government contended that the ALJ committed error in finding that Respondent was a more credible witness than the Government's witness, a Diversion Group Supervisor (GS). *Id.* at 2. The Government further argued that accepting the credibility of the testimony of the GS over Respondent's testimony would require sustaining the Government's remaining recordkeeping charges because the ALJ's recommendations regarding those charges ''hinge[d] on his evaluation of the credibility of the Government's investigator and the Respondent.'' *Id.* at 2 & n.3. Respondent did not file a response to the Government's Exceptions.

Thereafter, the ALJ forwarded the record to me for final agency action. Having considered the record in its entirety, including the Government's Exceptions, I agree with the ALJ's conclusions that the Government failed to prove its first, second, third, and fifth recordkeeping charges that Respondent failed to maintain an initial inventory, maintain complete and accurate dispensing records, provide the DEA 222 form dated January 16, 2014, and maintain his inventory and dispensing records at the registered location. I also agree with the ALJ that the Government sustained the Show Cause Order's first charge regarding Respondent's pre-signing of prescriptions and the Order's fourth recordkeeping charge regarding Respondent's failure to properly annotate two DEA 222 forms. Furthermore, I agree with the ALJ that the sustained fourth recordkeeping charge also constituted a violation of the MOA. Finally, I also agree that Respondent has accepted responsibility for both of these charges.

Most importantly, while I agree with the ALJ that the sum of Respondent's misconduct does not warrant revocation of Respondent's registration, I disagree with the ALJ's recommendation that the sanction in this case should be limited to the ALJ's recommended restrictions to Respondent's registration. Accordingly, and for reasons I set forth more fully below, I conclude that the relevant factors support suspension of Respondent's registration for a period of one month, in addition to the imposition of the restrictions that the ALJ recommended following termination of the suspension. As the ultimate fact finder, I make the following findings of fact.

Findings of Fact

Respondent is the holder of DEA Certificate of Registration BN4578057, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 5106 McLanahan Drive, Suite B, North Little Rock, Arkansas. *See* Attachment to ALJ Ex. 7; Respondent's Exhibit (hereinafter RX) A, at 1. Respondent's registration was due to expire on October 31, 2016. *See id.* On September 12, 2016, Respondent submitted a renewal application.[5] Government's Proposed Findings of Fact and Conclusions of Law (ALJ Ex. 20), at 1 n.2. Because Respondent has submitted a timely renewal application, I find that Respondent's DEA registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c); *Perry County Food & Drug,* 80 FR 70084, 70089 n.17 (2015).

Respondent is an allopathic physician who is licensed to practice medicine in Arkansas. Transcript (Tr.) 137; RX D. His specialty is anesthesiology, and his current medical practice focuses on pain management. Tr. 32, 137–38. During the hearing, Respondent submitted evidence establishing that his Arkansas license to practice medicine was active and due to expire on April 30, 2017. RX D, at 1. I have reviewed the official website of the Arkansas State Medical Board (ASMB), and it shows that his Arkansas medical license is still active and is now due to expire on April 30, 2019. Thus, I take official notice that Respondent currently holds an active license to practice medicine from the ASMB.[6]

The Prior Criminal and Administrative Proceedings

The parties agreed to 12 stipulations, most of which relate to Respondent's prior criminal and administrative proceedings.

Prior State Administrative Proceedings

The parties stipulated that on June 8, 2006, the ASMB issued an Emergency Order of Suspension suspending Respondent's Arkansas medical license. ALJ Ex. 9, at 1. The Order alleged that Respondent violated Ark. Code Ann. §§ 17–95–409(a)(2)(e), 17–95–409(A)(2)(g), and 17–95–704(E)(1), (2) and federal laws ''regulating the possession, distribution, or use of narcotic or controlled drugs'' because ''he prescribed or administered scheduled drugs intended to manage

[5] The parties stipulated that Respondent had previously renewed his DEA registration on December 9, 2010 and on October 21, 2013. ALJ Ex. 9, at 2.

[6] Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

pain for a patient who had chemical dependencies on said controlled drugs and who was diverting said medication for his addiction.'' Government Exhibit (GX), at 1. This Order also alleged that

> more specifically, he has pre-signed prescriptions leaving the name of the patient, substance and the instructions for taking the medication blank and permitting his office personnel, who are not licensed physicians, to fill in the prescription. A prescription pad, which had all the prescriptions signed by Brian Thomas Nichol, M.D. with the rest left blank, was found in his office pursuant to a [federal] search warrant . . . on the 19th of April 2006.''

Id. at 1–2. In the same vein, the Order alleged that Respondent permitted such office personnel to dispense and administer scheduled medications to at least three patients, and fraudulently billed one of these patients for $22,600. *Id.* at 2–3. The Order further alleged that Respondent ''performed medical procedures and engaged in the practice of medicine in the State of Arkansas . . . while not having a valid Arkansas license'' to do so. *Id.* at 2. Based on these allegations, the ASMB found that Respondent's acts ''endanger[ed] the public health, safety and welfare'' and suspended his state license on an emergency basis pending a hearing. *Id.* at 3.

The parties further stipulated that on August 17, 2006, the ASMB held an administrative hearing based on the allegations set forth in the ASMB's Emergency Order, and issued its Final Order on the same day. *See* ALJ Ex. 9, at 1; GX 2. The parties also stipulated that ''[t]he ASMB's final order did not include all of the allegations made in the 'Emergency Order.' '' ALJ Ex. 9, at 2. However, the ASMB's Final Order does state findings that Respondent ''admitted in testimony that he has violated the laws of the United States and the State of Arkansas regulating the prescribing of scheduled medication, more specifically, he has pre-signed prescriptions, and not written on the prescription the name of the patient, the substance prescribed, and instructions for taking the medication.'' GX 2, at 1. The ASMB also found that Respondent admitted that he ''permitted his office personnel, . . . who are not licensed as physicians, nor authorized to prescribe medication, to fill in the blanks on the prescription pad and distribute them to patients, even without Dr. Nichol being present.'' *Id.*

The parties stipulated that the ASMB found that this conduct violated Arkansas and federal laws. ALJ Ex. 9, at 1–2; *see* GX 2, at 3. As a result of these findings, it is also undisputed that the ASMB suspended Respondent's Arkansas medical license for six months and that the ASMB lifted this suspension on February 2, 2007. *See* ALJ Ex. 9, at 2; GX 2, at 3. I also find that, in its final order, the ASMB fined Respondent over $10,000 and directed him to complete ''courses in (1) Office Management, (2) The Prescribing of Scheduled Medication and [DEA] Laws and Regulations . . ., and (3) a course on boundaries.'' GX 2, at 4.

During the hearing, Respondent testified that he ''did'' what ''was alleged to have happened'' by the ASMB in 2006. Tr. 162. That is, he admitted that he improperly pre-signed prescriptions for controlled substances and that he ''take[s] responsibility'' for it. *Id.* at 274. Respondent testified, however, that there were no allegations of ''diversions [sic] resulting from that'' conduct. *Id.* at 162. Respondent later testified more broadly that he agreed to the conditions of the MOA ''even though there was [sic] never any allegations of diversion.'' *Id.* at 174. However, the ASMB's earlier Emergency Order alleged that Respondent ''prescribed or administered scheduled drugs intended to manage pain for a patient who had chemical dependencies on said controlled drugs *and who was diverting said medication* for his addiction.'' GX 1, at 1 (emphasis added). More specifically, the ASMB also alleged that Respondent ''prescribed or administered controlled substances when he knew or should have known that his patient was utilizing the drugs for non-therapeutic purposes and was chemically dependent on said drugs.'' *Id.* at 3. Thus, while I accept Respondent's testimony that he admitted to improperly pre-signing prescriptions, I do not accept Respondent's statement that there were never any allegations of diversion against him.

Based on Respondent's representation in his testimony, the ALJ found that Respondent has written every prescription himself since the expiration of the state's suspension. R.D., at 10 (citing Tr. 166). The Government introduced no evidence contradicting Respondent's testimony. Thus, I find that there is no evidence that Respondent resumed pre-signing prescriptions after his suspension by the ASMB.

Prior Federal Criminal Proceedings

The parties stipulated that on January 8, 2008, 11 months after the reinstatement of his state medical license, Respondent pled guilty in the United States District Court for the District of Arkansas to a one-count criminal information charging him with felony health care fraud under 18 U.S.C. 1347. ALJ Ex. 9, at 2; *see also* GXs 3–4. That federal court sentenced Respondent to five years of probation and directed him to pay $15,400.69 in restitution and criminal penalties. ALJ Ex. 9, at 2; GX 4, at 2, 4. It is also undisputed that the court terminated Respondent's probation period early on September 20, 2011. R.D., at 6; Tr. 8.

The parties also stipulated that on October 20, 2008, the U.S. Department of Health and Human Services (HHS) excluded Respondent from participation in the Medicare and Medicaid programs for five years pursuant to 42 U.S.C. 1320a–7(a). ALJ Ex. 9, at 2; *see* GX 5. The parties agree that HHS removed this exclusion on August 11, 2014. R.D., at 7; Tr. 9.

Prior DEA Administrative Proceedings

The Group Supervisor testified that DEA ''first bec[a]me aware of Dr. Nichol'' in 2011 after DEA received an application for a registration as a researcher from Moore Clinical Trials. Tr. 28. ''[I]n the review of that application, we became aware that Dr. Nichol was associated with Moore Clinical Trials . . . we saw that there was a current research study going on[,] and we noticed several violations of [DEA regulations] and the Controlled Substances Act.'' *Id.* More specifically, she testified that DEA conducted an investigation of both Moore Clinical Trials and Respondent and ''looked at the records and found that the receiving records and dispensing records weren't up to the regulations.'' *Id.* at 28–29. As a result, DEA brought separate administrative actions against each of them in 2011—one against Moore Clinical Trials to deny its application for a DEA registration as a researcher, and the other against Respondent to revoke his DEA registration as a practitioner. *See id.* at 28–29; GX 6.

With respect to Moore Clinical Trials, the GS testified that ''subsequently the application for Moore Clinical Trials was denied.'' *Id.* at 29. In fact, the Agency issued and published its final decision and order denying Moore Clinical Trials' application pursuant to an August 8, 2011 Show Cause Order. *Moore Clinical Trials, L.L.C.,* 79 FR 40145, 40145 (2014). In that decision, the then-Administrator found that Moore Clinical Trials ''entered into a contract with Dr. Brian Nichol, an interventional pain management specialist, to perform clinical research for it pursuant to contracts it might obtain from CROs [contract research organizations].'' *Id.* at 40148. The then-Administrator noted the ALJ's finding that '' 'the documents kept by Dr.

