registration). Respondent made no argument that convinces me to ignore the statutorily mandated show cause order process or to limit the Agency's enforcement discretion and prerogatives by addressing her modification request based merely on a chronological sequence of events. 21 U.S.C. 823(c). The *Wedgewood Village Pharmacy* case Respondent cited explicitly articulates this process and DEA's enforcement discretion and prerogatives when it states that, ''[w]hen an application for modification of an existing practitioner's registration is received by DEA, and before an approval may be given, DEA must determine whether there is any need to conduct a further investigative inquiry.'' *Wedgewood Village Pharmacy, Inc.* v. *Ashcroft,* 293 F. Supp. 2d, 462, 467 (D.N.J. 2003). Here, Respondent's loss of APRN authority in Wisconsin was reason ''to conduct a further investigative inquiry.'' *Id.* Similarly, I reject Respondent's alternative argument that, even if I revoke her registration, ''then the application for modification should continue and be granted.'' Resp Opposition, at 4.

Respondent suggested that, even if I revoke her registration, her requested modification should continue and either be granted or be the subject of an order to show cause and a demonstration that ''granting the application is not in the public interest.'' *Id.* She did not, however, address how to implement the regulatory requirement of maintaining the modification with the ''old certificate'' until its expiration when the old certificate already expired due to revocation. 21 CFR 1301.51(c).

Respondent argued that the statement in 21 CFR 1301.51(c), that a ''request for modification shall be handled in the same manner as an application for registration,'' means that the Agency is ''required to register an applicant, unless it determines that the applicant's registration would be inconsistent with the public interest.'' Resp Opposition, at 2 (citing 21 U.S.C. 823). The further support Respondent provided for her argument is the *Wedgewood Village Pharmacy* federal district court decision. *Id.* (citing *Wedgewood Village Pharmacy, Inc.* v. *Ashcroft,* 293 F. Supp. 2d at 469).

Respondent's arguments ignore the entirety of 21 U.S.C. 823. That statutory provision premises a public interest analysis, in the first instance, on an applicant's existing authorization ''to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Respondent admitted that she lacks authority to dispense controlled substances in Wisconsin. Accordingly, if she were to apply for a registration in Wisconsin, the public interest portion of section 823 would not be reached due to her failure to meet the threshold eligibility requirements for a registration. Thus, Respondent's reliance on the district court's decision in *Wedgewood Village Pharmacy* is unavailing. Although Wedgewood Village Pharmacy retained its state authorization to dispense controlled substances during its litigation and, as such, its eligibility for a registration, Respondent has not.

Respondent did not address past Agency decisions concerning the precise portion of 21 CFR 1301.51(c) that she cited. Those decisions starkly show the weakness of Respondent's position. Most recently, my predecessor noted that this portion of the regulation ''does not mean that a modification request is the same as an application for a new registration in every respect.'' *Parth S. Bharill, M.D.,* 84 FR 39014 n.2 (2019) (citing *Craig S. Morris, D.D.S.,* 83 FR 36966, 36967 (2018)). In *Craig S. Morris, D.D.S.,* my predecessor had noted that ''[u]nlike a timely renewal application, a request to modify the registration address of an existing registration . . . does not remain pending after the registration expires, nor does it operate to extend when that registration expires.'' 83 FR at 36967.

Respondent also cited the Administrative Procedure Act (hereinafter, APA) as ''clearly indicat[ing] a governmental policy, by which agencies must consider a timely application before terminating a current registration,'' and 21 CFR 1301.36(i) for the proposition that ''as long as a current DEA registrant submits his renewal application in a timely manner, an Order to Show Cause in administrative revocation proceedings will not void the registration.'' Resp Opposition, at 2 (citing 5 U.S.C. 558 and *Wedgewood Village Pharmacy,* 293 F. Supp. 2d at 467). Both of these arguments fail because both section 558 of the APA and section 1301.36(i) of DEA's regulations concern applications for reregistration (renewal) or for a new registration. 5 U.S.C. 558 (''When the licensee has made timely and sufficient application for a renewal or a new license . . .''); 21 CFR 1301.36(i) (''In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration . . .'').

Respondent's request under 21 CFR 1301.51(c) was not to renew or obtain a new registration. Her request was ''for modification of her DEA registration, to change the address of her registration'' from Wisconsin to Florida. Resp Opposition, at 1. As discussed above, the regulations are clear that the request to modify is not an extension of an existing registration, but shall be handled in the same manner as an application. *See Cleveland J. Enmon, Jr. M.D.,* 77 FR 57,116, 57,125 (2012) (''[W]hile the address change request is pending with the DEA, the registrant is not authorized to handle controlled substances at the new location until the DEA approves the modification.'').

Accordingly, I will order that Respondent's DEA registration in Wisconsin be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MH1088182 issued to Lisa Hofschulz, N.P. This Order is effective January 11, 2021.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–27239 Filed 12–10–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–13]

George Pursley, M.D.; Denial of Application

I. Introduction

On December 1, 2017, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to George Pursley, M.D. (hereinafter, Applicant), of Augusta, Georgia. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposed the denial of Applicant's application for a DEA certificate of registration on the ground that his registration ''would be inconsistent with the public interest,'' citing 21 U.S.C. 823(f). *Id.*

The substantive grounds for the proceeding, as more specifically alleged in the OSC, are that Applicant unlawfully pre-signed and pre-printed prescriptions, committed violations of applicable federal and state recordkeeping requirements, unlawfully prescribed controlled substances, and, citing 21 U.S.C. 823(f)(5), did not exhibit candor during DEA's investigation. *Id.* at 2–8.

The OSC notified Applicant of his right to request a hearing on the

allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 9 (citing 21 CFR 1301.43). Applicant timely requested a hearing by letter dated January 3, 2018. ALJX 3 (Order for Prehearing Statements dated January 10, 2018), at 1 (interpreting ALJX 2 (Request for Hearing)).

The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge (hereinafter, ALJ) Mark M. Dowd. The parties agreed to nine stipulations.[1] ALJX 8 (Prehearing Ruling dated February 12, 2018), at 1.

The hearing in this matter spanned four days and took place in Augusta, Georgia. The Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD) is dated August 20, 2018. Both parties filed exceptions to the RD. Transmittal Letter, at 1. With his exceptions, Applicant filed a Motion for Leave to Supplement Evidence Post-Hearing. The Government filed an opposition to Applicant's Motion on September 12, 2018. *Id.* The ALJ denied Applicant's Motion on September 14, 2018.

Having considered the record in its entirety, I find that it establishes, by substantial evidence, that Applicant violated controlled substance recordkeeping requirements and unlawfully prescribed controlled substances. I disagree with the RD that it is in the public interest for Applicant to be granted a DEA registration. I find that Applicant's acceptance of responsibility was insufficient and that, even if it were sufficient, Applicant did not offer adequate remedial measures. Further, for the reasons stated in his Order, I agree with the ALJ's denial of Applicant's Motions for Leave to Supplement Evidence Post-Hearing.

Accordingly, I conclude that Applicant's application for a DEA registration should be denied. I make the following findings.

II. Georgia Physicians' Standard of Care

According to the Controlled Substances Act (hereinafter, CSA), ''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute, . . . dispense, or possess with intent to . . . distribute[ ] or dispense, a controlled substance.'' 21 U.S.C. 841(a)(1). The CSA's implementing regulations state, among other things, that a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

Applicant's registration application is for his medical practice in Georgia. As such, I also evaluate the record evidence according to the applicable laws and standard of care in Georgia.[2] The Government offered two exhibits about the standard of care in Georgia. Applicant did not object to the admission of either exhibit.[3]

The Government offered Georgia Composite Medical Board Rule 360–3–.06, entitled ''Pain Management.'' GX 4 (hereinafter, GA Pain Management Rule). The GA Pain Management Rule initially notes that section 43–34–8 of Georgia's statutes authorizes the Georgia Composite Medical Board (hereinafter, GCMB) to discipline licensees for unprofessional conduct, ''which includes conduct below the minimum standards of practice.''[4] GX 4, at 1 (360–3–.06(2)); *see also* transcript page (hereinafter, Tr.) 185 (the Government's expert, Dr. Kaufman, testifying that these standards apply to all individuals holding a medical license). With respect to prescribing controlled substances to treat pain and chronic pain, the GA Pain Management Rule states, ''Physicians cannot delegate the dispensing of controlled substances to an unlicensed person.'' GX 4, at 1 (360–3–.06(2)(a)). When ''initially prescribing'' a controlled substance to treat pain or chronic pain, ''a physician shall have a medical history of the patient, a physical examination of the patient shall have been conducted, and informed consent shall have been obtained.'' *Id.* (360–3–.06(2)(c)); *see also* Tr. 195–201 (testimony of Dr. Kaufman discussing the applicable standard of care in Georgia). The GA Pain Management Rule addresses such a non-terminal patient's prior diagnostic records in significant detail: ''[T]he physician shall obtain or make a diligent effort to obtain any prior diagnostic records relative to the condition for which the controlled substances are being prescribed and shall obtain or make a diligent effort to obtain any prior pain treatment records.'' GX 4, at 1 (360–3–.06(2)(d)). The physician ''shall'' maintain the prior treating physician's records ''for a period of at least ten . . . years.'' *Id.* If the physician, after trying diligently, is not able to obtain prior diagnostic records, the physician ''must document the efforts made to obtain the records'' and ''must order appropriate tests to document the condition requiring treatment for pain or chronic pain.'' *Id.* at 1–2.

According to the GA Pain Management Rule, when a ''physician determines that a patient for whom he is prescribing controlled scheduled substances is abusing the medication, then the physician shall make an appropriate referral for treatment for substance abuse.'' *Id.* at 2 (360–3–.06(2)(e)). For patients being treated for chronic pain with a schedule II or III controlled substance for ninety or more days, the physician ''must have a written treatment agreement with the patient and shall require the patient to have a clinical visit at least once every three . . . months to evaluate the patient's response to treatment, compliance with the therapeutic regimen through monitoring appropriate for that patient, and any new condition.'' *Id.* (360–3–.06(f)). Physicians are explicitly charged with ''respond[ing] to any abnormal result of any monitoring'' and told to ''record

[1] ''1) Prior to and on August 11, 2015, [Applicant] maintained Schedule II–V controlled substances at his office of 1219 West Wheeler Parkway, Augusta, GA 30909.

''(2) Three hundred sixteen pre-signed prescriptions were seized from [Applicant's] office on August 11, 2015.

''(3) On August 11, 2015, DEA investigators seized [Applicant's] patient sign-in list for August 6–7, 2015.

''(4) On August 11, 2015, DEA seized pre-printed, unsigned prescriptions dated August 11, 2015 from [Applicant's] office.

''(5) [Applicant] no longer works at the location listed on his application for a DEA [registration], 1219 West Wheeler Parkway, Augusta, GA 30909.