Nichol,' who was supervising . . . clinical trials on behalf of [Moore Clinical Trials], 'were deficient' and that the order forms for Schedule II controlled substances (DEA–222) 'were lacking.' '' *Id.* at 40147 (quoting ALJ's Recommended Decision). ''The ALJ also found that 'Dr. Nichol transported controlled substances to [Moore Clinical Trials'] location,' where he was not registered to dispense them.'' *Id.* The then-Administrator also noted that ''the ALJ found that the evidence is clear that Nichol's records did not comply with the Controlled Substances Act or DEA regulations'' and '' 'Nichol[] fail[ed] to meet his responsibilities as a registrant.' '' *Id.*

The then-Administrator made additional specific fact findings in *Moore Clinical Trials* regarding Respondent. Specifically, she found that on March 30, 2011, Moore Clinical Trials and Respondent ''entered into a Clinical Trial Agreement (CTA) with Quintiles, to participate in the NKTR–118 [7] long-term safety study.'' *Id.* at 40149. She further found that, during the investigation of Moore Clinical Trials, the DI in the case ''contacted Mr. Jim Phillips, Dr. Nichol's attorney,'' who ''acknowledged that Nichol was involved in the study and that he was transporting the controlled substances to [Moore Clinical Trials] and dispensing them.'' *Id.* at 40150. ''The DI also requested of Mr. Phillips that Dr. Nichol provide his records, including the dispensing records and the schedule II order forms (DEA Form 222).'' *Id.* The then-Administrator found that the ''evidence also shows that in response to the GS's request (through Dr. Nichol's attorney) for Dr. Nichol's dispensing records, Nichol provided the GS with the records.'' *Id.* at 40156. The then-Administrator accepted the GS's testimony that the original DEA 222 forms related to the NKTR–118 study ''were kept at Dr. Nichol's registered location'' and that ''the forms did not indicate the date the drugs were received and the quantity received.'' *Id.* at 40151 (internal quotations and citations omitted), 40156 (adopting GS's testimony that ''she examined the Schedule II order forms and noted that they had not been completed by indicating the date the drugs were received and the quantity received''). Ultimately, the then-Administrator concluded that ''the record clearly establishes that Dr. Nichol violated both the separate registration provision and DEA recordkeeping requirements.'' *Id.* at 40155.[8]

With respect to the instant charges against Respondent, the parties stipulated that DEA issued a Show Cause Order against Respondent on September 27, 2011 proposing the revocation of his DEA registration on the ground that it is ''based, *inter alia,* on the findings of the ASMB and respondent's exclusion from Medicare and Medicaid.'' ALJ Ex. 9, at 2; *see also* GX 6. More specifically, the 2011 Show Cause Order proposed to revoke his registration as ''inconsistent with the public interest'' based on three allegations. GX 6, at 1 (citing 21 U.S.C. 823(f), 824(a)(4)). First, the 2011 Order alleged that Respondent's pre-signing of controlled substances prescriptions, as found by the ASMB, warranted revocation. *Id.* (citing 21 U.S.C. 824(a)(3), (4)). Second, the 2011 Order alleged that Respondent's registration must be revoked because of his exclusion for five years from participation in a Medicare and Medicaid program under 42 U.S.C. 1320a-7(a). *Id.* at 2 (citing 21 U.S.C. 824(a)(5)). Lastly, the 2011 Order alleged that, ''[o]n or about September 17, 2010, [Respondent] contracted with a controlled substance researcher [Moore Clinical Trials] to administer controlled substances [9] to research subjects. The owner/operator of this research clinic has no experience handling controlled substances, and you [Respondent] and the owner/operator [of Moore Clinical Trials] gave conflicting information about the operation of this research clinic.'' *Id.*

The parties have further stipulated that Respondent entered into an MOA with DEA to resolve the allegations in the 2011 Show Cause Order,[10] and that the MOA became effective on April 27, 2012.[11] ALJ Ex. 9, at 2; GX 7. The GS testified that the MOA was ''an intermediary step trying to get [Respondent] into compliance.'' Tr. 29.[12] Both Respondent and his investigator/assistant, Matilda Buchanan, testified that the MOA was the product of back-and-forth negotiations by the parties. *Id.* at 173–74 (Respondent testifying that ''there was some negotiation back and forth before we settled on the final agreement'' and ''I think it was the third or fourth [version] that we were both able to agree to terms on''), 425–26 (Ms. Buchanan testifying that ''drafts were sent back and forth'' and that ''we went over line by line both what the MOA said and then what does that mean by what it said'').

The MOA imposed the following conditions, in pertinent part, on Respondent:

1. Respondent must ''abide by all Federal, State and local statutes and regulations relating to controlled substances.''

2. Respondent must ''make and keep records of all controlled substances that he

[7] ''NKTR–118'' is the drug Naloxol 6a-methoxyhepta (ethylene glycol) ether. *Id.* at 40148. ''The [full] name of the study was: 'An Open-Label 52-week Study to Assess the Long-Term Safety of NKRT–118 in Opioid-Induced Constipation (OIC) in patients with Non-Cancer-Related Pain.' '' *Id.* at 40148 n.4.

[8] The then-Administrator also found that ''it is undisputed that the dispensing record for each study—which Dr. Nichol provided—was not created until August 27, 2012, well after all of the dispensings were made. The CSA requires, however, that a dispensing record be 'maintain[ed], on a current basis.' 21 U.S.C. 827(a)(3).'' *Id.* at 40156 (internal citations omitted).

[9] The Memorandum of Agreement resolving the 2011 Order, discussed more fully *infra,* specified that the alleged controlled substance referenced in that Order's third allegation was NKRT–118. *See* GX 7, at 1.

[10] This stipulation is also consistent with how the then-Administrator characterized the MOA. *Moore Clinical Trials,* 79 FR at 40151 n.10 (''Notwithstanding these allegations [in the 2011 Show Cause Order], the Agency allowed Dr. Nichol to retain his registration subject to various terms and conditions'' set forth in a Memorandum of Agreement (MOA)); *see also* GX 7.

[11] The Special Agent in Charge for DEA's New Orleans Division approved and signed the MOA on April 17, 2012, Respondent and his counsel signed it on April 20, 2012, and DEA's counsel signed it on April 27, 2012. GX 7, at 4.

[12] The ALJ questioned this testimony based on his finding that that the MOA ''does not address any of the alleged violations contained in the 2011 [Show Cause Order].'' R.D., at 10. The ALJ's assessment is confusing for at least two reasons. *First,* the parties stipulated that the MOA does, in fact, resolve the 2011 Order's allegations against Respondent, ALJ Ex. 9, at 2, and the ALJ accepted the parties' stipulation. R.D. at 7. That the parties repeated the allegations from the 2011 Show Cause Order in the MOA itself, *see* GX 7, at 1–2, makes the fact that the parties intended the MOA to address and to resolve the 2011 Order's allegations irrefutable. Apart from the parties' agreement, the third allegation of the 2011 Order (though unartfully worded) clearly references Respondent's role in the operations of Moore Clinical Trials. As already noted, Moore Clinical Trials received its own Show Cause Order in August 2011, less than two months before the September 2011 Show Cause Order that was issued to Respondent.

From there, Respondent and Moore Clinical Trials took two different procedural paths. Respondent entered into an MOA and retained his DEA registration subject to the MOA's conditions; Moore Clinical Trials went to hearing and the Agency issued a final decision and order denying its application for a DEA registration. As already noted, *Moore Clinical Trials* discussed Respondent's recordkeeping violations (which precede the ones in this case) at length. When comparing that discussion to the MOA, it is obvious that the MOA addresses the allegations against Respondent and reflects the ''intermediary step'' that the GS referenced in her testimony. *See* 79 FR at 40151 n.10 (''Notwithstanding these allegations, the Agency allowed Dr. Nichol to retain his registration subject to various terms and conditions'' set forth in the MOA).

Second, in any event, even if the MOA had failed to address the allegations in the 2011 Show Cause Order, as the ALJ suggested, he failed to explain why that is relevant. What is relevant is the fact that Respondent and the Government agreed that the MOA resolved the 2011 Show Cause Order.

prescribes, dispenses and administers at his DEA registered location. These . . . dispensing records shall include all the information . . . set forth and required by 21 CFR 1306.05(a) and 1304.21 where applicable. These . . . dispensing records shall be available for inspection as set forth in paragraph 4 of this Agreement.''

3. Respondent must ''make and keep a legible log of all Schedule II–V controlled substances that he prescribes for his patients.''

4. Respondent must ''retain the records of the prescribing, administering and dispensing records, as described in paragraph 2, at his DEA registered location and agrees to allow DEA personnel access to his controlled substance records for [these] records as described in paragraph 2 for purposes of verifying his compliance with this Agreement and with all Federal, state and local statutes and regulations relating to controlled substances.''

5. ''During the duration of the Agreement, Dr. Nichol shall notify DEA in writing if he will prescribe, dispense, or administer controlled substances at any other location other than his DEA registered address or Springhill Surgery Center. . . .''

6. Respondent ''shall not order or receive any controlled substances except for controlled substances that he orders and receives at his DEA registered location. . . . As the physician, who is contracted to administer the FDA approved study drug NKTR–118, [Respondent] will administer that drug at either his DEA registered location or at an approved site for the current drug study. . . . [Respondent] agrees that for the duration of this agreement if he is asked to participate in additional drug studies involving controlled substances, he will notify DEA in advance of commencing the study.''

7. Respondent ''understands and agrees that any violations of the Agreement may result in the initiation of proceedings to revoke or immediately suspend and revoke his DEA Certificate of Registration. . . . DEA and [Respondent] agree this is a final agency action on all matters in dispute. DEA will not seek to revoke [Respondent's] DEA registration or deny any renewal applications unless [Respondent] substantially violates this Agreement or unless [Respondent] commits additional acts that constitute grounds under 21 U.S.C. 823(f) and 824(a).''

GX 7, at 2–4. The MOA also stated that these conditions would remain in effect for three years. *Id.* at 4.

The Quintiles Clinical Trial and Study

On July 11, 2012, Respondent, Moore Clinical Trials, and Quintiles, Inc. entered into a ''Clinical Trial Agreement Effective July 6, 2012'' (hereinafter, CTA) to conduct a study related to opiate induced constipation. RX N, at 1, 11; Tr. 35. The CTA prescribed a role for each party. Respondent was the ''principal investigator'' of the study. Moore Clinical Trials, located at 3508 JFK Blvd., Suite #1, North Little Rock, Arkansas, was the ''INVESTIGATIVE SITE'' for the study. RX N, at 1. And Quintiles was an independent contractor acting on behalf of the ''Sponsor'' of the study (Purdue Pharma, L.P.) and would ''arrange and manage'' the clinical trial. *Id.*

This study was designed to be a double blind study in which Respondent would dispense oxycodone, which is a schedule II controlled substance, to study patients. Tr. 35, 182 (the study was a ''double blind, double dummy placebo controlled study''). However, because this was a double blind study, Respondent did not know what other type of medication a study patient received. *Id.* at 35, 184. Respondent first placed an order for controlled substances related to the study on December 3, 2012, and on December 31, 2012, he notified the GS (by letter from his attorney) that he was participating in the study. *Id.* at 93–94, 120–21; *see* RX R, at 1. In the letter, Respondent's attorney, Mr. Phillips, added that ''[t]his trial is to begin in January 2013. . . . [T]his notice is our compliance with paragraph 6 of the MOA. Dr. Nichol will only administer the study drugs at his DEA approved address.'' RX R, at 1.

Although the complete email that the GS sent in response to Mr. Phillips' December 31, 2012 letter is not in the record, the January 17, 2013 letter that Mr. Phillips sent to the GS in response to that email was admitted into evidence. *See id.* at 3. Specifically, the January 17, 2013 letter states that it is in response to two questions posed in a January 11, 2013 email that the GS had sent to Mr. Phillips in response to his earlier letter. *Id.* The response to the first question apparently posed by the GS regarded when the study would begin and how long it would be. *See id.* Mr. Phillips stated that ''the study we referred to should begin January 2013. The study length is approximately 22 weeks for each subject enrolled. . . . Enrollment is ongoing until the clinical trial end points are met. In all likelihood, the study will be about a year in length.'' *See id.* The second response was to the GS's ''other question'' asking ''What is the location and your understanding of the 'approved' DEA address?'' *Id.* Mr. Phillips stated that the address to which he was referring was Respondent's registered location of ''5106 McLanahan, Suite B, North Little Rock, AR 72116,'' and that ''[a]ll study drugs will be administered at this DEA-approved address.'' *Id.*

Mr. Phillips' response to the first question is consistent with Respondent's testimony at the hearing. Specifically, he testified that ''we expected to start enrolling patients in the study . . . to start in Januaryish [sic].'' Tr. 401. Respondent testified that enrollment is when they have ''met all the qualifications for it and are actually starting to see me as a patient. That's enrolled.'' *Id.* There is no evidence in the record contradicting this testimony. Thus, I find that Respondent began enrolling patients for the Quintiles study in January 2013.

Mr. Phillips' response to the second question is consistent with the GS's and Respondent's testimony regarding the study. The GS testified that it was her ''understanding that Dr. Nichol does the physical evaluations and actual dispensing of the controlled substances from his registered location.'' Tr. 36. ''[T]he other types of monitoring and testing is done at Moore Clinical Trials.'' *Id.* The GS further testified that it was her understanding that the study ''concluded in June of 2014.'' *Id.* Respondent testified that he first saw study patients in February 2013. *Id.* at 210–211. Respondent's dispensing log is also consistent with this testimony, showing that the first time he dispensed a controlled substance (here, oxycodone) to a patient as part of the study was February 18, 2013. RX U, at 1.[13] Thus, I find that Respondent first dispensed controlled substances to study patients on February 18, 2013. *Accord* R.D., at 13.

During the term of the CTA, Quintiles and the Sponsor reserved the ''right to audit'' Moore Clinical Trials' ''facilities, records and documentation.'' RX N, at 6. Respondent testified that such audits included Quintiles inspectors visiting Respondent's office as well to review his study documentation. Tr. 189–90. Respondent testified that Quintiles' inspectors or monitors ''would do a complete inventory of all the narcotics.'' *Id.* at 190. Respondent also said that the monitors required him ''to get the inventory down to the serial number of each individual kit, down to the serial number of each individual bottle. Any returns that the patient had, they would count each individual one. They would account for those quantities.'' *Id.* Finally, Respondent stated that he would ask the monitor ''when she was wrapping things up is is [sic] my pill count fine. . . . And every time I had

[13] Respondent testified that he ''had seven or eight'' study patients who ''actually enrolled in the study and only one patient, I think, or two patients that completed this study all the way to the end.'' Tr. 358, 398 (''I had two [patients who] completed it''). Respondent defined ''completed'' as ''when they've gone through the full length of the study to . . . where they actually completed the study at the end.'' *Id.* at 401.

full count of the narcotics. So there wasn't any diversion.'' *Id.* at 191.

Most important, Respondent testified that Quintiles had provided records that allowed for a calculation of every controlled substance pill received and that Quintiles accounted for every pill at the end of the study. *Id.* at 187, 301. To support this claim, Respondent introduced a series of documents prepared by others which the ALJ admitted into the record. For example, Respondent introduced copies of a series of reports or reviews prepared by Quintiles (and obtained from Moore Clinical Trials) of Quintiles monitors' site visits to Respondent's office to ensure he was following the drug study protocol. *See* RX Y; Tr. 262–63, 378–79, 454–56. Respondent also introduced accountability logs kept at Moore Clinical Trials for the drug study. RX Z; Tr. 456–57. Finally, Respondent introduced copies of work records that Quintiles had created during site inspections and while conducting their inventories. RX AA; Tr. 457–58. However, none of these documents, separately or taken together, were sufficient to make an accurate pill count. Moreover, Respondent failed to introduce any other documentary evidence or testimony from a Quintiles employee corroborating Respondent's testimony that Quintiles' records allowed for an accurate ''pill count'' of the pills Respondent had received. *Accord* R.D., at 18 nn. 22–23. At the same time, the Government offered no documentary evidence or testimony from a Quintiles employee to rebut Respondent's testimony. *See id.*

Indeed, it is equally possible for Quintiles to have done a ''complete inventory'' and found that Respondent's pill count was ''fine,'' and at the same time for Respondent to have nonetheless failed to maintain complete and accurate dispensing records pursuant to the CSA and as alleged in the Show Cause Order's second recordkeeping charge. Respondent's recordkeeping is what is at issue in this case, not Quintiles' recordkeeping. Without a showing by a preponderance of the evidence that the recordkeeping requirements of Quintiles and the CSA are coextensive, I find that Respondent's testimony regarding the Quintiles audits and documents in the record rests on too thin a reed for me to accord it meaningful evidentiary weight regarding whether Respondent's recordkeeping complied with the CSA and DEA's regulations.

The July 9, 2014 On-Site Inspection

Inspection of Respondent's Registered Location

The parties stipulated that on ''July 9, 2014, while the MOA was still in effect, DEA conducted an on-site inspection of Respondent's registered location.'' ALJ Ex. 9, at 3. Three DIs participated in the inspection. *See id.;* ALJ Ex. 7, at 4 & n.1; ALJ Ex. 11, at 1 n.1. The DI who had lead responsibility for conducting the inspection was unable to testify at the hearing for medical reasons. ALJ Ex. 11, at 1 n.1. Although a third DI accompanied the GS and the lead DI who conducted the on-site inspection, that third DI also did not testify. Thus, only the GS testified on behalf of the Government at the hearing. *Id.*

The GS testified that the DIs ''went to Dr. Nichol's registered location . . . to ensure that he was in compliance with the MOA.'' Tr. 31. Under the MOA, Respondent had agreed ''to allow DEA personnel access to his controlled substance records for the prescribing, administering, and dispensing records . . . for purposes of verifying his compliance with [the MOA] and with all Federal, state and local statutes and regulations relating to controlled substances.'' GX 7, at 2. Although the inspection was unannounced, Respondent allowed the DIs ''access onto the premises to review records . . . [a]nd he signed an actual Notice of Inspection.'' Tr. 99; *see also id.* at 31–32; July 9, 2014 Notice of Inspection (GX 8). The inspection period was from December 19, 2012 through July 9, 2014. Tr. 38, 62. The inspection took one hour, and the GS testified that Respondent's ''assistant Xeroxed for us the documents we needed.'' *Id.* at 102.

Initially, the DIs asked Respondent where the ''study drugs'' were ''because at that point in time we didn't know the study had been completed.'' Tr. 99. Once it became clear that Respondent no longer had any study drugs and ''that there were no drug destructions during that time period or theft or losses'' (*id.* at 39–40), the GS testified that ''we asked for any incoming documents [sic] receipts. We asked for any inventories. We also asked for any outgoing records which could include dispensing records, returns, theft and loss reports, drug destruction. Anything showing the movement of controlled substances in or out of that registered location.'' *Id.* at 36–37. The GS stated that ''this is typical of any inspection.'' *Id.* at 36. When asked if she could ''be more specific about what inventories and dispensing records you specifically asked for,'' she responded that ''[w]e asked for an initial inventory . . . We asked for receipts. And because these are Schedule II controlled substances, we asked for DEA order form 222s.'' *Id.* at 37–38; *see also id.* at 102 (''We asked for dispensing records, inventories. . . . we ask for any kind of documents showing receipts or dispensations.''). She also testified that ''[h]e did not have an inventory on hand.'' *Id.* at 52.

Respondent testified that he did not ''recall'' whether the GS had asked for his DEA 222 forms or dispensing logs and stated that he ''d[id]n't think'' she had asked for his inventory. Tr. 213. Instead, he stated that the DIs ''wanted my paperwork for the study.'' *Id.* at 212–13, 214 (''When they found out there weren't any drugs there to collect, they wanted the paperwork''). In response, Respondent stated that he made his DEA 222 forms ''available for Agent Barnhill to review,'' and the GS acknowledged that the DIs reviewed at least some of these forms. *Id.* at 39, 214; *see also* RX S. Respondent also stated that he ''kept a green binder with all of the computation charts'' (that Respondent stated included an initial inventory) and ''provided'' them and his dispensing log ''to the agents when they came to see me in my office on July 9th.'' Tr. 224, 226, 236–37; RX U; RX V.[14]

The GS acknowledged that Respondent ''did give us some documents'' and that the DIs reviewed these documents ''in his office.'' Tr. 101, 102 (''he showed us some documents''). The GS recalled that Respondent ''produced five DEA 222 order forms for purchase. And he gave us two DEA order forms for returns back to the supplier.'' *Id.* at 39; *see* GX 9 (DEA 222 forms submitted by the Government). During cross-examination, Respondent's attorney asked the GS:

> Q Did [Respondent] show you documents other than the 222 forms? He did, didn't he?
> A I don't recall that.
> Q You don't recall that?
> A No.

Tr. 102–03. Whatever other documents Respondent may have provided to the GS, she did not recognize them as an initial inventory or as dispensing records. *See id.* at 39 (GS's testimony that Respondent ''was unable to produce the initial inventory that we requested. And he was unable to produce dispensing records'').

The GS testified that she did not recall giving Respondent a ''written list

[14] The ALJ recommended that I find that ''Respondent provided the DEA investigators his 222 Forms, his dispensing logs, and an initial inventory.'' R.D., at 15 (citing Tr. 214). In the testimony cited by the ALJ, however, Respondent only testified that he made the DEA 222 forms ''available for [the GS] to review.'' *See* Tr. 214.

of items'' that the DIs had requested. Tr. 100. She also testified that she did not provide Respondent (1) a list of items that the DIs did in fact receive, (2) a list of items to which she had testified were missing, or (3) a list of items that the DIs photocopied on the date of inspection. *Id.* at 100–01, 112 (''Records can be fabricated. So, no, we don't leave a list. The records must be onsite when we arrive.''). Respondent testified that, had the DIs advised him that he was missing something, he would have provided it to them. *Id.* at 236.

The GS's use of the phrase ''we'' or ''us'' is significant and occurs frequently throughout her testimony regarding the inspection. In these instances, she was either testifying to what she remembered hearing someone else (presumably, the lead DI) ask Respondent, *e.g.,* Tr. 103 (GS testifying that she was ''present when [the lead DI] asked [Respondent] for documents''), or she was testifying to what she would typically request from a registrant during an inspection (or to both). *See id.* (GS's testimony that she did not ''take notes of what was asked for'' but noted that ''[i]t's the same things we ask for every time'').[15] In any event, the GS did not testify that she herself made these requests of Respondent, and she did not ''take notes of what was asked for.'' *Id.* Thus, while the record is clear that the GS did not recall reviewing documents that she recognized as an initial inventory or as dispensing logs at Respondent's office during the inspection (*id.* at 39), the record is unclear whether the other two DIs reviewed and recognized what Respondent submitted were his initial inventory and dispensing logs.[16]

For this reason, I disagree with the ALJ's statement that ''[t]here is a conflict in testimony concerning what the DEA investigators specifically asked for'' during the inspection because both the GS's and Respondent's testimony could be accurate. R.D., at 15 n.6. That is, the GS may be correct that DIs conducting inspections (''we'') typically ask registrants for DEA 222 forms, inventories, and dispensing logs. Tr. 103 (''[i]t's the same things we ask for every time''). Indeed, the GS has conducted over 400 audits in her more than 28 years with the DEA and had been a Group Supervisor for over six of those years, so she should know how DIs typically conduct audits. *See id.* at 25, 59; ALJ Ex. 24, at 4–5. Likewise, Respondent may also be correct in his recollection that, for his particular inspection, the DIs asked more generally for ''paperwork'' related to the Quintiles study. *E.g.,* Tr. 212–13. Moreover, the same could be true for whether Respondent provided an initial inventory and dispensing log. Thus, the fact that the GS herself did not see or recognize these documents does not preclude the possibility that Respondent provided them to one of the other DIs at the inspection.

Rather than reflecting a conflict, this testimony highlights a gap in the Government's evidence. The GS's testimony that DIs conducting inspections typically ask for DEA 222 forms, inventories, and dispensing records is insufficient to establish by a preponderance of the evidence that the lead DI asked for these documents in this particular case. The lead DI who the GS testified had made the requests for this paperwork (and who was most likely to have received the response) during the inspection did not testify at the hearing. Moreover, the Government did not offer as a witness the third DI present during the inspection to corroborate the GS's testimony.[17] For these reasons, the record created by the Government is insufficient to establish by a preponderance of the evidence that Respondent failed to provide the DIs with what Respondent characterized as his initial inventory[18] and dispensing logs during the July 9, 2014 inspection.

And for the same reasons, I need not reach the credibility issue raised by the ALJ and the Government in its Exceptions of whether the GS's testimony was more credible than Respondent's testimony regarding the paperwork that the DIs requested and received from Respondent during the inspection. The ALJ found that the GS's testimony in this context (and others) lacked credibility because the ALJ found the GS's testimony in conflict with Respondent's testimony. R.D., at 3–4, 15 n.17, 17 n.20, 19 n.25, 21 n.28, 34. In its Exceptions, the Government disagreed with the ALJ's credibility findings and stated that, ''[a]ssuming the DEA investigator's testimony is accepted over Respondent's testimony, then it would be established that the initial inventory, dispensing records, and missing DEA–222 form were not provided to the investigators at the time of DEA's on-site visit and therefore DEA's allegations in the Order to Show Cause would be sustained.'' ALJ Ex. 24, at 2 n.3. However, and for the reasons already noted, even assuming *arguendo* that the GS's testimony was credible, it would be insufficient to establish by a preponderance of the evidence that Respondent failed to provide the DIs with an initial inventory or dispensing logs during their July 9, 2014 inspection.

Inspection of Moore Clinical Trials

Later the same say, after conducting their inspection of Respondent's registered location, the DIs went to Moore Clinical Trials. *See* Tr. 56. Although the GS and Respondent provide conflicting testimony regarding why Respondent directed the DIs to Moore Clinical Trials,[19] the Government

[15] In its Exceptions, the Government argues that the GS's ''use of the term 'we' . . . was intended to emphasize that more than one investigator had requested the needed materials from Respondent.'' ALJ Ex. 24, at 4. However, the record fails to reflect this intent.