''(6) [Applicant] has not filed any materially falsified applications.

''(7) [Applicant] has not been convicted of a felony relating to a controlled substance or a List I chemical.

''(8) [Applicant] has not had his state license or registration suspended, revoked, or denied despite full disclosure to all entities and boards of the DEA investigation including, but not limited to [the Centers for Medicare and Medicaid Services (Department of Health and Human Services)], the Georgia Medical Composite Board, and the South Carolina Board of Medical Examiners.

''(9) [Applicant] has not been excluded from participation in a Medicaid or Medicare program.''

[2] *See Gonzales* v. *Oregon,* 546 U.S. 243, 269–71 (2006).

[3] Applicant did not offer any exhibit purporting to address or memorialize the Georgia standard of care.

[4] According to section 43–34–8, unprofessional conduct ''need not have resulted in actual injury to any person'' and includes ''any departure from, or failure to conform to, the minimum standards of acceptable and prevailing medical practice and shall also include . . . the prescribing or use of drugs, treatment, or diagnostic procedures which are detrimental to the patient as determined by . . . rule of the board.'' Ga. Code Ann. § 43–34–8(a)(7) (West, Westlaw: Effective January 1, 2013, to May 8, 2017). This provision of the Georgia Code also defines unprofessional conduct as failure ''to maintain appropriate medical or other records as required by board rule.'' *Id.* at § 43–34–8(a)(19).

. . . [such response] in the patient's record.'' [5] *Id.*

While the GCMB does not have a ''magic formula for determining the dosage and duration of administration for any drug,'' it ''does have the expectation that physicians will create a record that shows evaluation of every patient receiving a controlled substance prescription.'' *Id.* The need for record documentation appears throughout the Ten Steps. The evaluation record that the GCMB expects is to show (1) ''[p]roper indication for the use of drug or other therapy;'' (2) ''[m]onitoring of the patient where necessary;'' (3) ''[t]he patient's response to therapy on follow-up visits;'' (4) [a]ll rationale for continuing or modifying the therapy;'' (5) ''[d]iscussion of risks/benefits;'' (6) ''[p]eriodic medical record review;'' and (7) ''[p]rescription records.'' *Id.* at 2.

According to the Ten Steps, a ''medical history and physical examination must be obtained, evaluated, and documented in the medical records.'' The medical record documentation ''should'' address the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse.'' *Id.* It also ''should document the presence of one or more recognized medical indications for the use of a controlled substance.'' *Id.* The ''workup'' is to be ''sufficient to support a diagnosis including all necessary tests, history and physical examination.'' *Id.* In sum, the ''medical record will need to document sufficient and appropriate H&P and diagnostic testing to support the diagnosis necessitating the use of controlled substances.'' *Id.*

Second, the Ten Steps calls for creation of a treatment plan, including the use of appropriate non-controlled drugs, and consideration of referrals to appropriate specialists. *Id.* The treatment plan is to ''state objectives that will be used to determine treatment success . . . and should indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* at 3.

Third, the Ten Steps calls for a determination, through trial or a documented history and physical, that non-controlled drugs are not appropriate or effective for the patient's condition. *Id.* Further, when controlled substances are used as a ''first-line therapy,'' ''it is important to document the rationale when used as such.'' *Id.*

According to the fourth step, the physician is to ''[r]eview the patient's prescription records and discuss the patient's chemical history before prescribing a controlled drug.'' *Id.*

Fifth, the physician is to ''discuss the risks and benefits of the use of controlled substances with the patient,'' taking the ''time to explain the relative risks and benefits of the drug,'' and ''record[ing] in the chart the fact that this was done.'' *Id.*

The sixth step addresses monitoring and states that regular monitoring, including ''frequent physical monitoring,'' of the patient is to be ''maintained.'' *Id.* at 4. Further, according to this step, ''it is very important to monitor the patient for the underlying condition which necessitates the drug and for the side effects of the drug itself'' when the regimen calls for prolonged need for use of the drug. *Id.*

Seventh, the ''physician must keep detailed records of the type, dosage and amount of the drug prescribed.'' *Id.* In addition, the prescribing physician ''should also monitor and personally control all refills.'' *Id.* According to this step, ''[o]ne good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time.'' *Id.* Further, this step states that a ''patient should receive prescriptions from one physician and one pharmacy whenever possible'' while advising that it is a ''felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time.'' *Id.* This step advises physicians to contact the local police or the Georgia Drug and Narcotics Agency if they ''are aware of these situations occurring.'' *Id.*

The eighth step suggests that the ''patient's family may be a valuable source of information on the patient's response to the therapy regimen and the patient's functional status.'' *Id.* This information is important because changes ''may be symptoms of dependency or addiction.'' *Id.*

Ninth, ''[m]aintaining adequate records is extremely important.'' *Id.* According to the Ten Steps, the ''physician who carefully manages pain treatment and maintains detailed records which reflect all the steps involved in the process will be able to assess and review the treatment course and progress.'' *Id.*

The tenth of the Ten Steps states, ''Document. Document. Document. Keep accurate and complete records'' to include medical history and physical exam; diagnostic, therapeutic, and laboratory results; evaluations and consultations; treatment objectives; medications; and instructions and agreements, including any pain contracts.

The second exhibit the Government offered about the standard of care in Georgia is GCMB Rule 360–3–.02, entitled ''Unprofessional Conduct Defined,'' GX 5. The rule starts by citing two Georgia statutes for the proposition that the GCMB is authorized to take disciplinary action against licensees for unprofessional conduct. Ga. Code Ann. § 43–34–8(a)(7) (West, Westlaw effective January 1, 2013, to May 8, 2017) (authorizing the GCMB to discipline a regulated person who engages in ''any unprofessional, unethical, deceptive, or deleterious conduct or practice harmful to the public,'' explaining that the conduct or practice ''need not have resulted in actual injury to any person,'' and explicitly including ''any departure from, or failure to conform to, the minimum standards of acceptable and prevailing medical practice'' and ''the prescribing or use of drugs, treatment, or diagnostic procedures which are detrimental to the patient as determined by the minimum standards of acceptable and prevailing medical practice or rule of the board'') and **G**a. Code Ann. § 43–1–19(a)(6) (West, Westlaw effective to May 2, 2016) (containing ''general provisions'' authorizing professional licensing boards to refuse to grant a license to an applicant, to revoke a license, and to discipline a licensed person when the applicant or licensee engaged in any unprofessional conduct or practice harmful to the public that materially affects the fitness of the licensee or applicant to practice the profession or is of a nature likely to jeopardize the interest of the public, and the conduct need not result in actual injury to any person or be related to the practice of the licensed profession). The Georgia Code also authorizes the GCMB to refuse to grant a license and to

[5] The GCMB adopted ''Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps'' (hereinafter, Ten Steps) on January 11, 2008. The Ten Steps are ''primarily intended to provide orientation for physicians intending to prescribe schedule II and III analgesics . . . [to treat] chronic pain conditions and do not necessarily apply to clinical conditions . . . such as acute pain management following surgery, emergency care pain management and end-of-life care.'' Ten Steps, at 1. The Ten Steps ''clarify the . . . [GCMB's] position on pain management, particularly as it relates to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management practices.'' *Id.* They are also intended to curtail drug diversion, ''a serious public safety concern for the . . . [GCMB] and law enforcement agencies.'' *Id.* The Ten Steps state that physicians ''should not fear disciplinary action from the . . . [GCMB] for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice.'' *Id.* According to the GCMB, ''[a]dherence . . . [to the Ten Steps] will not only improve quality medical practice but will also improve the . . . [GCMB's] efficiency in its investigations by distinguishing legitimate practice from foul play.'' *Id.*

discipline a regulated person who has ''[f]ailed to maintain appropriate medical or other records as required by . . . [GCMB] rule.'' [6] Ga. Code Ann. § 43–34–8(a)(19) (West, Westlaw effective January 1, 2013, to May 8, 2017); *see also* Ga. Comp. R. & Regs. § 480–28–.02 (West, Westlaw effective 2002) (''All practitioners who dispense drugs shall comply with all record-keeping, labeling, packaging, and storage requirements imposed upon pharmacists and pharmacies with regard to such drugs and those regulations contained in this Chapter.'') and Ga. Comp. R. & Regs. § 480–28–.04(5) (West, Westlaw effective 2002) (establishing controlled substance invoice, inventory, and filing requirements).

Having read and analyzed all of the record evidence, I agree with the ALJ's determination to recognize Dr. Kaufman as an expert in the area of pain management.[7] Tr. 183. Dr. Kaufman testified that the GA Pain Management Rule establishes the minimum standard of care in Georgia for prescribing controlled substances, regardless of the prescriber's medical specialty. *Id.* at 180, 182, 192–93. He noted that a prescriber's failure to conform to the requirements of the GA Pain Management Rule is unprofessional conduct subject to disciplinary action. *Id.* at 185; GX 5, at 4 (Rule 360–3–.02(22)). Dr. Kaufman testified that prescribing controlled substances for a known or suspected habitual drug abuser or other substance abuser in the absence of substantial justification is also unprofessional conduct under Georgia law. Tr. 185, 208–10; GX 5, at 1 (Rule 360–3–.02(1)). Further, he stated that writing a controlled substance prescription for immediate family members, except in a documented emergency, constitutes unprofessional conduct. Tr. 185–86, 215–16 (''everybody knows this''); *id.* at 489–90; GX 5, at 1 (Rule 360–3.02(2)).

Dr. Kaufman's testimony provided additional detail about the standard of care for prescribing controlled substances in Georgia. Regarding the requirement that a physician review the medical history of a patient when initially prescribing a controlled substance to treat pain or chronic pain, Dr. Kaufman testified that a history ''doesn't just say, the patient has back pain. You have to say how long, how did it get hurt, what things have they tried to get better before they came to see you, what types has another physician tried, what types of evaluations have they done.'' Tr. 195. Concerning the physical examination called for by the Georgia standard of care, Dr. Kaufman testified that it has to be ''appropriate to the problem.'' *Id.* at 196.

> So, if you're saying that someone has a back problem, you have to do an examination of the back. Obviously, my examination of the back might be different than a family practitioner's. But there are some sort of basic things that are involved with a physical examination that have to be done.''

Id.

The standard of care in Georgia states that physicians ''should always start with the easiest treatment plan,'' non-addicting options, such as physical therapy, chiropractic, tens unit, and anti-inflammatories. *Id.* at 203. Through physician-patient conversations, the physician evaluates whether the treatment is working and documents ''what's going on.'' *Id.* at 204. This process may lead to the prescribing of controlled substances. *Id.*

Regarding the requirement that a physician obtain the patient's informed consent when initially prescribing a controlled substance, Dr. Kaufman explained that ''[t]here's no reason a patient should know anything about opioids and you have an obligation to explain that things like they can be habit forming, that you cannot take extra ones, because these could really cause issues, you shouldn't have alcohol.'' *Id.* at 196–97. According to Dr. Kaufman, ''It's just a general discussion and explanation of what they are getting into . . . because they might not know that it's habit forming, they may not know that they are going to develop physical dependence, and you have to explain these things.'' *Id.* at 197. In addition, the physician has an obligation to inform the patient that he ''should go to one pharmacy so that we can really keep track'' and ''should really only go to one physician to write these prescriptions.'' *Id.* The physician should tell the patient ''about the interactions with other medications or other medical problems that they might have as it relates to these medications.'' *Id.* at 196–97.

Dr. Kaufman elaborated on the requirements for a physician prescribing a Schedule II or III controlled substance for ninety or more days to treat a patient with a non-terminal condition in chronic pain. *Id.* at 189–90. He testified that the physician must have a written treatment agreement with the patient and require the patient to have a clinical visit at least once every three months. *Id.* at 190. The physician must monitor the patient's compliance with the therapy and identify any new condition. *Id.* Although the standard of care does not specify a physician's exact response to the monitoring's results, it ''insist[s] that you document that something was abnormal and encourage[s] you to write down what you are thinking and why it is you do whatever it is you do.'' *Id.* The standard of care calls for the physician to make a referral to an appropriate practitioner when the physician determines that the patient has a new condition ''beyond his scope of training.'' *Id.*

Dr. Kaufman explained that the written treatment agreement is a component of the physician's discussion with the patient being treated for more than ninety days. *Id.* at 197. The doctor explores what physical and emotional impacts the patient is experiencing. *Id.* This discussion leads to written goals for the therapy. *Id.* ''You ask . . . [the patient], can you climb the stairs, can you go to the mailbox, can you stand and make your lunch.'' *Id.* at 204.

> You want to have a plan. . . . . You want to have some things that are laid down as goals, and you tell patients, or at least . . . you're supposed to tell patients. And if were [sic] not effective, we give it a period of time and if it's not working, if we don't see some objective improvement, we're going to stop these medicines. We don't want to just turn you into a person who got a dependency on medications unless were [sic] getting somewhere, unless were [sic] doing something.

Id. at 197–98. Dr. Kaufman further explained the standard of care with an analogy to blood pressure medication—after prescribing blood pressure medication, the physician records the changes in the patient's blood pressure. *Id.* at 201–02. For patients in pain, there is a ''visual analog scale'' and, as

[6] Although not charged in this administrative proceeding, provisions of the Georgia criminal code address related matters. For example, only an authorized, registered practitioner acting in the usual course of his professional practice for a legitimate medical purpose may prescribe or order the dispensing of a controlled substance. Ga. Code Ann. § 16–13–41(f) (West, Westlaw effective since 2011).

Regarding prescriptions for Schedule II controlled substances, the Georgia criminal code states, among other things, that they ''shall be signed and dated by the practitioner on the date when issued.'' Ga. Code Ann. § 16–13–41(b) (West, Westlaw effective since 2011); *see* OSC, at 2 (unlawful pre-signed and pre-printed prescriptions allegation). The same issuance-related requirement applies to Schedule III, IV, and V controlled substances. Ga. Code Ann. § 16–13–41(d)(2) (West, Westlaw effective since 2011). Further, regarding recordkeeping, the Georgia criminal code states that persons registered to dispense controlled substances ''shall keep a complete and accurate record of all controlled substance on hand, received, . . . sold, dispensed, or otherwise disposed of and shall maintain such records and inventories in conformance with the record-keeping and inventory requirements of federal law and with any rules issued by the State Board of Pharmacy.'' Ga. Code Ann. § 16–13–39 (West, Westlaw effective since 1982); *see* OSC, at 2 (recordkeeping violations allegation).

[7] Applicant's counsel did not object to this determination. Tr. 183.

already discussed, objective improvements in the patient's physical ability. *Id.* at 202. ''[A]t the very least,'' he testified, ''you need to find out how they're doing and document whether they got better, or worse or what's going on.'' *Id.* at 204. If the current therapy does not work, the physician is to try something else. *Id.* at 205. Since there are ''severe issues, complications'' for a patient on the equivalent of more than 90 milligrams of morphine, ''it's recommended that non-specialists don't really go above that level . . . [and that] they then send those patients to specialists.'' *Id.* at 206.

Dr. Kaufman explained that a narcotics agreement advises the patient that controlled substances are ''very serious medications, they're not to be sneezed at.'' *Id.* at 198. The patient is told that a controlled substance may be taken only as prescribed, that drinking ''a whole bunch of alcohol'' while taking a controlled substance will result in ''horrible side effects,'' and that it is important to be ''very careful the first few times if they're going to be driving a vehicle or climbing a ladder, because there's all kinds of side effects from this.'' *Id.* at 199. Further, the prescribing physician is to explain the screening procedures to the patient, including urine drug screens whose results are recorded in the patient record, the possibility of pill counts, and the unavailability of early refills. *Id.* at 199, 201.

Dr. Kaufman also testified about the standard of care for the maintenance of medical records. He explained that complete medical records help prevent a physician from making a mistake due to the difficulty of recalling everything that transpired with the passage of time. *Id.* at 210. He noted that the GCMB reviews medical records to determine if the physician ''followed everything and if you did, everything is okay and there's no problem.'' *Id.* Dr. Kaufman emphatically testified that errors or sloppiness are not an ''adequate explanation of a failure to document properly'' and, ''at the end of the day, I'm responsible for anything that's in that chart'' and ''I take ownership'' of anything in the chart ''once I sign off on it,'' ''just as everybody else does.'' *Id.* at 211. He affirmed that this is the standard of care in Georgia. *Id.* at 212.

In sum, having read and analyzed the relevant legal authorities and the record evidence, I find that Dr. Kaufman's testimony about the Georgia standard of care applicable to this adjudication is credible. I give it controlling weight in this proceeding.[8] The testimony of Applicant's expert witnesses is not cited in this section because, to the extent that they addressed the applicable standard of care in Georgia, they did not detail a perspective that is contrary to the much more comprehensive and credible testimony of Dr. Kaufman.[9] Further, to the extent that the testimony of Applicant or his experts about the applicable standard of care in Georgia conflicts with Dr. Kaufman's testimony, I will credit Dr. Kaufman's testimony. *See, e.g., infra* section IV.

III. Findings of Fact

A. Applicant's Current Medical Licensure

The Georgia Composite Medical Board (hereinafter, GCMB) issued medical license number 31308 to Applicant. According to Applicant, his Georgia medical license was renewed on April 3, 2019. Applicant's Second Motion for Leave to Supplement Evidence Post-Hearing dated February 7, 2020, at 2.[10]

B. The Investigation of Applicant and His Recent Registration History

During the course of the DEA Diversion Investigator's (hereinafter, DI) duties conducting an administrative inspection at an area pharmacy, he received information from a pharmacist who claimed to have work experience at Applicant's office. Tr. 29, 82, 85; *see also id.* at 136 (testimony of Group Supervisor (hereinafter, GS)). According to that information, Applicant ''would pre-sign prescriptions and then would be filling prescriptions without evaluation or without seeing them, sometimes for long periods of time.'' *Id.* at 30; *see also id.* at 44. DI asked the pharmacist to repeat this information to DI's supervisor. *Id.* at 31. He then recommended that DEA conduct an inspection of Applicant's office. *Id.* DI's supervisor agreed. *Id.*

C. The Allegations of Dispensing and Non-Dispensing Violations

The OSC alleges four bases for the denial of Applicant's registration application: The pre-signing and pre-printing of prescriptions (citing 21 CFR 1306.04 and 1306.05; Ga. Code Ann. § 16–13–41(b)); recordkeeping violations (citing 21 U.S.C. 842(a)(5); 21 CFR 1304.04(a), (f)(1), (f)(2), and (g), 1304.11(b) and (c), 1304.21(a); Ga. Code Ann. §§ 16–13–39, 16–13–42(a)(3)); the unlawful prescribing of controlled substances (citing 21 CFR 1306.04; Ga. Code Ann. § 16–13–41(f); GCMB Rules 360–03–.02(2) and 360–03–.06; the Georgia Guidelines for the Use of Controlled Substances for the Treatment of Pain (hereinafter, GA Guidelines)); and lack of candor (citing 21 U.S.C. 823(f)(5)).[11]

There is factual agreement among the witnesses on a number of matters. When there is factual disagreement, I apply my credibility determinations and, to the extent that I agree with them, any credibility recommendations of the ALJ.[12] *See, e.g., supra,* section II; *infra* sections III.D., III.E., and IV.B.3.

[8] I agree with the RD that Dr. Kaufman ''generally offered detailed assessments of individual prescriptions and actions by the . . . [Applicant], and tied these directly to the relevant regulation or statute.'' RD, at 76. I do not, however, adopt all of the statements in the RD about Dr. Kaufman's credibility. *Id. Infra* n.28.

[9] The RD states that ''[a]s to patients DC and M.B., by all accounts, these are exceptional patients, legacy pain patients, by their history and according to Dr. Downey, warranting a different evaluation and treatment standard than that afforded non-legacy pain patients.'' RD, at 113. I find that this portion of the RD is not complete; it does not include Dr. Downey's testimony explicitly acknowledging that the provisions of the Georgia Pain Management Rule apply to all controlled substance prescriptions written since 2012, including for so-called ''legacy pain patients,'' such as patients whom an applicant treated since 1994. Tr. 601–03.

[10] My citation to this document is solely for the purpose of noting the status of Applicant's Georgia medical license and does not change my finding that the ALJ was correct to deny Applicant's motions. *Supra* section I.

[11] The Government abandoned two of the patient files (H.B. and K.K.) cited in the unlawful prescribing of controlled substances charges. Tr. 244. The Government subsequently withdrew the lack of candor charge entirely. *Id.* at 9–10.

[12] I appreciate the ALJ's work and the work of Applicant's and Government's counsel on this matter. I considered the entire record certified to me and, as the ultimate Agency decision maker, found facts, assessed credibility, and determined how the findings of fact measure against the applicable law. In doing so, I carefully considered the ALJ's RD and the parties' submissions. *See Universal Camera Corp.* v. *N.L.R.B.,* 340 U.S. 474, 487–97 (1951) (holding that the standard of proof specifically required by the Taft-Hartley Act is the same as that to be exacted by courts reviewing every administrative action subject to the Administrative Procedure Act, finding that the Courts of Appeals determine whether there is substantial evidence to support agency findings on the record as a whole, stating that the reviewing court is directed to determine the substantiality of evidence on the record including the examiner's report, and concluding, ''We do not require that the examiner's findings be given more weight than in reason and in the light of judicial experience they deserve. The 'substantial evidence' standard is not modified in any way when the Board and its examiner disagree.''); *Reckitt & Colman, Ltd.* v. *Administrator, Drug Enf't Admin.,* 788 F.2d 22, 26–27 (1986) (''The agency, and not the ALJ, is the ultimate factfinder. . . . While it is true that reviewing courts must take the ALJ's findings into account as part of the record, . . . the significance to be ascribed to them 'depends largely on the importance of credibility in the particular case.' . . . The dispute in this case centered not on the occurrence or nonoccurrence of historical facts, or other issues for which demeanor evidence would be highly probative, but rather on matters of scientific judgment and expertise. The ALJ conceded that Dr.