[16] I agree with the ALJ that it is possible, if not ''likely,'' that the DIs reviewed but ''may not have recognized Respondent's Exhibit V as an initial inventory because it contained far more information than would normally be contained in an initial inventory.'' R.D., at 17 n.20.

[17] The Government stated in its Exceptions that ''[t]he third investigator had been reassigned to another DEA field office.'' ALJ Ex. 24, at 4 n.4. However, nothing in the record explains why this reassignment precluded the third DI from testifying at the hearing.

[18] As discussed more fully *infra,* I also dismiss the Government's first recordkeeping charge regarding Respondent's initial inventory for legal reasons.

[19] The GS testified that Respondent directed the DIs to Moore Clinical Trials because that was where they could find records related to the study. Tr. 478–79. This testimony is consistent with Respondent's testimony that the DIs ''wanted my paperwork for the study.'' *Id.* at 213. After this point, however, the clarity ends. Respondent testified that the question of patient names and addresses came up and that he therefore referred the DIs to Moore Clinical Trials for paperwork more specifically related to patient names and addresses (the Quintiles Study precluded Respondent from knowing the patients' names). *See id.* at 279, 374. On rebuttal, the GS testified that the DIs went to Moore Clinical Trials because Respondent advised that he did not have in his office the records related to the study that they cared about—*i.e.,* an initial inventory and dispensing records—at his registered location because they were at Moore Clinical Trials. *Id.* at 56 (''Upon learning that the dispensing records were at Moore Clinical Trials . . . [and a]fter our onsite inspection completed at Dr. Nichols, we went straight to Moore Clinical Trials . . . that same day . . . [T]he purpose of going to Moore Clinical Trials'' was ''to obtain the documents that Dr. Nichol told us was there, which would be inventory and the dispensing records''); *see also id.* at 478. The GS also rejected the notion that the DIs had any interest in the patients' names and addresses because the inspection was focused on drugs, not people. *Id.* at 478.

The ALJ rejected the GS's explanation and found Respondent's ''more credible'' because (1) the stated purpose of the inspection was to ensure compliance with the MOA; (2) the inspection pursuant to the MOA focused on recordkeeping, not drugs; (3) Respondent had advised DEA by letter (to which DEA did not respond) in August 2012 that he could not provide patient names for a double blind study; and (4) the ALJ accepted that Respondent provided the DIs with Respondent's Exhibit U, which Respondent represented to be his dispensing log. R.D., at 15 n.16.

Assuming that the purpose of the inspection was to determine whether Respondent's recordkeeping was in compliance with the MOA, the CSA, and DEA regulations, that purpose is consistent with the

Continued

offered the GS's testimony regarding the DIs visit there to establish the Show Cause Order's allegation that Respondent had improperly maintained his inventory or dispensing records at a location other than his registered location. Upon arriving at Moore Clinical Trials, the DIs spoke with Kianna Marshall, who was an assistant to Moore Clinical Trials owner Greta Moore. *Id.* at 56–57. The GS testified that the DIs asked Ms. Marshall for the inventory and dispensing log for the study so DEA ''could complete an accountability audit. And Kianna gave us a folder that had the dispensing records in it. However, she did not have any inventory.'' *Id.* at 57; *see* GX 11.

Respondent denied that he failed to maintain his inventory and dispensing records in his office because he represented that he kept them in his office and presented them to the DIs during the inspection. *See* Tr. 278–79; RX U; RX V. As already noted, the GS did not recall seeing (or saw but failed to recognize) the documents in Respondent's office as his inventory or dispensing records (RX U and RX V), and it is unclear what the other DIs understood because they did not testify. Importantly, the fact that Ms. Marshall provided the DIs with documents that she believed were responsive to the DIs' requests does not mean that those documents were, in fact, Respondent's dispensing records nor that Respondent intended to maintain his dispensing records at Moore Clinical Trials. *Accord* R.D., at 19 n.25 (''there is no credible evidence before me that [what Ms. Marshall provided to the DIs] is in fact, the Respondent's dispensing records'').

Likewise, the fact that the GS believed that these documents could qualify as Respondent's dispensing records, or that Ms. Marshall may have advised the DIs that they were Respondent's dispensing records, is not dispositive of whether they were, in fact, what Respondent maintained as his dispensing records under the CSA and DEA's regulations. *Accord id.* Instead, I agree with the ALJ that the records provided by Ms. Marshall were more likely worksheets used as part of the Quintiles study to reconcile differences between what the study patients entered into their electronic monitors and the actual pill count. *Id.* at 20. Although the worksheets include all of the data in Respondent's dispensing log maintained in his office, the worksheets contain additional information not included in Respondent's dispensing log. *Compare* GX 11 *with* RX U.[20]

Neither the Government nor Respondent called Ms. Marshall as a witness to establish what Respondent may have told her about maintaining his dispensing records at Moore Clinical Trials or what she believed she had provided to the DIs. Thus, I find that the Government has provided insufficient evidence for me to find by a preponderance of the evidence that Respondent, in fact, failed to maintain inventory and dispensing records at his registered location.

Respondent's DEA 222 Forms

The GS testified that DEA 222 forms are three-part forms that DEA registrants use to order controlled substances. *See* Tr. 38, 42. Registrants request a book of DEA 222 forms in advance of ordering controlled substances, and then DEA sends back a book of DEA 222 forms—each one preprinted with the registrant's name, DEA registration number, the date he or she ordered the forms, and the schedules for which he or she is authorized to prescribe. *See id.* at 43–44. These forms have carbon paper in between each copy so three parties can each get a copy. *Id.* at 38, 42. ''One is the purchaser's copy, one is the supplier's copy, and the third copy goes to DEA once the order is completed.'' *Id.* at 44–45. The GS testified that ''[Respondent] or his representatives fills out the supplier name, the date, and the requested drugs. And he tears off that first copy, the purchaser's copy. He holds onto that. And then the second two copies, the DEA copy and the supplier copy, get sent to the supplier.'' *Id.* at 45.

When Respondent is placing an order, he retains the copy that states ''PURCHASER'S Copy 3.'' *Id.; e.g.,* GX 9; RX S, at 5, 9–12, 16. For example, the DEA 222 forms that Respondent provided to the DIs during their inspection show that Fisher Clinical Services (FCS) was the supplier of the drugs Respondent used in the study. *Id.* When Respondent ''is shipping drugs back to his supplier, Fisher [Clinical] Services,'' then his name would appear on the DEA 222 form as the supplier, FCS would be the registrant, and Respondent would retain ''SUPPLIER'S Copy 1.'' Tr. 48–50; GX 10; RX S, at 13–14. When filling out a supplier's copy, the supplier must fill out several fields on the form, including the number of packages, the size of the packages, the packages shipped, and the date when they were shipped. Tr. 50; GX 10; RX S, at 13–14.

Respondent's Annotation of DEA 222 Forms

In this case, Respondent provided DEA with two DEA 222 forms in which he was the ''supplier'' and FCS was the registrant because he was returning unused drugs from the clinical trial back to FCS. Tr. 48–50, 253–54; *see also* GX 10; RX S, at 13–14. FCS had provided Respondent with a packing list that included instructions on how to fill out the DEA 222 forms as the supplier, including instructions that he should enter the number of kits shipped and the date shipped. RX S, at 15; Tr. 376–77. However, Respondent left the ''Packages Shipped'' and ''Date Shipped'' boxes next to the identified kits blank in both DEA 222 forms in which Respondent was the supplier. RX S, at 15; Tr. 50. As a result, the GS testified that when these boxes are left blank, DEA ''do[es] not know if th[e kits are] indeed what Dr. Nichol shipped back.'' Tr. 50. This negatively impacts DEA's ability to conduct an audit of a registrant, according to the GS, ''because the DEA 222 order form is a primary record . . . as far as auditing purposes, these are the only documents we are supposed to look at.'' *Id.* at 51.

In his testimony, Respondent admitted that he failed to properly annotate the ''Packages Shipped'' and Date Shipped'' boxes:

> Q . . . Now, as you're sitting here today, do you realize that you completed this [first 222] form that you left off a date and the packets that were shipped back?
>
> A Yes sir, I did. . . .
>
> Q . . . So at least what [the GS] said about the return of this 222 form, that was correct, what she said; is that right?

GS's explanation that the DIs' focus was on drugs and not patient names. The relevant recordkeeping requirements focus on tracking the movement of controlled substances (inventory, dispensing logs, DEA 222 forms), not the identity of patients. Moreover, as already noted, the more recent January 11, 2013 correspondence from DEA to Respondent prior to the inspection asked when the Quintiles study would commence and where the study drugs would be located (both of which relate to MOA requirements) and not the identity or addresses of Respondent's study patients. *See* RX R, at 3.

Most importantly, I need not reach the question of whether the GS's explanation of why the DIs visited Moore Clinical Trials was more or less credible than Respondent's because, as discussed more fully *infra,* I reject the Government's charge that Respondent failed to maintain his inventory and dispensing records at his registered location.

[20] For this reason, the Government's claim that it could not complete an accountability audit at Respondent's registered address is unavailing. The worksheets obtained from Moore Clinical Trials included everything contained in the dispensing logs maintained in Respondent's office, which was sufficient to complete the audit. *See* Tr. 484. The GS testified that the DIs had difficulty using the worksheets because ''[t]here are numerous cross-outs and circles and initials and changing of dates . . . it's very hard to determine what's coming in and what's going out.'' Tr. 59. However, the GS conceded that having cross-outs or even confusing records does not violate DEA regulations, and they ultimately did not preclude the DIs from completing their audit. *Id.* at 69–70.

A Yes. . . . I did not fill out the date and I did not fill out the package quantity.

Tr. 256–57; *see also id.* at 258 (''Q Okay. And again you made the same clerical error on that [second 222] form? A I did.''). Accordingly, I find that Respondent failed to properly annotate two DEA 222 supplier's copy forms set forth in Government's Exhibit 10 because he failed to complete the ''Packaged Shipped'' and Date Shipped'' entries. GX 10; RX S, at 13–14.[21]

Respondent's Allegedly Missing DEA 222 Form

In its Show Cause Order, the Government alleged that Respondent failed during the onsite inspection to provide a January 16, 2014 DEA 222 form.[22] ALJ Ex. 1, at 3. On the first day of the hearing, the GS testified that Respondent ''produced for . . . inspection'' ''five DEA 222 order forms for purchase'' and ''two DEA order forms for returns back to the supplier,'' and that Government Exhibits 9 and 10 included copies of these seven forms. *See* Tr. 39, 40–41, 52, 56 (''the only thing we received were a grand total of seven completed DEA form 222s''); GXs 9–10. These exhibits did not include Respondent's purchaser's copy of the January 16, 2014 DEA 222 form. In addition, the GS testified that they did not ask Respondent why there were only five purchaser DEA 222 forms and not six such forms—even though the DIs knew that Respondent had made six orders of controlled substances when they arrived for the onsite inspection. Tr. 76, 505–06. Respondent testified that, had the DIs advised him that he was missing any records, he would have endeavored to find and to provide them to the DIs. *Id.* at 236.

Although her testimony was not always clear on this subject, the GS ultimately testified on rebuttal that Respondent (or someone in his office) ''presented'' to the DIs ''a folder with all of the 222s.'' Tr. 507; *see also id.* at 290–91 (Respondent testified that ''[t]he DEA 222s were kept in a hanging file folder in a safe next to my office—or in my office in a safe next to my desk. . . . [Respondent] provide[d] that folder to the DEA investigators on the date of the onsite inspection.''). Also during rebuttal, the GS acknowledged that Respondent had provided a folder to the DIs that not only included completed DEA 222 forms reflected in Government Exhibits 9 and 10 but also included ''voided and unused DEA 222s.'' *Id.* at 475. The GS stated that she was uninterested in the ''voided out and unused DEA 222s'' and therefore only obtained ''copies of the [completed] 222 order forms that were within our audit'' period. *Id.*

Respondent introduced Respondent's Exhibit S, which the ALJ accepted into evidence as the contents of the entire folder of DEA 222 forms (22 pages) that Respondent provided to the DIs during the onsite inspection. *See* Tr. 214–15; RX S. The exhibit included unused, voided, and completed DEA 222 forms (both Purchaser's Copies and Supplier's Copies) as well as a completed DEA 222 form from a previous drug study. Tr. 261, 475; RX S. Most significantly, Respondent's exhibit included a copy of the allegedly missing DEA 222 form related to the January 16, 2014 controlled substances shipment to Respondent. RX S, at 16. The GS did not recall seeing that form, and Respondent did not recall to which DI he gave the folder. Tr. 291 (''Q Do you [Respondent] remember which agent you gave these to? A ''I do not.''); *id.* at 475.