D. The Government's Case

The Government's documentary evidence consists primarily of medical records. The Government called three witnesses: A DEA Diversion Investigator, DI, GS, and Dr. Gary Kaufman, the Government's expert witness.

DI testified about his investigation-related actions, including execution of the Notice of Inspection (hereinafter, NOI), Applicant's voluntary consent to the inspection, Applicant's polite and cooperative demeanor, Applicant's subsequent voluntary surrender of his DEA registration, and the handwritten statement Applicant voluntarily provided. Tr. 31–44; GX 3 (DEA–82 (Notice of Inspection of Controlled Premises) that Applicant signed consenting to the inspection on August 11, 2015); GX 2 (DEA–104 (Voluntary Surrender of Controlled Substances Privileges) that Applicant signed concerning BP1660338 and XP1660338 on August 11, 2015); GX 96 (Applicant's undated handwritten statement).[13] After Applicant voluntarily surrendered his registration, DI ascertained that there were controlled substances in Applicant's office. Tr. 39, 43.

DI testified that he seized a ''clear plastic tub full of pre-signed prescriptions'' and ''[u]nsigned, pre-printed prescriptions . . . sitting right there in plain view.'' *Id.* at 43–44; GX 87 (''pre-signed prescriptions,'' including prescriptions for controlled substances); GX 88 (''pre-printed, unsigned controlled substance prescriptions''); *see also* Tr. 45–49. DI also testified that, according to Applicant and Applicant's staff, Applicant was not in the office on August 7, 2015, and he was only in the office for half of August 6, 2015. Tr. 49–53. While conducting the inspection, DI also seized patient sign-in sheets that Applicant's staff provided as evidence of the patients who were in the office on August 6 and 7, 2015. *Id.* at 56–58; GX 86. DI testified that GX 86 was ''the only thing that . . . [Applicant's] Office provided . . . [him] as evidence of who was in the office those two days,'' and that Applicant's staff did not indicate that ''there was any other evidence or sign-in logs that would indicate who was in the office on August 6th and August 7th.'' Tr. 58.

DI testified about the seizure of Applicant's patient files, DEA's analysis of those files, and the identification of ''red flags'' in those files.[14] *Id.* at 58–68; GX 51 (D.C. patient files); GX 59 (M.B. patient files); GX 77 (patient files for Applicant's daughter (hereinafter, Applicant's (or his) daughter)); GX 52–58 (prescriptions that Applicant issued to D.C.); GX 60–76 (prescriptions that Applicant issued to M.B.); GX 78–84 (prescriptions that Applicant issued to his daughter). The analysis of Applicant's patient files, according to DI's testimony, led to the retention of a medical expert to analyze the legitimacy of Applicant's controlled substance prescribing and to the issuance of subpoenas to pharmacies for prescriptions that Applicant issued to these patients and that the patients filled.[15] Tr. 68–79.

In addition to his testimony about the origin of DEA's investigation of Applicant and execution of the NOI, *id.* at 136–37, GS testified about the controlled substance records that registrants are legally required to maintain, his request for Applicant's controlled substance records, his NOI-related interactions with Applicant and Applicant's staff, and the seizure of controlled substances from Applicant's office.[16] *Id.* at 137–73.

GS explained that the mandatory controlled substance records include an initial inventory, a biennial inventory, dispensing records, purchasing records, return records, and destruction records, and that these records must be maintained in a manner that allows them to be readily retrievable upon the registrant's receipt of an authorized request for them. *Id.* at 138–40. According to GS, both federal law and Georgia law require controlled substance recordkeeping. *Id.* at 141. When he learned that Applicant had controlled substances in his office, GS asked to see ''the records for any controlled substances that you might have on hand.'' *Id.* at 138. More specifically, he testified that he asked for ''any initial inventory, the bi-annual inventory, the purchasing records, the dispensing records, any type of destruction records, any other type of record dealing with controlled substances that they would be required to maintain for a period of two years in a readily retrievable format on site.'' *Id.* at 141–42.

GS testified that Applicant's office was not able to produce any of the records that he requested. *Id.* at 142, 155, 156–57, 160, 168, 172–73.

> There was no bi-annual inventory, when a schedule of a drug changes, say . . . [as] hydrocodone did on October 6, 2014. There would have been a required new inventory for that, so there wasn't an initial inventory for that. There were no purchasing records on site. No 222s. No invoices. No destruction of controlled substance records. No controlled substance records whatsoever.

Id. at 155. GS also testified that no one in Applicant's office stated that the required controlled substance records were maintained electronically. *Id.* at 144; *see also id.* at 170. Also, GS specifically testified that (1) anyone's testimony that Applicant's ''pharmacist'' showed him ''the computer'' and that he was not ''interested in it'' is not accurate, (2) a statement that Applicant's staff ''pointed . . . [him] to two notebooks where the invoices were kept'' is not accurate, (3) he did not ask ''if all the data was on the computer,'' (4) he does not recall ''a discussion with . . . [Applicant's staff] that they should scan the filled prescriptions back into the EMR records,'' (5) he does not recall telling Applicant and Applicant's staff that ''there were some minor problems, but in general they were in compliance;'' he recalls ''telling . . . [the staff] there were recordkeeping violations, and . . . that's when . . . [he] said it could be a letter of admonition, a memorandum of agreement, civil fine, up the gamut,'' and (6) he does not recall stating that ''they would likely get a letter within the next 30 days with a corrective plan.'' *Id.* at 169–71.

GS specifically testified about the documents in RX 11F. On cross-examination, GS looked through RX 11F and concluded that he saw in there ''clear[ ] violations of the recordkeeping requirements.'' *Id.* at 166. On re-direct, GS testified that, if RX 11F had been presented to him on August 11, 2015, he ''absolutely'' would still have cited Applicant for recordkeeping violations ''[b]ecause they are not in compliance with the federal regulations of the United States [C]ode.'' *Id.* at 173.

Zelesko was 'a highly qualified and experienced chemist' but simply found the petitioner's experts more persuasive. On such matters the Administrator remains free to disagree. We conclude that the Administrator's conclusion is supported by substantial evidence.''); 5 U.S.C. 557(b) (''On appeal from or review of the initial decision [by the ALJ], the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule.'').

[13] Tr. 97 (Applicant's counsel purported to read Applicant's handwritten statement into the record during his cross-examination of DI: ''I've been practicing medicine in the State of Georgia for 25 years. I have never willfully tried to be unlawful in my practice with my patients. Evidently, today I found out that I have been in violation of federal drug code with my practice. I will surrender my DEA license and hope that a hearing would be obtained to hopefully reconcile this matter.'').

[14] DI explained that ''red flags'' is a ''term of art, that we use for signs indicative of opioid or other prescription medical abuse or diversion.'' Tr. 65.

[15] The DEA subpoena did not result in the seizure of every prescription that Applicant issued.

[16] GS also testified that Applicant was ''very cordial'' during execution of the NOI. Tr. 137.

When Applicant's staff asked him what could happen when a registrant does not produce the required records, GS testified that he outlined the possible ramifications ranging from a verbal, on-site warning to a criminal prosecution. *Id.* 148–49; *see also id.* at 171. In response to questioning by Applicant's counsel, GS stated that he had never before seen the paperwork counsel was showing him during the cross-examination. *Id.* at 163. GS testified that, had Applicant or Applicant's staff given him RX 11 during the inspection, he would not have accepted it. *Id.* GS pointed out pages in the paperwork that did not concern controlled substances, were not relevant to the required time period, or exhibited clear violations of the recordkeeping requirements. *Id.* at 163–68 (regarding RX 11F, RX 11G, RX 11I, RX 11J); *see also* Tr. 160–61 (regarding RX 11B). GS testified that, if Applicant had offered the DEA team the required records that he had requested, ''even the next day,'' the team would have taken them. Tr. 156. ''We probably would have been like, yes, that's what we're looking for. We probably would have taken them and explained that you need to make sure in the future that you have that. . . . [W]e have done that in the past,'' he testified. *Id.*

When GS learned that Applicant had voluntarily surrendered his registration, his request for required records ''became a moot point,'' and he seized the controlled substances in Applicant's office.[17] *Id.* at 156, 150–51. The DEA Form 7 memorializing the seizure of Applicant's controlled substances was admitted as GX 94. *Id.* at 153–55.

I find that GS and DI presented as objective, rational, careful law enforcement officers, whose testimonies deserves full credibility.[18] *Id.* at 28–173.

The Government's expert, Dr. Gary Kaufman, is a physician licensed in Georgia and Board certified in both pain medicine and neurosurgery. *Id.* at 175–77; GX 93 (Curriculum Vitae of Dr. Gary Kaufman, M.D.).[19] He explained that he read all of Applicant's medical files that he was given and, taking into account his training and experience, assessed Applicant's compliance with the standard of care in Georgia for the treatment and management of pain patients.[20] *Id.* at 191–93. He explicitly stated that he was not providing an opinion of the ''medical care'' Applicant provided as a family practitioner. *Id.* at 192, 399 (''I'm not in a position to say if . . . [Applicant's medical care] was good, bad or indifferent.''); *contra id.* at 1082–84 (Counsel for Applicant's statement, after admitting his client ''made mistakes,'' that ''ultimately, going back to the quality of care, even Dr. Kaufman said, look I can't criticize his quality [of] care''). The ALJ recognized Dr. Kaufman as an expert and authorized him to give expert testimony in the area of pain management. *Id.* at 183.

From his review of Applicant's medical records, Dr. Kaufman concluded that Applicant failed to comply fully with the applicable standard of care with respect to obtaining the patient's history, conducting a physical exam, and obtaining informed consent before prescribing controlled substances.[21] *See, e.g., id.* at 285–87 (concluding that Applicant's documentation of M.B.'s history is ''terrible. There's essentially no reasonable history of back pain or neck pain documented. . . . [T]here was never an examination of the back documented. There was never an examination of the neck documented, and there was . . . an x-ray in 2008, plain x-ray which didn't show anything, and the next time she had any radiographic exam and the first time she probably had a legitimate medical problem that could be treated with scheduled medications, was in 2014 when she fell and landed on her back, had a compression fracture.''). Dr. Kaufman explained that the lack of a history, a physical, and any supporting document means ''there's no diagnosis of any illness that should be treated with schedule[d] medications.'' *Id.* at 286. ''None,'' he emphasized,

[17] GS testified that DEA's inspection put him at Applicant's office ''for probably at least three hours.'' Tr. 156.