After the pending Show Cause Order was served on Respondent, Respondent telephoned Mathilda Buchanan, an Arkansas-licensed private investigator with whom Respondent had worked since 2006. Tr. 262, 417. Respondent provided the same folder of DEA 222 forms (Respondent's Exhibit S) to Ms. Buchanan that he had provided to the DIs. *See id.* at 262. When Ms. Buchanan examined the contents of the folder, she testified that she discovered that the allegedly missing purchaser's copy of January 2014 DEA 222 form was in fact within the folder but stuck between unused DEA 222 forms. *Id.* at 452–53, 462; RX S, at 16. Moreover, the DEA 222 form that Ms. Buchanan found was a purchaser's copy for an order of controlled substances dated January 13, 2014, which corresponded to the January 16, 2014 shipment of controlled substances to Respondent reflected on the supplier's copy submitted into evidence by the Government. *See* Tr. 260; GX 13, at 1; RX S, at 16.

The ALJ recommended that I make the fact finding that the January 16, 2014 DEA 222 form ''was available to the DEA investigators during the inspection'' and that ''[i]t is highly probable that the alleged missing 222 Form was caught up in the carbon copies of the other 222 Forms contained in the folder where the Respondent kept his records.'' R.D., at 22, 34. In other words, the ALJ believed that the DIs simply overlooked the January 16, 2014 DEA 222 form during the onsite inspection. *Id.* at 34. I agree, and I find that it is more likely than not that the purchaser's copy of the January 2014 DEA 222 form was indeed in Respondent's folder of DEA 222 forms on the date of the onsite inspection.[23]

The December 2014 Meeting

In December 2014, the lead DI contacted Respondent to set up a meeting with him. Tr. 237. This was the first time the DIs had contacted Respondent since the July 9, 2014 onsite inspection. *See id.* On December 16, 2014, two DIs—the GS and the lead DI—met with Respondent and Ms. Buchanan ''to report on the July 9, 2014 inspection.'' ALJ Ex. 9, at 3; Tr. 481. During the meeting, the DIs advised Respondent that his ''inventory was off.'' Tr. 237. Respondent stated that he offered to compare his inventory with DEA's inventory, but the DIs refused. *Id.* at 238, 437, 507–08. The DIs also discussed the accuracy of Respondent's dispensing records and that Respondent had failed to provide the DIs with sufficient information to complete a proper audit, which in turn required the DIs to go to Moore Clinical Trials to supplement the information. *Id.* at 439, 461. The DIs did not ask Respondent for any records during the meeting. *Id.* at 500.

On December 19, 2014, Respondent's attorney wrote a letter to the lead DI and to the GS on behalf of Respondent in response to the December 16, 2014

[21] During the hearing, the GS also testified to recordkeeping errors made by Respondent in filling out the purchaser's copies of the DEA 222 forms. *See, e.g.,* Tr. 47–48 (Respondent improperly used three lines to order one drug when ''[t]he regulations state that when you are ordering a drug, it's one drug per line''). She stated that Respondent's failure to accurately complete the initial DEA 222 forms caused accountability errors in the audit. *Id.* at 488. The Government did not, however, allege these errors in its Show Cause Order or Prehearing Statements. Thus, I agree with the ALJ's recommendation not to consider this evidence in determining the sanction in this case. R.D., at 3 n.2.

[22] As noted *supra* in footnote 2, the Show Cause Order erroneously referenced an August 28, 2013 DEA 222 form. The Government corrected the date of the allegedly missing DEA 222 form to January 16, 2014 in its May 12, 2016 Prehearing Statement and during Government counsel's Opening Statement at the administrative hearing. *See* ALJ Ex. 7, at 8; Tr. 15. I further note that January 16, 2014 represents the shipping date, not the January 13, 2014 date on which Respondent actually ordered the controlled substances. *See* GX 13, at 1; RX S, at 16.

[23] For the same reason, I again need not reach the question of the GS's credibility regarding the allegedly missing DEA 222 form raised by the ALJ in his Recommended Decision and the Government in its Exceptions. R.D., at 34; ALJ Ex. 24, at 2 n.3, 5. Specifically, because I find (as did the ALJ) that the DIs overlooked the DEA 222 form in question, the GS could credibly testify that she did not see the form during the onsite inspection. Likewise, Ms. Buchanan could credibly testify that her (apparently more thorough) review of the folder of DEA 222 forms did uncover the allegedly missing form. Accordingly, I find that there is no credibility issue regarding the allegedly missing DEA 222 form because it is more likely than not that the testimony of both witnesses is accurate.

meeting. RX X. The letter memorialized Respondent's understanding that DEA's ''audit was not available to us'' and asked for ''written documentation of specific points you think are lacking so we can do better.'' *Id.* The letter also stated that records related to the identification of patients ''must be kept at Moore Clinical Trials and are separate from the records at Dr. Nichol's office which only contain the patients' identifying numbers.'' *Id.* Respondent never received a reply to his attorney's letter, and the Government filed its Show Cause Order on March 14, 2016. Tr. 443; ALJ Ex. 1.

Discussion

Under the Controlled Substances Act (''CSA''), ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In the case of a physician, who is deemed to be a practitioner, *see id.* § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

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

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

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

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

Id. § 823(f).

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that 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.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[24]

Under the Agency's regulation, ''[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. [§]824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, I have considered all of the factors and concluded that the Government's evidence with respect to Factors Two and Four support the conclusion that Respondent has committed acts which render his ''registration inconsistent with the public interest.'' 21 U.S.C. 823(f), 824(a)(4). While I agree with the ALJ's conclusion that a sanction is appropriate, I find that the record supports a stronger sanction than what the ALJ recommended.

Factor One—The Recommendation of the State Licensing Authority

The Government sought to revoke Respondent's DEA registration based on Factors Two, Four, and Five. However, the ALJ considered Factor One as well in his Recommendation. R.D., at 27. I agree with the ALJ's finding that the ASMB has not made a recommendation to the Agency regarding whether Respondent's DEA registration should be suspended or revoked in this case. *See id.* The record only shows that the ASMB suspended Respondent's state medical license for six months based on his pre-signing of controlled substance prescriptions, which his staff (who were not licensed to prescribe controlled substances) issued to patients outside Respondent's presence and without consulting him. The ALJ noted that the ASMB reinstated Respondent's medical license after six months and stated that ''[t]he reinstatement of the Respondent's medical license can be interpreted as a recommendation of the ASMB'' under Factor One. R.D., at 27 (citing *Tyson D. Quy, M.D.,* 78 FR 47412, 47417 (2013); *Vincent J. Scolaro, D.O.,* 67 FR 42060, 42064–65 (2002)). As a result, the ALJ recommended that I find that ''the ASMB's reinstatement of the Respondent's medical license only weighs slightly in favor of not revoking the Respondent's registration.'' R.D., at 28.

To be sure, the Agency's case law contains some older decisions which can be read as giving more than nominal weight in the public interest determination to a State Board's decision (not involving a recommendation to DEA) either restoring or maintaining a practitioner's state authority to dispense controlled substances. *See, e.g., Gregory D. Owens,* 67 FR 50461, 50463 (2002) (expressing agreement with ALJ's conclusion that the Board's placing dentist on probation instead of suspending or limiting his controlled substance authority ''reflects favorably upon [his] retaining his . . . [r]egistration, and upon DEA's granting of [his] pending renewal application''); *Scolaro,* 67 FR at 42065 (concurring with ALJ's ''conclusion that'' state board's reinstatement of medical license ''with restrictions'' established that ''[b]oard implicitly agrees that the [r]espondent is ready to maintain a DEA registration upon the terms set forth in'' its order). However, these cases cannot be squared with the Agency's longstanding holding that ''[t]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Garrett Howard Smith, M.D.,* 83 FR 18882, 18904 n.30 (2018) (quoting *Mortimer Levin,* 57 FR 8680, 8681 (1992)); *Lon F. Alexander, M.D.,* 82 FR 49704, 49724 n.42 (2017) (same). Indeed, neither *Owens* nor *Scolaro* even acknowledged the existence of *Levin,* let alone attempted to reconcile the weight it gave the state board's action with *Levin. Smith,* 83 FR at 18904 n.30; *Alexander,* 82 FR at 49724 n.42.

While in other cases, the Agency has given some weight to a Board's action in allowing a practitioner to retain his state authority even in the absence of an express recommendation, *see Quy,* 78 FR at 47417, the Agency has repeatedly held that a practitioner's retention of his or her state authority is not dispositive of the public interest inquiry. *See, e.g., Smith,* 83 FR at 18904 n.30; *Alexander,* 82 FR at 49724 n.42; *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)). Accordingly, I find that the ASMB's reinstatement of Respondent's state license is not dispositive of the public

[24] In short, this 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 or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, findings under a single factor can support the revocation or suspension of a registration. *MacKay,* 664 F.3d at 821.

interest inquiry in this case, and I give it no weight.[25]

Factors Two and Four—The Respondent's Experience in Dispensing Controlled Substances, or Conducting Research With Respect to Controlled Substances, and Compliance With Applicable Laws Related to Controlled Substances

Pre-Signed Prescriptions Allegation

The Show Cause Order's first charge alleged that Respondent's pre-signing of prescriptions for controlled substances violated 21 CFR 1306.05(a). Under the CSA, it is ''unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense,[26] or possess with intent to manufacture, distribute, or dispense, a controlled substance'' ''[e]xcept as authorized by'' the Act. 21 U.S.C. 841(a)(1). According to the CSA's implementing regulations, ''[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.'' 21 CFR 1306.05(a).

The Agency has long held that pre-signing prescriptions violates the CSA and 21 CFR 1306.05(a). *Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016); *Alvin Darby, M.D.,* 75 FR 26993, 26999 (2010) (''DEA has long interpreted the CSA as prohibiting the pre-signing of prescriptions.''); *Jayam Krishna-Iyer, M.D.,* 71 FR 52148, 52158, 52159 n.9 (2006) (''Respondent further violated federal law and DEA regulations by giving [his nurse] pre-signed prescriptions and allowing him to issue them to a patient [Respondent] had not attended to. . . . [T]his conduct of Respondent violated 21 CFR 1306.05(a)''), *vacated on other grounds,* 249 Fed. Appx. 159 (11th Cir. 2007); *Leslie,* 68 FR at 15230–31; *James Beale,* 53 FR 15149, 15150 (1988) (''It is a violation of 21 CFR 1306.05(a) to pre-sign prescriptions for controlled substances.''). Most importantly, the Agency has held that pre-signing prescriptions ''would be inconsistent with the public interest'' under the CSA because such conduct ''create[s] a substantial risk that the drugs would be diverted and abused.'' *Singh,* 81 FR at 8248, 8249.

As noted earlier, it is undisputed that on August 17, 2016, the ASMB issued a final order suspending Respondent's medical license for six months because he pre-signed prescriptions for controlled substances. During the ASMB hearing leading up to its final order, Respondent admitted in testimony that he pre-signed prescriptions in which he failed to write the name of the patient on the prescription, the substance prescribed, and instructions for taking the medication. In addition, Respondent admitted during the ASMB hearing that he permitted his office personnel, who were not licensed as physicians nor authorized to prescribe medications under Arkansas law, to fill in the blanks on the prescription pad and distribute them to patients without Respondent being present.

Thus, I agree with the ALJ's recommendation that I find (and I do so find) that Respondent's pre-signing of prescriptions violated 21 CFR 1306.05(a). I also find that this conduct constituted a serious violation of the CSA and created a substantial risk that the drugs would be diverted and abused. *Krishna-Iyer,* 71 FR at 52159; *Singh,* 81 FR at 8249. I further find that Respondent violated federal law by giving the pre-signed prescription forms to office personnel who lacked the authority to lawfully prescribe controlled substances under federal or state law. *See* 21 CFR 1306.03(a); *see also Krishna-Iyer,* 71 FR at 52159. Accordingly, the Government's first charge of pre-signing prescriptions is sustained and supports a finding that Respondent's continued registration would be inconsistent with the public interest.

Recordkeeping Allegations

The Show Cause Order sets forth five recordkeeping charges based on DEA's July 4, 2014 on-site inspection of Respondent's registered location. ''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Paul H. Volkman,* 73 FR 30630, 30644 (2008). As the Agency recently held:

> [T]he CSA and DEA regulations require that a registrant take an actual physical count of the controlled substances on hand, and an accurate actual count, as memorialized in either an initial or biennial inventory[. This] is essential in conducting an accurate audit. Likewise, an accurate audit is essential in determining whether a registrant is maintaining complete and accurate records of both the controlled substances he receives and those he ''deliver[s] or otherwise dispose[s] of.'' 21 U.S.C. 827(a)(3). . . . [G]enerally, it is diversion that results in recordkeeping irregularities and not the other way around.

Peter F. Kelly, D.P.M., 82 FR 28676, 28692 n.41 (2017), *pet. for rev. denied, Kelly* v. *DEA,* No. 17–1175, 2018 WL 3198774 (D.C. Cir. May 18, 2018).

The Show Cause Order's first recordkeeping charge alleged that Respondent failed to maintain an initial inventory of all controlled substances ''in violation of 21 U.S.C. 827(a)(3) & 842(a)(5) and 21 CFR 1304.11(b).'' ALJ Ex. 1, at 2. As a threshold matter, the ALJ correctly noted ''that it appears that the Government made an error because § 827(a)(3) requires a registrant to maintain a dispensing record'' and not an initial inventory as § 827(a)(1) requires. *See* R.D., at 31 n.34. The ALJ also noted accurately that the ''Government, however, also correctly cites to 21 CFR 1304.11(b).'' *Id.* Section 1304.11(b) states that ''[e]very person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances.'' Thus, I agree with the ALJ that the Government intended to charge Respondent with failing to maintain an initial inventory, despite its reference to § 827(a)(3) instead of § 827(a)(1), and I further find that Respondent had adequate notice of this charge.

Most importantly, the CSA and DEA's regulations only require a practitioner like Respondent to maintain an initial inventory when he ''first engages in . . . dispensing controlled substances.'' 21 CFR 1304.11(b); 21 U.S.C. 827(a)(1). ''After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years''—that is, a ''biennial inventory.'' 21 CFR 1304.11(c); *accord* 21 U.S.C. 827(a)(1). Thus, the CSA and DEA's regulations only required Respondent to maintain an initial inventory when Respondent *first* engaged in dispensing controlled substances after obtaining his DEA registration, even if the initial inventory was zero when Respondent ''commence[d] business.'' 21 CFR 1304.11(b). After that, the CSA and DEA regulations required Respondent to

[25] As to Factor Three, there is no evidence that Respondent has been convicted of an offense under either federal or Arkansas law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d at 822. The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[26] ''The term 'dispense' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing . . . of a controlled substance.'' 21 U.S.C. 802(10).

maintain a biennial inventory. 21 U.S.C. 827(a)(1); 21 CFR 1304.11(c).

Here, the Government's first recordkeeping charge cannot be sustained as a matter of law because Respondent was not legally required to maintain an initial inventory as of the date of the alleged violation—*i.e.,* at the time of the July 9, 2014 inspection. It is undisputed that Respondent was dispensing controlled substances at least as far back as 2006 under his current DEA registration, and that Respondent has maintained, and timely renewed, his DEA registration ever since.

Although the CSA and DEA regulations required Respondent to maintain an initial inventory when he first commenced the business of dispensing controlled substances under his current DEA registration for two years, he was only required to maintain a biennial inventory thereafter. Yet the Government's first recordkeeping charge centers on whether Respondent maintained an initial inventory when he ordered controlled substances in December 2012, not on when Respondent first ''commence[d the] business'' of dispensing controlled substances under his current DEA registration. Thus, even if Respondent began dispensing controlled substances for the first time as late as 2006—the earliest dispensing activity under Respondent's current DEA registration reflected in the record—he had no legal obligation to maintain an initial inventory beyond 2008. Instead, as already noted, he was legally obligated to maintain a biennial inventory thereafter. However, the Government did not charge Respondent with failing to maintain an accurate biennial inventory in December 2012 or at the time of the July 2014 inspection. Accordingly, I do not sustain the Government's first recordkeeping charge.[27]

The Government's second recordkeeping charge alleged that Respondent failed to provide dispensing records to the DIs during the July 9, 2014 inspection. Both the CSA and DEA regulations require registrants to ''maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold . . . or otherwise disposed of by him.'' 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a). As found above, *supra,* the Government failed to establish by a preponderance of the evidence that Respondent failed to provide the DIs with the relevant dispensing logs during the inspection. Furthermore, I agree with the ALJ's recommended finding (and I so find) that the dispensing log that Respondent testified that he provided to the DIs (RX U) was sufficient to rebut the Government's allegation that he failed to maintain complete and accurate dispensing records in violation of 21 U.S.C. 827(a)(3), 842(a)(5) and 21 CFR 1304.21(a). *See* R.D., at 32–33. Thus, I do not sustain the Government's second recordkeeping charge.

For related reasons, I cannot sustain the Government's fifth recordkeeping charge that Respondent failed to maintain his inventory and dispensing records at his registered location and maintained them instead at Moore Clinical Trials. The CSA requires that registrants maintain ''[a] separate registration . . . at each principal place of business or professional practice where the applicant . . . dispenses controlled substances.'' 21 U.S.C. 822(e). ''In short, the requirements that a practitioner be registered at each principal place of professional practice where he dispenses controlled substances . . . [is one] of the fundamental features of the closed regulatory system created by the CSA.'' *Moore Clinical Trials,* 79 FR at 40155.

However, as found above, the Government has provided insufficient evidence for me to find by a preponderance of the evidence that Respondent, in fact, (1) maintained his dispensing records at Moore Clinical Trials and (2) failed to maintain inventory and dispensing records at his registered location.[28] *See supra.* Thus, I agree with the ALJ's recommendation that I find (and I do so find) that the Government failed to sustain the fifth recordkeeping charge. *See* R.D., at 36.

The Government's third recordkeeping charge alleged that Respondent failed to provide a January 2014 DEA 222 form during the inspection. DEA regulation 21 CFR 1305.17(a) requires the purchaser of controlled substances to ''retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.'' *See also* 21 CFR 1304.04(a) (requiring registrants to keep dispensing records and every inventory for at least two years). However, here too, I have already found that the Government's evidence is insufficient to support this charge. Specifically, I found *supra* that it is more likely than not that the purchaser's copy of the allegedly missing January 2014 DEA 222 form was, in fact, within Respondent's folder of DEA 222 forms that he presented to the DIs on the date of the onsite inspection. Thus, I do not sustain the Government's third recordkeeping charge.

The Government's remaining (fourth) recordkeeping charge alleged that Respondent failed to properly annotate two DEA–222 order forms (dated August 15, 2013 and June 24, 2014) in violation of 21 U.S.C. 842(a)(5) and 21 CFR 1305.13(b). The DEA 222 forms at issue in the fourth recordkeeping charge were suppliers' copies, and DEA regulations require suppliers to ''record on Copies 1 and 2 [of the DEA 222 form] the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser.'' 21 CFR 1305.13(b). Here, as already noted, Respondent admitted that he failed to properly annotate on both forms (1) the date when he shipped controlled substances back to FCS and (2) the amount shipped. Accordingly, I find that the Government sustained its fourth recordkeeping charge that Respondent failed to properly annotate two DEA 222 supplier's copy forms pursuant to 21 U.S.C. 842(a)(5) and 21 CFR 1305.13(b). These violations support a finding that Respondent's continued registration would be inconsistent with the public interest under Factors Two and Four.

Factor Five—Other Conduct Which May Threaten the Public Health and Safety

The Government argues that Respondent engaged in ''other conduct'' actionable under Factor Five because he violated the MOA.[29] Under the fifth

[27] In any event, as noted *supra,* I found that the Government failed to establish by a preponderance of the evidence that Respondent failed to provide the DIs with an inventory consistent with the CSA and DEA's regulations during the July 9, 2014 onsite inspection.

[28] The Government also alleged in its fifth recordkeeping charge that Respondent's inventory and dispensing records were not ''readily retrievable'' pursuant to 21 CFR 1304.04. Section 1304.04(g) requires registered individual practitioners like Respondent to keep ''records of controlled substances in the manner prescribed in paragraph (f) of this section.'' Section 1304.04(f), in turn, requires that ''records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.'' Here, the controlled substance used during the Quintiles study was oxycodone, a Schedule II controlled substance. 21 CFR 1308.12(b)(1)(xiii).

[29] The Government also argued that Respondent's alleged violations of the MOA should be considered under Factor 2. ALJ Ex. 20, at 19. In addition, the Agency has held that ''where an MOA term imposes the same requirements as a law or regulation, a violation of that term falls under Factor Four because it is also a violation of a duly enacted law or regulation.'' *Roberto Zayas, M.D.,* 82 FR 21410, 21422 n.26 (2017). To the extent that I have already addressed Respondent's alleged recordkeeping violations under Factors Two and Four, I will not consider them again under Factor Five because they would not then constitute ''other conduct'' under

public interest factor, the Agency considers ''[s]uch other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). The Agency has clarified that Congress' use of the word ''may'' in Factor Five means that it intended the Agency to consider conduct which creates a probable or possible (and not necessarily an actual) threat to public health and safety. *Mark P. Koch, D.O.,* 79 FR 18714, 18735 (2014) (collecting cases); *ChipRX, L.L.C., d/b/a City Center Pharmacy,* 82 FR 51433, 51438 n.10 (2017) (''Factor Five does not require that the Government prove an actual threat to public health or safety''). Thus, the Government is not required to establish that a specific violation of the MOA by Respondent created an actual threat to the health and safety of the public under Factor Five.

DEA has long held that a registrant's failure to comply with the terms of an MOA can constitute acts which render his registration inconsistent with the public interest. *Erwin E. Feldman, D.O.,* 76 FR 16835, 16838 (2011) (revoking practitioner's registration under Factors Two and Five for violating MOA) (internal citation omitted); *cf. Fredal Pharmacy,* 55 FR 53592, 53593 (1990) (revoking pharmacy's registration for violations of its MOA ''which threatens the public health and safety''). This is so even if the violation of the MOA does not establish a violation of the CSA or its implementing regulations. *Feldman,* 76 FR at 16838. In its Proposed Findings of Fact and Conclusions of Law, the Government argued that this case is similar to *OTC Distribution Company,* where the Agency revoked the registration of a distributor for ''its inability or unwillingness to fully comply with its recordkeeping and report obligations under the MOA.'' ALJ Ex. 20 at 20–21 (quoting *OTC Distribution Company,* 68 FR 70538, 70542 (2003)). The Government further argued that, ''[a]s in *OTC,* the Respondent here has demonstrated, over a period of years, an unwillingness or inability to follow DEA's recordkeeping requirements even after being placed under an MOA with strict monitoring requirements.'' ALJ Ex. 20 at 21.[30]

Indeed, the history of Respondent's recordkeeping violations (and other violations) directly led to the MOA that attempted to resolve them. As I already noted *supra,* the GS testified that DEA first became aware of Respondent as part of its 2011 investigation of his recordkeeping (and other) violations regarding the earlier NKRT–118 study he conducted with Moore Clinical Trials. Tr. 28–29. This 2011 investigation not only led to the 2011 Show Cause Order against Respondent; it also led to a separate 2011 Show Cause Order against Moore Clinical Trials. However, unlike Respondent, who resolved the Show Cause Order against him by entering into an MOA, the Order against Moore Clinical Trials resulted in a final published order. *Moore Clinical Trials, L.L.C.,* 79 FR 40145 (2014).

Most importantly, in *Moore Clinical Trials,* the Agency found that Respondent committed recordkeeping and other violations related to the NKRT–118 study that correspond to the terms of the MOA. For example, the Agency noted the ALJ's findings that Respondent's ''documents'' ''were deficient and that the order forms for Schedule II controlled substances (DEA–222) were lacking'' in connection with the NKRT–118 study. *Id.* at 40147 (internal quotations omitted). The Agency also noted the ALJ's finding that Respondent had improperly transported controlled substances to Moore Clinical Trials' location where he was not registered to dispense them in connection with that study. *Id.* The then-Administrator also found that Respondent's DEA 222 forms related to the NKRT–118 study did not properly indicate the date the drugs were received and the quantity received. *Id.* at 40151, 40156. The then-Administrator concluded that ''the record clearly establishes that Dr. Nichol violated both the separate registration provision and DEA recordkeeping requirements.'' *Id.* at 40155. The DEA therefore entered into the MOA (which expressly referenced the NKRT–118 study) with Respondent as an intermediary step to get Respondent into compliance and to address Respondent's recordkeeping and separate registration violations related to the NKRT–118 study described and found by the Agency in *Moore Clinical Trials.*[31]

Respondent agreed to meet the following seven conditions set forth in the MOA:

(1) Abide by all Federal, State and local statutes and regulations relating to controlled substances.