[18] The RD does not address the credibility of DI and GS in one spot. It concludes, for example, that there was ''no indication from . . . [the testimony of DI or GS] that any partiality interfered with their telling the truth'' and that DI and GS did not target Applicant for ''unequal treatment.'' RD, at 72. *See also id.* at 71–72, 94.

[19] GX 93 is incomplete; it does not reference that Dr. Kaufman has a DEA ''X'' number authorizing him to prescribe Suboxone. Tr. 181.

[20] According to the RD, the ''Government offered testimony from its expert fairly characterized as general conclusions regarding . . . [Applicant's] practice, and that the prescriptions charged were merely examples of a larger number of violative prescriptions within the files.'' RD, at 30. It concludes that ''[d]ue process requires more specificity and more notice than that'' and, as such, ''[t]hey have not been considered herein, as substantive evidence in support of the allegations.'' *Id.*

This section of the RD references three transcript cites, the first of which it quotes in footnote 30. The first transcript cite, Tr. 209–10, concerns whether Dr. Kaufman's review of Applicant's medical records indicates that any of Applicant's patients are ''suspected or known drug abusers.'' *See* RD, at n.30. Second, the RD references Tr. 213, apparently for Dr. Kaufman's statements that he identified improper prescriptions written by Applicant in ''the various case files'' although he did not attempt an exhaustive identification of every improper prescription. Third, the RD references Tr. 224, apparently when the ALJ requested clarification about Dr. Kaufman's having said that ''there were so many [prescriptions written for Applicant's daughter], it looked like this was a continual treatment'' and Dr. Kaufman responded that ''there are prescriptions that are not here, but there were quite a few more.''

I agree with the RD that conclusory statements about unspecified record evidence in this matter are insufficient to prove the allegations in the OSC. I note, though, that there is sufficient evidence in the record to prove the Applicant issued improper controlled substance prescriptions, prescribed controlled substances for suspected or known drug abusers, and wrote multiple controlled substances prescriptions for his daughter.

[21] Portions of the RD are critical of aspects of Dr. Kaufman's testimony. The results of my close examination of the RD and the portions of Dr. Kaufman's testimony it criticizes give me no pause in crediting Dr. Kaufman's testimony. For example, the RD, while explicitly stating that it is ''not directly contradictory to Dr. Kaufman's earlier testimony regarding the lack of physical exam,'' states that an MRI of D.C.'s lumbar spine in September 2013 and a chest x-ray in August 2013 ''were relevant to Dr. Kaufman's opinion regarding the absence of a back examination, and diminishes his opinion on this issue in that regard.'' RD, at 28. I disagree. Dr. Kaufman's testimony was that Applicant's treatment of DC with controlled substances ''over several years'' for ''chronic pain . . . sometimes described as chronic headaches, . . . sometimes from knee pain, . . . sometimes the back pain'' was supported by ''very inadequate and not credible at all'' physical exams ''[a]s documented'' in the medical records for DC Tr. 229. I see no evidence in the record to support the RD's conclusion that one chest x-ray and one MRI in August and September of 2013 are a sufficient basis to support Applicant's prescribing controlled substances ''over several years.'' *Id.* While Dr. Kaufman's testimony does not specify the several year period he referenced, I note that there are medical records in Applicant's file for DC dated as far back as the late 1990s. Accordingly, I disagree with the RD's statement that this portion of the record ''diminishes . . . [Dr. Kaufman's] opinion on this issue in that regard.'' RD, at 28.

By way of further example, the RD states that ''Dr. Kaufman was confronted with a referral by . . . [Applicant] to a specialist in lumbar osteoporosis in 2003, a referral to a pain specialist in 2002, and to a headache specialist in 2003'' and that those documents ''certainly qualified Dr. Kaufman's . . . opinion . . . that . . . [Applicant did not] pursue testing or alternative treatment for DC's pain issues.'' *Id.* The pain and headache specialist referrals referenced in the RD, however, concern M.B., not DC, and Dr. Kaufman cautioned against using opioids to treat headaches ''because they cause rebound headaches.'' Tr. 485–86. I do not agree that these matters ''certainly qualified Dr. Kaufman's subject opinion,'' and they do not change my positive assessment of Dr. Kaufman's testimony. RD, at 28.

Further, Dr. Kaufman's testimony about a patient named in the OSC, and whom the Government subsequently withdrew from the adjudication, shows the expert's willingness to accept Applicant's *post hoc* injection of information and justification for a prescribing pattern Dr. Kaufman had concluded was outside the applicable standard of care. Tr. 226–27 (Dr. Kaufman testifying that ''I always want to give the physician the benefit of the doubt. And after reading what he had written, I was willing to say that if that material was correct, then I would not judge that substandard care'' and noting that, under the applicable standard of care, Applicant's *post hoc* information and justification ''should have been in the [medical] records.'').

concluding that any controlled substance that Applicant prescribed for M.B. before the 2014 compression fracture was issued outside the usual course of professional practice in Georgia. *Id.; see also id.* at 326; *id.* at 343–46; *id.* at 455 (''[T]he last two months, it's very clear that since her fall she's being treated [with pain medicine] for the fall. The preceding 11 years or so, it's impossible to know why she's in treatment.'').

Dr. Kaufman found Applicant's controlled substance-related actions to be below the standard of care based on the documentation in the medical records of Applicant's practice.[22] *Id.* at 230–31 (Dr. Kaufman testifying about D.C.'s complaint of knee and back pain and Applicant's medical records for D.C.: ''So, there was no [ ] examination of the back, there was no examination of the knee. Furthermore, this is pretty disturbing, every physical examination documented a normal rectal examination, a normal prostate examination, normal testicles, and I would seriously doubt that that was done on every visit. . . . I don't think it's credible at all.''); *id.* at 231 (Dr. Kaufman testifying about Applicant's medical records for D.C.: ''[I]n the face of repeated normal prostate exams, there is a diagnosis of prostate hypoplasia, which means enlargement of the prostate. Which is something you would pick up on a prostate exam. So, if you're going to do a prostate exam every visit and you're going to give the diagnosis of an enlarged prostate, you should document, at least once, that there's an enlarged prostate. And that was never done [against the Georgia standard of care].''); *id.* at 501–05 (Dr. Kaufman agreeing that there needs to be follow through on language in a patient's medical records to meet the standard of care); *id.* at 226–27 (Dr. Kaufman determining that medical records show a pattern of prescribing that is outside the standard of care and that did not comply with Georgia's rules, and even though additional information provided by Applicant, if accurate, would change the substandard care conclusion, it is still a violation of the Georgia standard of care not to have that information in the medical records); *id.* at 451–53 (Dr. Kaufman discussing internally inconsistent information in a patient file and countering the suggestion that the inconsistency is the patient's fault by explaining that only the physician (not a scribe or the patient) is allowed to enter the history of the present illness ''[a]nd so, it was . . . [Applicant's] obligation to enter this, nobody else and it is not correct.'').[23]

Dr. Kaufman found that Applicant did not re-evaluate patients, did not always document the changes he made to a patient's therapy, and did not always document the impact of a change in therapy. *Id.* at 204, 202, 207–08, 346–48.

Dr. Kaufman concluded that Applicant did not comply with the applicable standard of care when, for example, he prescribed controlled substances for M.B., who exhibited signs of abusing, or being addicted to, controlled substances. *Id.* at 287–326 (explaining that signs of patient addiction include requesting early controlled substance refills and an abnormal urine drug screen, evaluating Applicant's response to the signs of addiction the patient exhibited over the course of years, noting that Applicant continued to prescribe controlled substances for M.B. despite signs of her addiction, thereby ''basically just feeding her addiction,'' concluding that Applicant did not apply his own protocols to his treatment of M.B. and did not implement the Georgia standard of care response to an abnormal urine drug screen, and calling Applicant's response ''a mockery of the rules,'' ''not excusable,'' ''irresponsible,'' ''beyond ridiculous,'' and outside the Georgia standard of care); *see also, e.g., id.* at 439–41 (Dr. Kaufman's explanation that the applicable standard of care for an abnormal urine screen is discussing it with the patient, documenting the abnormality in the chart, and documenting ''what you as the treating physician are thinking about this abnormality,'' and that implementation of the standard of care involves ''com[ing] up to some solution that you and the patient work out,'' and cautioning that the ''fact that [the patient] stopped being positive doesn't indicate that she all of a sudden listened to . . . [Applicant] necessarily. Perhaps she stopped obtaining that medication in whatever fashion she was obtaining it. . . . I do know that it wasn't documented and there was no explanation and this went on for quite some time.''); *id.* at 327–32, 336–42, 459 (Dr. Kaufman's testimony about Applicant's failures to comply with the standard of care regarding abnormal urine drug screens, and opinion that Applicant did too little too late because ''[i]t just keeps going on and on and there's no consequence and it's nuts, sir. This is not the standard of care.''); *id.* at 332 (concluding that Applicant's failure to refer a patient to an addiction specialist ''because she's clearly addicted to medications and clearly needs help and she's not getting any help. She's just getting more medication'' violates Georgia's pain management rules and constitutes ''unprofessional conduct.'').

Dr. Kaufman identified issues with, and testified about, Applicant's controlled substance prescribing. For example, he testified that Applicant prescribed, and continued to prescribed, controlled substances groundlessly. *Id.* at 323–26 (Dr. Kaufman stating that ''it's the same repetitive situation where there's no complaints to justify it. There's no exam that justifies this. The urines are all out of whack. The patient has been told she won't get these . . . without a letter from a pain specialist which is nowhere to be seen . . . it's all wrong. . . . [T]he patient is not needing refills and you give her refills. Something is clearly off.'').

Dr. Kaufman also testified about specific controlled substances that Applicant prescribed. More specifically, he pointed out Applicant's inadequate actions and, therefore, the illegality of, and danger posed by, Applicant's methadone prescribing for D.C. *Id.* at 232–39. He explained that methadone is used in two ways. First, it is prescribed for people who have an addiction. Tr. 232. The correct methadone dose suppresses cravings for a day and keeps the patient out of withdrawal. *Id.* In Georgia, only narcotic treatment clinics may dispense methadone, and they only dispense it to treat addiction. *Id.* at 498; *see id.* at 233–34 (''If you were to go to a methadone clinic and say, I have chronic knee pain. Could you give me methadone? They would turn you down. It's not their expertise. . . . So, anybody who is going to a methadone clinic is a person who has an addiction issue.''); *see also id.* at 605 (testimony of one of Applicant's experts (Dr. Downey), *infra* section III.E., that, in Georgia, only specially licensed narcotic treatment programs are authorized to issue methadone for addiction).[24]

Second, Dr. Kaufman explained, methadone is used as a pain medicine. *Id.* at 232. He testified that, when

[22] In the case of one of the patients whose treatment is referenced throughout this decision, M.B., Dr. Kaufman reviewed fifteen years of Applicant's medical records for the patient. Tr. 338.

[23] The context of this testimony referenced in the penultimate citation was a medical record cited in the OSC that the Government subsequently abandoned.

[24] *See, e.g.,* GX 51, at 672, 675 (Applicant's medical record documenting D.C.'s office visit on August 10, 2012, stating in the ''Diagnoses'' section that D.C. ''went to clinic this morning so he has two weeks[']' worth of methadone 190 mg QD [once a day] and would like to RTC [return to clinic] at the end of two weeks and begin to be tapered off of it to try the Suboxone for his chronic pain instead (will not be for dependence) OK per Dr P dose will be dropped to 180 mg on 8/24/2012.'').

prescribed for pain, methadone is taken more than once a day, depending on the dose. *Id.* at 233. When prescribed for pain, Dr. Kaufman elaborated, methadone ''has a lot of difficult issues related to the way it's metabolized in the body.'' *Id.* at 232. He testified that, although it constitutes ''less than five percent of the pain prescriptions in the United States,'' it accounts for thirty percent of the overdose deaths. *Id.* at 233. ''One of the reasons, is that the pain effect wears off, and the patient will take an extra pill, even though they are not supposed to,'' he explained. *Id.* ''When they take that extra pill,'' he continued, ''because of the very long half-life, the medicine tends to accumulate in the body and people stop breathing.'' *Id.*

Dr. Kaufman testified that Applicant's methadone prescriptions for D.C., with their instructions to ''taper as directed,'' were dangerous. *Id.* at 254 (Dr. Kaufman's analysis of Applicant's medical records for D.C.: ''It just says, 'taper as directed.' So, you don't know what the dosage is. I mean, if the patient was, in fact, cutting back. It should be indicated on the chart, what the dosage is at the current time. But you have no idea. I have no idea what's going. I don't think anybody did.'').[25]

Dr. Kaufman concluded that Applicant unlawfully prescribed methadone for D.C. for addiction. *Id.* at 246–48 (Dr. Kaufman's explanation for his opinion that Applicant unlawfully prescribed methadone for addiction, not for pain, in the context of the RX 17, at 60 version of Applicant's office notes for D.C.'s visit on May 28, 2013: ''I believe that . . . [methadone] is being given for addiction. It had been given for addiction in the clinic. The clinic will not treat patients for chronic pain. They are a treatment for addiction. The statement due to chronic pain, he became dependent on opioids, so there is a dependency. And the [handwritten] statement [on the RX 17, at 60 version] about where the Suboxone came from, is probably not correct, but it's not clear. . . . It's an illegally obtained substance. So, that's really a problem. Again, who knows. . . . He certainly did not get this . . . [in] a methadone clinic and . . . [Applicant] did not prescribe it until the next month. This is a problem.''); *id.* at 248–51 (continuing Dr. Kaufman's explanation for his opinion that Applicant unlawfully prescribed methadone for addiction, not for pain, in the context of the RX 17, at 64–68 version of Applicant's office notes for D.C.'s visit on June 25, 2013: ''[T]here's no mention of a back examination. It's not even listed as a possibility. There's no mention of the knee examination. And on the next page, there's further examinations, where again, no back exam, no knee exam. . . . And then the next page is the list of diagnosis. And the first diagnosis is lumbago, which means back pain. And the medicine for that is Tylenol. And it says, 'opioid dependence, counseled patient on the condition, advise him to seek group or individual therapy, anxiety state, take the medicines as prescribed.' And another diagnosis is 'long term use of medications, with a urine drug screen having been performed.' . . . [The methadone is] not being used as a pain reliever, because it's not be[ing] given several times a day, what you notice is the methadone pain effect wears off, so they're going to tell you the pain is much worse at night, because it's worn off. It's not a pain medicine anymore. It will still work to prevent you from being an addict prevent the addictive behavior, but it's not going to work for the pain. . . . But if you give somebody Suboxone, you [are] going to really make the methadone not work as a pain medicine, whatever pain medicine effect it was having. And they're going to say my pain is much, much worse. . . . Yes, [methadone was given as related to addiction a]nd very inappropriately, because they are both being given at the same time.'').[26]

Dr. Kaufman addressed other issues with Applicant's controlled substance prescribing during his testimony that Applicant prescribed both Percocet 10/650 and Lorcet 10/650, two short-term opioids, to M.B. It was ''not good medicine in any term,'' he testified. *Id.* at 447. Dr. Kaufman explained that ''there could be no other reason to give two drugs'' than for ''breakthrough pain.'' *Id.* at 446. Yet, he testified, prescribing two controlled substance pain medications for M.B. ''doesn't make much sense'' because they have the ''same duration of action.'' *Id.* at 447. Further, both Percocet and Lorcet are preparations containing 650 mg. of Tylenol. *Id.* at 446. This means that one dose of the two controlled substances is 1300 mg. of Tylenol. ''If you go above 4,000 mg. in a day,'' Dr. Kaufman continued, ''it's exceptionally bad for your liver.'' *Id.* at 447.

In the face of suggestions that M.B.'s narcotic-seeking actions were caused by obsessive compulsivity, not addiction, Dr. Kaufman answered that one of the problems he had with the patient's chart was assessing the credibility of the controlled substance prescribing given that ''there are many things that are listed, many things, many things that are stated . . . they're not always documented and in fact I would've paid it a lot more credence if I kn[e]w she did see a onetime psychiatrist . . . if she's getting some ongoing suggestions . . . but that wasn't the case.'' [27] *Id.* at 435.

Dr. Kaufman addressed the allegation that Applicant unlawfully prescribed controlled substances for his daughter. Based on his review of the record, he concluded that Applicant violated the applicable standard of care by prescribing controlled substances for his daughter because ''there was . . . nothing in . . . the chart to reflect an emergency.'' *Id.* at 490. In response to the ALJ's questioning about Adderall and Vyvanse, that the ALJ described as ''like a maintenance medication for ADHD or ADD,'' Dr. Kaufman pointed out a preauthorization insurance form. *Id.* at 494. According to the form, Dr. Kaufman testified, the physician for Applicant's daughter had cancelled the treatment, but Applicant sought to revive it ''indefinitely.'' *Id.*

Applicant's counsel suggested that a physician treating a patient or a family member might try to get insurance approval for a long period of time

[25] Applicant's testimony acknowledged dangers associated with his methadone prescribing. *Infra* section III.E.

[26] Dr. Downey's testimony on this matter was not helpful. He testified that he thinks Applicant prescribed methadone for D.C. for pain, adding that ''[i]f someone's treating pain with methadone, the prescription should say for pain, just to make it clear.'' Tr. 615, 618. Dr. Downey did not, however, identify any record evidence showing that Applicant wrote ''for pain'' on any of the methadone prescriptions he issued.

[27] In addition, according to Dr. Kaufman's testimony, Applicant's medical records for M.B. indicate that Applicant, himself, suspected that M.B.'s drug seeking behavior was due to addiction, not obsessive compulsive disorder. Tr. 454–55 (Dr. Kaufman's interpretation of Applicant's medical record for M.B.). Applicant is not an orthopedic surgeon, a neurosurgeon, or an interventionalist, so he sent M.B. to obtain Dr. Bundy's opinion about the proper treatment of her compression fracture. If Dr. Bundy said that the fracture was not bad enough for M.B. to have a procedure or to have pain medications, and if Dr. Bundy did not think anything should be done, Applicant indicated in the medical record that ''we're going to stop the pain meds and we're going to start her on Suboxone.'' This, according to Dr. Kaufman, shows that ''there's a suspicion [on the part of Applicant] that maybe . . . [M.B. is] a drug seeker and she should be put on Suboxone.'').

When Applicant's counsel suggested that Applicant's ''putting up with and that's probably a poor choice of terms, being willing to undertake to continue to treat a patient like . . . [M.B.] speaks . . . well of him, does it not,'' Dr. Kaufman responded that ''perhaps . . . [Applicant] should've referred . . . [M.B.] to somebody with more expertise.'' *Id.* at 489. Dr. Kaufman also pointed out that there are ''very different approaches to treatment'' for obsessive compulsive behavior and for addiction to narcotics, indicating that a physician is ''only going to get . . . [the patient] better by treating'' the actual cause. *Id.* at 499–500.

because, even if the physician ''may mentally think that it's not going to last that long[,] . . . you don't want to have to keep going back to the insurance company every month or every special occasion.'' *Id.* at 495. Applicant's counsel, then, asked ''[w]ouldn't it be common just to say, well this could go on for a while?'' *Id.* Dr. Kaufman replied that, ''unfortunately, this medication you cannot prescribe to a family member unless it's an emergency and if you're going to do this several times, . . . that is not the way to deal with an emergency.'' *Id.* at 495–96. He elaborated that an ''emergency is three days and then the real doctor shows up to take care of this.'' *Id.* at 496. When Applicant's counsel opined that Applicant did not commit a legal violation, Dr. Kaufman stated that ''[e]very one of these is a violation because you're saying that there were five 30-day emergencies in which a physician couldn't be reached.'' *Id.* He restated that ''a 30-day prescription is certainly not an emergency.'' *Id.*

In sum, I find that Dr. Kaufman's testimony about pain management and about the applicable standard of care is of sufficient clarity, authority, and candor to merit controlling weight in this adjudication.[28] *See also supra* section II. Accordingly, when Dr. Kaufman's testimony conflicts with other record evidence, I will credit Dr. Kaufman's testimony.

E. Applicant's Case

At the hearing, Applicant testified after calling two expert witnesses, four staff witnesses, four character witnesses, and one witness from the software company whose application he used to manage his in-office pharmacy.[29] The ALJ admitted into evidence thirty-seven Applicant exhibits, including ''a small trove of favorable letters'' from colleagues, patients, and others that the ALJ admitted over the Government's objection. RD, at 70.

During his testimony, Applicant addressed his family life, his employment experience before enrolling in medical school, including as a nursing assistant on a hospital's acute drug and alcohol detox unit, his medical internship and residency, and his varied positions as a medical doctor. Tr. 960–75. He testified about his private practice of about 4,400 active patients, his twenty-six years of emergency room work, and his simultaneous positions as medical director for the Youth Development Center of the Georgia State Department of Juvenile Justice, as Assistant Medical Director for a large hospice home health company attesting to patients' need for hospice care, as medical director for about seven nursing homes, and as attending to nine nursing homes serving ''probably'' 1,600 patients in a year and ''probably at any one time'' 900 nursing home patients. *Id.* at 975–81. In response to a question asking how he organized his staff to assist his medical practice, Applicant stated that his employees ''just try to get the patient organized so that I could see the patient, examine the patient and make a good decision, based on, you know, the information to [sic] labs and a physical exam and then we come up with an assessment and plan.'' *Id.* at 998. Applicant confirmed that RX 2 and RX 3 ''relating to protocols with controlled substances and new patients'' are ''accurate as to what . . . [he] wanted the staff to be doing as far as controlled substances and prescriptions.'' *Id.* at 1000.