(2) Make and keep (and make available for inspection) records of all controlled substances that he prescribes, dispenses, and administers at his registered location pursuant to 21 CFR 1306.05(a) and 1304.21.

(3) Make and keep a legible log of all Schedule II–V controlled substances that he prescribed and provide that to DEA on a quarterly basis for three years.

(4) Retain his prescribing, administering and dispensing records at his registered location.

(5) Notify DEA if he will prescribe, dispense, or administer controlled substances at any location other than his registered location or the Springhill Surgery Center where he routinely administers drugs during a scheduled medical procedure.

(6) Order, receive, administer, and dispense controlled substances only at his registered location.

(7) Notify DEA in advance of commencing any drug study involving controlled substances additional to the NKTR–118 study.

GX 7, at 2–4. It is undisputed that Respondent did not violate the MOA's third and fifth conditions. *See* Tr. 92, 93, 117–19.

The Government argued that the same five alleged recordkeeping violations also violated the MOA's first, second, fourth, and sixth conditions.[32] *See* R.D.,

Factor Five. *See id.* at 21427 n.40. However, I will consider whether the proved recordkeeping violations already discussed are sufficient evidence to establish a violation of the MOA under Factor Five.

[30] In his Recommendation, the ALJ disagreed with the Government's characterization of Respondent's past recordkeeping conduct because ''the Respondent does not have a history of failing to keep the required records.'' R.D., at 39. However, as discussed more fully *infra,* Respondent's history of recordkeeping violations is already documented in published Agency precedent. *See, e.g., Moore Clinical Trials,* 79 FR at 40151, 40155.

[31] *See supra* footnote 12.

[32] During the hearing, the Government alleged that Respondent violated the MOA's seventh condition for failing to notify DEA in advance of commencing the Quintiles Study set forth in the CTA. *See* Tr. 93–94, 119–21, 181–82; GX 7, at 3 (''if [Respondent] is asked to participate in additional drug studies involving controlled substances, he will notify DEA in advance of commencing the study''). Although the ALJ questioned whether the Government had provided sufficient notice to Respondent that the Government would rely on a violation of this MOA condition, the ALJ proceeded to analyze the issue and recommended that I find that Respondent did not violate this MOA condition. *See* R.D., at 10 n.11.

I agree (and I do so find) that Respondent did not violate this MOA condition for the following reasons. Although the GS testified that ''[i]n DEA's mind'' the study commenced when Respondent placed his first order for controlled substances related to the study on December 3, 2012 (Tr. 93–94, 121), the Government has identified no provision of the CSA, DEA's regulations or Agency precedent supporting this statement. Moreover, the MOA did not define what constituted ''commencing the study.'' Absent additional evidence of the parties' intent when entering into the MOA, I find that the Quintiles Study commenced when Respondent first dispensed controlled substances. If, hypothetically, Respondent had ordered and received controlled substances for the Quintiles Study, enrolled study patients for it, but never ultimately dispensed the controlled substances to the enrolled study patients, then the study still would not have commenced.

Here, on December 31, 2012, Respondent notified the GS (by letter from his attorney) that he was participating in the study. As noted *supra,* I found that Respondent began enrolling patients for the Quintiles study in January 2013, and that he first dispensed controlled substances to study patients

Continued

at 40; Tr. 91–93, 178–79. I discussed all of the recordkeeping allegations in my analysis of Factors Two and Four, wherein I concluded that the Government proved only one recordkeeping violation by a preponderance of the evidence—Respondent's failure to properly annotate two supplier DEA 222 forms. With respect to Factor Five, I also find that these two recordkeeping failures violated the MOA's first condition that Respondent abide by all Federal regulations because (as already noted) failing to properly annotate a supplier's DEA 222 form violates 21 CFR 1305.13(b). Thus, I agree with the ALJ's recommendation that I find (and I do find) that Respondent violated the MOA based on his failure to properly annotate two supplier DEA 222 forms. R.D., at 40.

I also agree with the ALJ's recommendation that the analysis of whether the MOA violation was sufficient to establish a violation of Factor Five does not stop here. Under the MOA, Respondent agreed that ''any violations of the Agreement may result in the initiation of proceedings to revoke or immediately suspend and revoke his DEA Certificate of Registration.'' GX 7, at 3. However, DEA agreed that it would ''not seek to revoke Dr. Nichol's DEA registration . . . unless Dr. Nichol *substantially violates* this Agreement or unless [he] commits additional acts that constitute grounds under 21 U.S.C. 823(f) and 824(a).'' *Id.* at 3–4 (emphasis added). In other words, DEA agreed not to seek to revoke Respondent's DEA registration unless he ''substantially violates'' the MOA. Here, I agree with the ALJ's recommendation that I find (and I do find) that Respondent's failure to properly complete two supplier DEA 222 forms alone is insufficient to establish that Respondent ''substantially violate[d]'' the MOA. R.D., at 40 (''I find that the violation of the 2012 MOA, of improperly completing the two supplier 222 Forms, standing along is not a *significant* violation of the 2012 MOA itself.'') (emphasis in original). Accordingly, I find that Respondent's non-substantial violation of the MOA nominally supports a finding that Respondent's continued registration would be inconsistent with the public interest under Factor Five.

Having considered all the factors above, I hold that the Government has established its *prima facie* case showing that Respondent's registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

Sanction

Where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '' 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.' ''thnsp;'' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination).

An applicant's acceptance of responsibility must be unequivocal. *See Alexander,* 82 FR at 49728 (collecting cases). Also, an applicant's candor during both an investigation and the hearing itself is an important factor to be considered in determining both whether he has accepted responsibility as well as the appropriate sanction. *Michael S. Moore,* 76 FR 45867, 45868 (2011); *Robert F. Hunt, D.O.,* 75 FR 49995, 50004 (2010); *see also Jeri Hassman,* 75 FR 8194, 8236 (2010) (quoting *Hoxie,* 419 F.3d at 483 (6th Cir. 2005) (''Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest[.]'')), *pet. for rev. denied,* 515 Fed. Appx. 667 (9th Cir. 2013).

While a registrant must accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct in order to establish that his registration would be consistent with the public interest, DEA has repeatedly held that these are not the only factors that are relevant in determining the appropriate disposition of the matter. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Volkman,* 73 FR at 30644; *see also Battershell,* 76 FR at 44369 (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

After considering (1) Respondent's unlawful pre-signing of prescriptions that his unlicensed staff members then issued to patients without further consulting Respondent and (2) Respondent's failure to properly annotate two supplier DEA 222 forms, the ALJ recommended a sanction of imposing restrictions on Respondent's DEA registration based solely on the sustained recordkeeping violation. R.D., at 41–46. He did not recommend that I impose a sanction of either suspension or revocation. *See id.* As set forth more fully below, I disagree with the ALJ's recommended sanction.

Pre-Signing Prescription Misconduct

With respect to Respondent's pre-signing of prescriptions, the ALJ recommended that I do not rely on this misconduct as a basis for any sanction whatsoever. *Id.* at 42–43 (recommending against relying upon ''Respondent's pre-signing of prescriptions as a basis for revocation or sanction''). The ALJ identified five mitigating actions or factors related to Respondent's unlawful pre-signing of prescriptions to support his Recommendation: (1) Respondent ''obtained high quality prescription pads that make reproduction difficult, and he writes all of his prescriptions by hand'' ''[t]o prevent forgery of his prescriptions;'' (2) ''his prescription pads produce a duplicate copy, which

on February 18, 2013. Thus, I find that Respondent did not violate the MOA's seventh condition because he notified DEA that he was asked to participate in the Quintiles Study on December 31, 2012, in advance of commencing the study on February 18, 2013.

the Respondent keeps in the medical file'' ''[t]o increase the likelihood that he can identify his prescriptions;'' (3) he ''began providing the DEA with copies of his prescriptions, as required by the MOA;'' (4) ''the DEA has renewed his registration multiple times since his medical license was restored;'' and (5) he ''had not been cited for any prescription violations in the past ten years'' and ''the amount of time that has passed since.'' *Id.* Based on these five factors and the fact that Respondent had accepted responsibility for unlawfully pre-signing prescriptions, the ALJ found that Respondent had taken sufficient ''mitigating actions'' and ''efforts at remediation'' that this unlawful conduct should not be the basis for any sanction whatsoever. *Id.* at 42–43.

Although I agree with the ALJ that Respondent accepted responsibility for unlawfully pre-signing prescriptions, I disagree that there exists sufficient mitigating evidence to warrant no sanction at all for Respondent's pre-signing of prescriptions. For example, Respondent's decision to handwrite his prescriptions on ''high quality prescription pads'' that ''produce a duplicate copy'' is an admirable effort to prevent prescription forgery. However, the ALJ failed to explain how these actions intended to prevent forgery of Respondent's signature on a prescription (the ALJ's first two factors) would remediate or prevent Respondent from again pre-signing prescriptions with his authentic signature in the future. It is manifest that a practitioner, whether he or she pre-signs a ''high quality'' or a ''low-quality'' prescription pad, is still the one signing the prescription in a case like this one involving unlawful pre-signing of prescriptions.

Here, there is no allegation that anyone forged Respondent's signature on prescriptions. It is Respondent's pre-signing of his own signature on prescriptions, not forgery, that is the basis for Respondent's unlawful prescription conduct at issue in this case. Thus, I find Respondent's efforts to prevent forgery would not and do not mitigate Respondent's unlawful pre-signing of prescriptions.

The ALJ's reliance on Respondent providing DEA with copies of his prescriptions as mitigating evidence (the ALJ's third mitigating factor) is similarly unavailing. As the ALJ concedes, Respondent only provided copies of his prescriptions to DEA because the MOA required him to do so. *See* R.D., at 42. I find that the fact that Respondent complied with this MOA requirement does not constitute sufficient mitigating evidence regarding his unlawful pre-signing of prescriptions to warrant no sanction for his unlawful conduct.

In addition, the ALJ's reliance on DEA's renewals of Respondent's registration in 2010 and 2013 after the ASMB restored Respondent's state license in 2007 as a mitigating factor is misplaced because it overlooks the chronology of DEA's investigation of Respondent. The GS testified that DEA first became aware of Respondent as part of its 2011 investigation of his violations regarding the NKRT–118 study he conducted with Moore Clinical Trials. DEA's 2011 investigation led to the 2011 Show Cause Order against Respondent. The 2011 Order included DEA's allegation that Respondent unlawfully pre-signed prescriptions and that the ASMB suspended him in 2006 for this conduct. Prior to 2011, there is no evidence in the record that DEA was aware of Respondent's misconduct—thereby making any renewals of Respondent's DEA registration prior to 2011 (including the 2010 renewal) irrelevant.

Moreover, Respondent and DEA attempted to resolve the 2011 Show Cause Order's allegations by entering into the 2012 MOA. Once Respondent's DEA registration came up for renewal in 2013, DEA renewed it because at that time DEA believed Respondent was complying with the CSA, DEA regulations, and the 2012 MOA. DEA did not learn that Respondent had violated the 2012 MOA until after DEA's July 2014 onsite inspection of Respondent's registered address. As a result of Respondent's violation of the MOA, DEA was entitled to issue a new Show Cause Order against Respondent, which it issued on March 14, 2016, that included the allegations set forth in the earlier 2011 Show Cause Order. Thus, I find that the fact that DEA renewed Respondent's registration in 2010 and 2013 does not constitute evidence mitigating Respondent's unlawful pre-signing of prescriptions.

However, I do agree with the ALJ that the final factor he identified constitutes mitigating evidence. Specifically, I find that the amount of time that has passed since Respondent unlawfully pre-signed prescriptions is mitigating evidence because he has not repeated this particular misconduct since 2006. *Koch,* 79 FR at 18736 (''time is certainly an appropriate factor to be considered'' where '' 'during that time [the] Respondent has learned from his past mistakes' '') (quoting *Leonardo V. Lopez, M.D.,* 54 FR 36915, 36915 (1989)). And it is this mitigating evidence, along with the fact that Respondent accepting responsibility, that I consider in imposing a sanction.