Applicant used testimonial narrative to address the medical care he provided patients named in the pending OSC charges against him. *Id.* at 1002–40. In other words, he rarely relied on a specific page or pages of any of the exhibits entered into the record. *Cf. id.* at 175–508 (Dr. Kaufman's testimony). Regarding D.C., Applicant painted the portrait of a man who began seeing him in the early 1990s, who worked hard at two jobs, and who suffered from depression and anxiety related to feeling the pressure of a ''very demanding wife.'' [30] *Id.* at 1003. According to Applicant's testimonial narrative, D.C.'s ''biggest problem and . . . the reason . . . [D.C.] ended up home dependent on pain medicine is he had cluster migraines.'' *Id.* Applicant described cluster migraines as ''probably the worst type of migraine headaches'' that cause ''very severe'' pain that usually comes on at night. *Id.* He explained that cluster migraines ''might come every other night or come every night'' and ''go on for three-four months and then, all of a sudden they just go away [a]nd then, . . . [the patient] might not have a headache for two or three years. And then they would come back.'' *Id.* at 1005. D.C. started having cluster migraines ''at a very early age'' and his doctors treated them with Demerol and Phenergan, ''which was a very common thing,'' according to Applicant. *Id.* at 1004.

Applicant testified that he treated D.C.'s headaches with medicine that ''would get rid of . . . [D.C.'s] headaches,'' but if Applicant's office ''wasn't open, . . . [D.C.] ended up going to the Emergency Room . . . [and] started to use more and more Demerol and all that sort of stuff.'' *Id.* at 1008. According to his narrative, Applicant told D.C. that ''you may want to go to try and find a pain center.'' *Id.* Applicant reported that D.C. followed his advice and that the pain center ''put . . . [D.C.] on methadone and

[28] I agree with the RD that Dr. Kaufman ''generally offered detailed assessments of individual prescriptions and actions by the . . . [Applicant], and tied these directly to the relevant regulation or statute.'' RD, at 76. I do not, however, adopt all of the statements in the RD about Dr. Kaufman. *Id.* I do not agree that Dr. Kaufman's assessments of Applicant's ''prescribing practices had a notable weakness: he did not review all of the relevant patient records.'' *Id.* My review of the record does not identify any ''relevant'' patient record that Dr. Kaufman did not review. *See, e.g.,* Tr. 505–07 (ALJ's questioning about Applicant's forty-page response to Dr. Kaufman's Report and Dr. Kaufman's confirmation that he adjusted, altered, and modified his opinions accordingly.). In response to the ALJ's questions about whether Dr. Kaufman was confronted with ''additional reports or medical records'' since his ''initial opinion,'' Dr. Kaufman replied that he thinks he saw ''a few things'' that he did not have originally, ''handwritten things.'' *Id.* In response to the ALJ's follow-up question, Dr. Kaufman indicated that these items did not change his opinion. *Id.* at 506. ''I think if you do great care 90 percent of the time but miss 10 percent, you've missed 10 percent, and that's the 10 percent I think we're discussing.'' *Id.* at 506–07.

Further, I do not agree that Dr. Kaufman's analysis of Applicant's prescribing practices is impugned because Dr. Kaufman did not hear Applicant's ''justification'' for those practices. RD, at 76. Dr. Kaufman's testimony addressed, as it should, whether Applicant complied with the applicable standard of care based on Applicant's actions documented in the medical records. *Post hoc* written or oral justifications for Applicant's actions are not controlling in this proceeding. *Lesly Pompy, M.D.,* 84 FR 57,749, 57,760 (2019) (''[A] physician may not expect to vindicate himself through oral representations at the hearing about his compliance with the standard of care that were not documented in appropriately maintained patient records.''). In addition, I found nothing persuasive enough in ''Dr. Downey's critique'' to outweigh Dr. Kaufman's testimony entirely. RD, at 76; *see also supra* section II and section III.D. and *infra* section III.E. Finally, although Dr. Kaufman admitted to missing or forgetting about some pages in Applicant's voluminous exhibited medical records, he also convincingly testified that those pages did not change his opinion about Applicant's compliance with the applicable standard of care. *E.g.,* Tr. 506–07.

[29] After the Government objected that the line of questioning was outside of the Prehearing Statement and the ALJ noted that the witness was the ''third . . . describing the same procedures,'' Applicant withdrew one staff witness who had worked at the front desk and was responsible for nursing home-related billings. Tr. 946.

[30] According to Applicant, D.C. died of mesothelioma. Tr. 1002. Although D.C. was a smoker, ''which made him . . . a greater risk to develop mesothelioma,'' mesothelioma was not an issue when D.C. first began seeing Applicant. *Id.* at 1002–03. Applicant's controlled substance prescribing to D.C. at issue in this proceeding is not related to D.C.'s mesothelioma diagnosis.

Regarding Applicant's medical records, I note that at least one record states that D.C. ''never smoked.'' GX 51, at 192. Other medical records for D.C. state that he smoked. *E.g.,* GX 51, at 138 (ten cigarettes a day). Thus, Applicant's medical records do not report consistently on whether or not D.C. smoked and some of Applicant's medical records conflict with Applicant's hearing testimony.

oxycodone.'' *Id.* Although Applicant stated that he was the doctor who ''still managed . . . D.C.'s] headaches,'' he attributed D.C.'s having ''entered himself into the methadone clinic'' to three areas of pain—migraines, osteoarthritis in both knees, and chronic low back pain concluding that ''actually, you know, the methadone helped.'' *Id.* at 1008–09; *see also id.* at 1010 (confirming that D.C. received methadone from a methadone clinic).

According to Applicant, he thought that the 190 milligrams of methadone that the methadone clinic was giving D.C. was too much, causing memory issues and ''more shortness of breath and coughing.'' *Id.* at 1009–10; *see also id.* at 1101 (''Methadone has a seven-day half life. Every methadone you take is going to stay in your body for seven days. For the first four days, you get adequate pain control. The—for the whole seven days you're at risk for respiratory depression. And that's what's dangerous about the drug because at 190 milligrams, I would really be worried about some of this shortness of breath also being respiratory suppression.''). D.C. agreed ''[b]ecause he wanted to go ahead and get down.'' *Id.* at 1011.

Applicant's testimony recounted what he determined to have been successful tapering of other chronic pain patients down from methadone, stating the way he ''did it was ten milligrams every week or every two weeks.'' *Id.* ''And then, usually what I would do is wait a week before I drop them again,'' Applicant explained. He stated that he ''had a lot of success with that,'' predicted that he could get D.C. ''down to you know 30 milligrams of methadone,'' and concluded that ''then I could switch him to a short acting substance like oxycodone and give him that for a week, four days a week . . . [to] keep him from going into withdrawal.'' *Id.* at 1011–12. According to Applicant, ''we finally got him down to I think 30 milligrams and I gave him the prescription that's been brought up in testimony and oxycodone 50 milligrams.'' *Id.* at 1013. ''I gave him that prescription to help him through that period . . . when he stopped the methadone, he would not go into complete withdrawal, but it would . . . help him to get to the point where he had the methadone out of his system and . . . he could take the Suboxone,'' Applicant testified. *Id.*

Applicant stated that D.C. reported his pain was no better and he just did not feel good even though he was not in withdrawal. *Id.* When Applicant increased the amount of Suboxone, D.C. ''ended up with a rash . . . [and] couldn't tolerate it.'' *Id.* So, D.C. ''ended up back on 60 milligrams of methadone, which . . . controlled his pain.'' *Id.* Applicant's testimony did not explain his plan to use Suboxone to treat D.C.'s pain, particularly in light of his own office procedures stating that ''Suboxone is not to be used to treat pain.'' RX 3C (Orientation Manual for Dr. George C. Pursley's Office Based Treatment of Opioid Dependence with Buprenorphine/Naloxone (Informally know[n] as the Suboxone Program)), at 11; *see also id.* at 2 (''Suboxone (buprenorphine + naloxone) is an FDA approved medication for treatment of people with opiate (narcotic) dependence.''); *id.* at 4 (''Who Can Prescribe Suboxone? Not all physicians can prescribe Suboxone. To prescribe Suboxone, a physician must either be a specialist in Substance Abuse treatment or they must have completed specialized training that certifies them as a Suboxone Provider. Once a physician is certified as a Suboxone Provider, they may care for up to 30 patients during their first year of practice and up to 100 patients per year thereafter.'').

At the end of his testimonial narrative of his medical care of D.C., Applicant concluded that D.C. ''was not a diverter. He was just somebody that had pain.'' Tr. 1015. He stated that ''pain is . . . like an emergency . . . everybody's definition of an emergency is different and everybody's definition of pain is different.'' *Id.* His testimony was that ''I've learned one thing in medicine, is patients don't sit in the waiting room waiting to see you for two or three hours, if they don't have something wrong [with] them . . . [and] it's your job to figure out what's wrong,'' and ''that's one thing I've learned in treating pain or any illness, . . . most of the majority of patients, they don't lie to you.'' *Id.* Applicant did not testify that he applied any specific step of the Georgia standard of care or any Georgia requirement, whether issued by the GCMB or the Georgia legislature, as he did his ''job to figure out what's wrong.'' *Id.* He did not describe any physical examination he performed or medical data he gathered to use in his analysis or to inform his assessment of what his patients were telling him about their pain. I find that Applicant's testimonial narrative of the medical care he gave D.C. did not rebut Dr. Kaufman's criticism of it nor did it attempt to counter Dr. Kaufman's exhibit page-by-exhibit page analysis. I find that Applicant did not address, let alone acknowledge, how unusual it would be for a Georgia methadone clinic to give D.C. methadone for pain. *Id.* at 1060–61. Instead, Applicant testified that he is ''still of the belief that all the prescriptions that . . . [he] issued for D.C. in this case were issued within the usual course of professional practice,'' and that he believes he ''complied with all the relevant rules and laws dealing with the prescriptions of controlled substances to D.C.'' *Id.* at 1051.