The Agency has long held that pre-signing prescriptions ''would be inconsistent with the public interest'' under the CSA because such conduct ''create[s] a substantial risk that the drugs would be diverted and abused.'' *E.g., Singh,* 81 FR at 8248, 8249. And as I noted earlier, Respondent's pre-signing of prescriptions constituted a serious violation of the CSA—not only because it created a substantial risk that the drugs would be diverted and abused but also because Respondent gave the pre-signed prescription forms to office personnel who lacked the authority to lawfully prescribe controlled substances under federal or state law. *See* 21 CFR 1306.03(a); *see also Krishna-Iyer,* 71 FR at 52159.

Unlike the ALJ, I find that the Agency's interest in deterring this misconduct in the future both on the part of Respondent as well as the community of registrants supports a sanction. The ASMB imposed a six-month suspension of Respondent's state license for unlawfully pre-signing prescriptions. Although there is precedent in the context of pre-signing prescriptions for imposing a sanction to match the ASMB's sanction, *cf. Walter S. Gresham, M.D.,* 57 FR 44213, 44214–15 (1992) (imposing same sanction against respondent who unlawfully pre-signed prescriptions as Georgia imposed), I believe Respondent's acceptance of responsibility for unlawfully pre-signing prescriptions, and the lack of any evidence that Respondent has engaged in this same misconduct since 2006, warrants a lesser sanction than that imposed by the ASMB. Accordingly, I find that suspending Respondent's DEA registration for one month is what is necessary to protect the public interest.

As for the issue of specific deterrence, a suspension of Respondent's registration for one month is not a bar on his practice, much less a permanent bar. And regarding general deterrence, those members of the regulated community who contemplate unlawfully pre-signing prescriptions need to know that the Agency takes such misconduct—and the grave risk of diversion that it creates—seriously and that there will be concomitantly serious consequences if they choose to engage in such misconduct. This interest would be compelling even if it was not the case that the nation faces an epidemic of opioid abuse.

Recordkeeping Misconduct

With respect to the recordkeeping violations, the ALJ stated that this ''violation [of DEA's regulations] is significant because without knowing the

quantity of controlled substances shipped back to Fisher, it is impossible to conduct an accurate audit of the Respondent's controlled substances using his records, and it is his records that are the subject of these proceedings.'' R.D., at 43. The ALJ recommended that I find that ''Respondent's recordkeeping violation to be egregious. It was egregious because it prevented the DEA from being able to use the Respondent's own records to conduct an accurate audit of the controlled substances for which the Respondent was accountable while he served as the principal investigator in the controlled drug study.'' *Id.* at 45.

Nevertheless, the ALJ found that Respondent can be entrusted with a DEA registration and recommended that I only place restrictions upon Respondent's registration, rather than revoking or suspending his registration. *Id.* at 42–43, 45–46. Although the ALJ acknowledged that Respondent ''has not taken any specific remedial steps to address his improper completion of supplier 222 forms,'' the ALJ reasoned that Respondent ''now knows how to properly complete a 222 form when he is a supplier, and he has stated that in the future he will fill out the form correctly.'' *Id.* at 43 (citing Tr. 257). In short, the ALJ believed that Respondent's ''egregious'' and ''significant'' recordkeeping violations nonetheless warranted only the imposition of restrictions on (and not suspension or revocation of) Respondent's DEA registration because it was the first time Respondent had committed recordkeeping violations.

In contrast, the Government argued in its Proposed Findings that Respondent ''has demonstrated, over a period of years, an unwillingness or inability to follow DEA's recordkeeping requirements.'' ALJ Ex. 20, at 21. The Government further argued that Respondent's ''recordkeeping violations that prompted DEA's 2011 Order to Show Cause, which was settled with the 2012 MOA, and his continued violations of these same recordkeeping requirements,'' ''warranted'' ''revocation.'' *Id.* at 19.

In his Recommendation, the ALJ disagreed because he believed that ''the Respondent does not have a history of failing to keep the required records.'' R.D., at 39. The ALJ reached this conclusion because ''Respondent entered into an MOA with the DEA'' ''[t]o resolve the September 2011 [Show Cause Order],'' and ''[n]owhere in the 2011 [Show Cause Order] are recordkeeping violations.'' *Id.* Elsewhere, the ALJ contested the Government's characterization of Respondent's history of recordkeeping violations:

> The Government's arguments are puzzling in this regard because the Respondent was not cited for any recordkeeping violations in the 2011 [Show Cause Order], and in its post-hearing brief, the Government does not cite to any recordkeeping violations that occurred prior to the current allegations. . . .
>
> Respondent does not have a *history* of failing to keep the required records. The Government's attempt to paint Respondent's current violations as a continuation of the DEA's concerns that prompted the issuance of the 2011 OSC is disingenuous at best! . . .
>
> Here, . . . there is no evidence that the Respondent has a *history* of improperly completing 222 Forms, either as a purchaser or as a supplier.

Id. at 44 (emphasis in original).

It is unclear why the ALJ was unaware of Respondent's history of recordkeeping violations, including a history of improperly completing DEA 222 Forms, in light of *Moore Clinical Trials.* As I noted earlier, Respondent's history of recordkeeping (and other) violations was referenced in the record. In its Proposed Findings filed post-hearing, the Government referenced the GS's testimony that she first became aware of Respondent after receiving an application for a DEA registration from Moore Clinical Trials, and that this application led to a DEA investigation of both Moore Clinical Trials and Respondent in 2011 that found recordkeeping violations. *See* ALJ Ex. 20, at 4.

The Government also referenced the GS's testimony that Moore Clinical Trial's DEA application was denied. *Id.* The ALJ even acknowledged this denial in his Recommendation. R.D., at 3. Although the Government could have better assisted the ALJ by directing him to a case citation to the Agency's decision, it does not change the fact that *Moore Clinical Trials*—like all other final agency actions issued by my office—was an Agency decision published in the **Federal Register**. As such, *Moore Clinical Trials* compels a finding that Respondent has a history of recordkeeping violations.

As already noted, the Agency found in *Moore Clinical Trials* that Respondent committed both separate registration and recordkeeping violations in connection with the NKRT–118 study Respondent conducted with Moore Clinical Trials that, not coincidentally, correspond to the terms of the MOA. *Moore Clinical Trials* even documented Respondent's history of recordkeeping violations in connection with DEA 222 forms. For example, the Agency noted the ALJ's findings that Respondent's ''documents'' ''were deficient and that the order forms for Schedule II controlled substances (DEA–222) were lacking'' in connection with the NKRT–118 study. *Moore Clinical Trials,* 79 FR at 40147 (internal quotations omitted). The then-Administrator also found that Respondent's DEA 222 forms related to the NKRT–118 study did not properly indicate the date the drugs were received and the quantity received. *Id.* at 40151, 40156. Most significantly, this type of recordkeeping violation involving DEA 222 forms—failure to properly record the date and quantity of controlled substances—is the same type of recordkeeping violation that Respondent committed in this case. Thus, contrary to the ALJ's conclusion, Respondent in fact ''has a *history* of improperly completing 222 Forms.'' *See* R.D., at 44.

The then-Administrator concluded in *Moore Clinical Trials* that ''the record clearly establishes that Dr. Nichol violated both the separate registration provision and DEA recordkeeping requirements.'' 79 FR at 40155. The DEA therefore entered into the MOA (which expressly referenced the NKRT–118 study) with Respondent as an intermediary step to get Respondent into compliance and to address Respondent's recordkeeping and separate registration violations related to the NKRT–118 study described and found by the Agency in *Moore Clinical Trials.*

The ALJ's finding that Respondent's recordkeeping violation in this case is not ''a minor oversight'' but an ''egregious'' and ''significant'' violation, combined with Respondent's history of recordkeeping violations, requires a stronger sanction than what the ALJ recommended. In that vein, I find that the Agency's interest in deterring this misconduct in the future both on the part of Respondent as well as the community of registrants supports imposing a two-part sanction. Although the ALJ's recommended restrictions on Respondent's registration could be a sufficient deterrent for a registrant who lacked a history of recordkeeping violations, that is not this case. Here, the Agency already attempted to address Respondent's prior recordkeeping violations by imposing the restrictions (rather than suspending or revoking his DEA registration) set forth in the MOA. To simply impose more restrictions after Respondent again committed recordkeeping violations would be no sanction at all in this case. *See Mark De La Lama, P.A.,* 76 FR 20011, 20020 (2011) (''granting Respondent's application subject to the restrictions proposed by the ALJ, which do no more than replicate the conditions imposed

by the MOA, amounts to no sanction at all. In short, adopting the ALJ's proposed sanction would send the wrong message to both Respondent . . . as well as other applicants/registrants''). For this reason, I find that suspending Respondent's DEA registration for one month (concurrently with the sanction I imposed for Respondent's unlawful pre-signing of prescriptions) is necessary to protect the public interest. In addition, I impose the same restrictions to Respondent's registration as proposed by the ALJ, and I direct that these restrictions—set forth *infra*—are set to begin at the conclusion of Respondent's one-month suspension.

The Agency's interests in both specific and general deterrence support this two-part sanction. As for the Agency's interest in specific deterrence, and as already noted, the one-month suspension of his DEA registration is not a bar on his practice, much less a permanent bar. In addition, the restrictions that I impose in this Decision and Order will hopefully deter Respondent from engaging in future misconduct. As for the Agency's interest in general deterrence, not only does the Agency have an obvious and manifest interest in deterring violations of the CSA and DEA's regulations by members of the regulated community, the Agency also has a manifest interest in ensuring that those members to whom it extends the forbearance of an MOA will comply with the terms of those agreements. *Roberto Zayas, M.D.,* 82 FR 21410, 21430 (2017).

I therefore conclude that the suspension of Respondent's DEA registration for one month, in addition to the imposition of the ALJ's recommended restrictions at the conclusion of Respondent's one-month suspension, are necessary to protect the public interest.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. BN4578057, issued to Brian Thomas Nichol, M.D., be, and it hereby is, suspended for one month. At the conclusion of this one-month suspension, I impose the following restrictions on Brian Thomas Nichol's DEA Certificate of Registration No. BN4578057:

1. That he may not participate in any drug studies in which he is required to order, maintain, store, or dispense controlled substances for a period of four years.

2. That he may not order, maintain, store, or dispense any controlled substances at his registered location for a period of four years.

3. That restrictions one and two, above, will not be lifted, even after four years, until the Respondent has completed a course in controlled substance recordkeeping, a course in controlled substance storage, and a course in the administration of controlled substances, and provides the DEA with evidence of completion of these courses. These courses may not be used to meet any continuing medical education requirement.

4. That prior to renewal of the Respondent's DEA registration, he sign a document consenting to inspections by DEA personnel of his medical practice without the need for DEA personnel to obtain an administrative inspection warrant prior to conducting an inspection. By the terms contained in the consent form, the consent shall be valid for four years from the date his current renewal application for a DEA registration is approved. This consent form is to be delivered to the Respondent's local DEA Field Office.

5. That prior to renewal of the Respondent's DEA registration, he sign a document consenting to the conditions set forth in Paragraphs one and two above and acknowledging his understanding that his failure to comply with the terms of those conditions will constitute an independent basis for administrative enforcement proceedings by the DEA. This consent and acknowledgement document shall be delivered to the Respondent's local DEA Field Office.

This Order is effective October 19, 2018.

Dated: September 5, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018–20383 Filed 9–18–18; 8:45 am]

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DEPARTMENT OF JUSTICE

[OMB Number 1121–0065]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection: National Corrections Reporting Program

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, 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 30 days until October 19, 2018.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Elizabeth Ann Carson, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *elizabeth.carson@usdoj.gov*; telephone: 202/616.3496).

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 Bureau of Justice Statistics, 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:* National Corrections Reporting Program. The collection includes the following parts: Prisoner Admission Report, Prisoner Release Report, Prisoners in Custody at Year-end Report, Post-Custody Community Supervision Entry Report, Post-Custody Community Supervision Exit Report.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number(s): NCRP–1A, NCRP–1B, NCRP–1D, NCRP–1E, NCRP–1F. The applicable component within the Department of Justice is the Bureau of Justice Statistics (Corrections Unit), in the Office of Justice Programs.

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