Applicant similarly presented a testimonial narrative about the medical care he provided M.B., even including some of the same themes that were part of his testimony about D.C. He repeatedly returned to his view that M.B. ''was a very difficult and hard patient to manage, but . . . [he] took it on.'' *Id.* at 1016. Calling M.B. ''a problem patient, a person with problems . . . [a]nd unlucky or another unfortunate person in life,'' Applicant listed physical and mental health challenges that M.B. faced and endured. *Id.* at 1026, 1016–34. Possibly in an attempt to exonerate himself, Applicant emphasized his belief that the physician who treated M.B. before she became his patient started her on a controlled substance. ''I think, he had her on Oxycontin like, 30 milligrams, twice a day or something,'' Applicant stated. *Id.* at 1018. He asked ''what am I going to do with this lady'' because ''when she came to see me, she was dependent.'' *Id.* at 1022. His own office procedures provided the answer to his question, although the record does not support the conclusion that he always followed those procedures. For example, he testified that ''I think, some of her hydrocodone, she got from her husband.'' *Id.* at 1025. According to the second page of Applicant's Pain Management/Drug Addiction Contract, RX 3A, Applicant's patients' relationship with him will be terminated for ''use [of] another person's medication.'' RX 3A, at 2. By way of further example, Applicant testified that he thinks M.B. ''also got a [hydrocodone] script from Dr. Bundy, I think.'' Tr. 1025. Again, according to Applicant's Pain Management/Drug Addiction Contract, Applicant's patients' relationship with him will be terminated if they ''seek or obtain controlled substances from any other doctor or clinic.'' RX 3A, at 2. Applicant did not explain why he did not follow the terms of his own contract when he believed M.B. had violated it.

As if it conclusively established his compliance with the applicable standard of care, Applicant stated that the doses of the controlled substances he started M.B. on when she became his patient, specifically mentioning Klonopin, Adderall, and Percocet,

''pretty much'' remained the same throughout his tenure as her physician. Tr. 1034. ''If you look at from the time I picked her up,'' he stated, ''she was pretty much on the same dosages all the time. . . . [D]id she have exacerbations . . .? Yeah. But I managed her, I dealt with her, . . . that's really, I think a true picture of what I was dealing with.'' *Id.*

While he stated that M.B.'s previous physician ''sent her to a very good psychiatrist'' who diagnosed her with obsessive compulsive disorder, attention deficit disorder, anxiety disorder, and a panic disorder, he also stated that ''Blue No Choice doesn't allow us to—we don't have psychiatrists in practice.'' *Id.* at 1018–19, 1022. Applicant did not address why he did not consult with the ''very good psychiatrist'' about options for their mutual patient. Although he admitted violating the Georgia standard of care when he stated that ''you had to overlook'' M.B.'s drug screens, he did not explain or justify his conscious violations. *Id.* at 1025 (''And so, was she compliant? No. Was she dismissible? No. I mean, but if you look at obsessive compulsive disorder, the more you try to control these people, the more they [sic] going to bunk you.'').

I find that Applicant's testimonial narrative of the medical care he gave M.B. did not rebut Dr. Kaufman's criticism of it or attempt to counter Dr. Kaufman's exhibit page-by-exhibit page analysis. I find that Applicant did not testify about, or seek the admission of, a statute, regulation, or any applicable standard of care that exempts practitioners treating patients with a diagnosed mental illness from the provisions of the GA Pain Management Rule, GCMB Rule 360–3–.02, or the Ten Steps. *Id.* at 1024–26. Instead, I find Applicant testified that he ''believe[s] that all the prescriptions that . . . [he] issued to M.B. . . . [were] issued within the usual course of professional practice.'' *Id.* at 1051.

Applicant addressed the medical care he provided his daughter. He admitted treating her, explaining that he ''thought it was an emergency.'' [31] *Id.* at 1038. He specifically admitted to issuing eight controlled substance prescriptions to her between August 2014 and June 2015. *Id.* at 1056. He also admitted that he did not follow his urine drug screen-related office procedures when treating his daughter. *Id.* at 1053–54; *see also* RX 4, at 2 (ADD and ADHD patients take a urine drug screen at visits). ''I understand it is wrong in hindsight. And, you know, I'm sorry I did it,'' he stated. Tr. 1038. His testimony was that he understood the GCMB position on treating family members, ''but it's not a perfect world and it's my daughter.'' *Id.* When asked if he was willing to make a condition of being granted a registration that he ''not treat anybody under . . . what is ultimately a Georgia regulation'' about the treatment of family members, Applicant stated, ''Oh, yeah. I mean, I make amends.'' [32] *Id.* at 1040.

Applicant testified about his position on his practice's compliance with his own office protocols and also addressed his medical recordkeeping. Regarding compliance with his own office protocols, Applicant stated that we got to have some kind of, you know, ordered system in which we all work in, whether we're digging ditches . . . [or] practicing medicine.'' *Id.* at 1063. He continued: ''I think, you try to, you set protocols, you try to stick with them. Does that always happen? No. . . . [E]verything 100 percent? No.'' *Id.* He restated that ''my practice was a big practice,'' pointed out that ''what we've looked in these charts have been mainly four or five patients,'' and concluded that, ''if you look at my overall practice, . . . I don't think that's a really a good statistical sampling, if I could memorize [sic] my statistics of my practice of that many people.'' *Id.* He then admitted, again, that he's ''sure'' his ''protocols weren't 100 percent.'' *Id.* On re-direct, he added that ''I think you need to be able to deviate from a protocol if you really find that it's necessary.'' *Id.* at 1064.

Regarding his medical recordkeeping, Applicant agreed that, when he signs off on a record of a patient office visit, he accepts responsibility for everything in that record.[33] *Id.* at 1052.[34]

Applicant described the instability in his medical practice after, and the ramifications of, his voluntary surrender of his registration. *Id.* at 981–85. He testified that both Georgia and South Carolina renewed his medical licenses after his surrender, and that he was able to retain his hospital privileges on a temporary basis for a year after the surrender. *Id.* at 983, 985–97. Applicant testified that he stabilized his practice by hiring a physician whom he knew, among other ways. *Id.* at 981–82, 987. They found other physicians for Applicant's Suboxone patients but a ''lot of the . . . heart failure, hypertension guy, diabetes, whatever patients, chronic, other chronic patients, we were able to just continue taking care of those people.'' *Id.* at 988. After sixteen months, though, Applicant testified that he closed his practice. *Id.* at 992. He stated that even though his nursing home business enabled him to pay for his staff and his building, he did not have a salary. *Id.* For the sixteen months, he testified, he ''was able to live off of some of . . . [his] medical director[']s reimbursement, being a medical director.'' *Id.* After he closed his practice, he testified, ''we have been able to just do the long-term care and I do some hospice work.'' *Id.* at 993–94. Subsequently, Applicant testified that ''if my mind stays good and I can practice, I'm going to practice as long as I can. . . . I'd like to just be able to

[31] Even though the OSC does not charge it, Applicant admitted treating his wife and stated ''I treated my wife, thought I was being helpful and I understand that it was wrong and I—it is what it is.'' Tr. 1039–40. I note that the OSC alleges that Applicant treated his daughter, but not his wife. I see the record evidence documenting the dispensing of controlled substances to his wife and the RD's analysis of Applicant's testimonial admission that it was wrong for him to treat his wife. *See, e.g., id.* at 1040; RX 11F, at 66; RD, at 56, n.42. Given the content of this case, I see no reason to consider Applicant's admission that it was wrong for him to treat his wife, and I do not do so.

[32] I note that it is incumbent on Applicant to follow the applicable standard of care regardless of his DEA registration status.

[33] I disagree with the RD's conclusion concerning Applicant's testimony on Tr. 1052. RD, at 56 (''Ultimately, . . . [Applicant] accepted full responsibility for everything within the medical records for which he signed off.''). Instead, Applicant was agreeing, on cross examination, with Government Counsel that ''You also understand that when you sign a record of a patient office visit, right. When you're done, if they're there, however you did it, you would sign off on a patient record? . . . You understand that once you've signed off on it, you accepted responsibility for everything that . . . was in that record.'' Tr. 1052.

I note Applicant's testimony indicating that he knowingly sacrificed having medical records that met the standard of care so that he could take care of his patients. *Id.* at 1041 (''I think I did the best documentation. I put more—my hands on the patient and taking care of the patient then [sic] I do treatment chart. But I know that's not what we need to do, but sometimes you got to give your patients the time and not a computer.'').

[34] RD footnote 43 correctly states that recordkeeping is a ''substantive allegation . . . upon which a denial of Registration can be based.'' RD, at 56, n.43. Its statement that ''deficiencies in maintaining . . . [Applicant's] medical files . . . [were] not alleged in the Order to Show Cause'' may be referring specifically to the OSC section entitled ''Recordkeeping Violations,'' as opposed to the OSC section entitled ''Unlawful Prescribing of Controlled Substances,'' whose legal underpinnings include medical record requirements related to controlled substance prescribing. OSC, at 3–8; *supra* section II and section III.

commit my practice to long-term care, home health, hospice.'' *Id.* at 1067–68.

Applicant also testified about his in-office pharmacy. He stated that ''the reason I started it, it was—I could get people medications for, like, $10, like . . . high blood pressure medicine, diabetes medications, COPD medications and so forth, anti-inflammatories. . . . '' *Id.* at 991. ''[O]r they would do copays on these same drugs I had, excluding schedules, for $4,'' he continued. *Id.* Regarding controlled substances, Applicant testified that ''we had some patients that did not have insurance and they did not have—they had to pay cash and so, . . . [the in-office pharmacy] was good for my patients.'' *Id.* Applicant admitted that he did not have a licensed pharmacist working at his in-office pharmacy. *Id.* at 1051–52. He stated he was unaware that only a licensed pharmacist may lawfully fill a written prescription. *Id.* at 1052. Since the OSC does not charge Applicant with a violation of this requirement, his admission is not relevant to this proceeding. *See id.* at 1080–81.

After he admitted to not being ''aware'' that the only person who is allowed to fill a written prescription is a licensed pharmacist, Applicant addressed his prospective compliance with applicable state and federal medical standards in response to questions from ALJ Dowd. He testified that it is his ''intention to become fully compliant with all of the regulations.'' *Id.* at 1068. ALJ Dowd asked ''[w]hat about learning any of these regulations. . . . [N]obody knows them by heart, but . . . you're responsible for knowing . . . both the Georgia regulations as well . . . [as] the DEA regulations if you're going [to] run a doctor's office.'' *Id.* Applicant answered, after having stated that his current age is 66, that he is ''always willing to learn anything.'' *Id.* at 1068–69. He added that, ''I think, the one thing, I don't think I left a lot of dead bodies laying around.'' *Id.* at 1069.

Having read and analyzed all of the record evidence, I find that Applicant is the witness with the most at stake in this adjudication.[35] I find that, while Applicant's testimony does include reliable statements, it also includes statements that lack credibility, are implausible, and/or are not persuasive. I find that Applicant's testimony must be considered with much caution, and where his testimony conflicts with credible record evidence, I do not credit it.

The ALJ certified Applicant's first expert, Dr. John Martin Downey, as an expert in pain management and interpretation of medical records.'' *Id.* at 534. Dr. Downey testified about his education, his military service, his medical practice, his affiliations, and his involvement with the Pain and Investigation Committees of the GCMB. *Id.* at 525–34. He confirmed on the record his familiarity with three Applicant exhibits: RX 17 (concerning D.C.), RX 18, RX 19 (concerning M.B.), and RX 20 (concerning a medical record that the Government abandoned). *Id.* at 534–37. Likewise, he denied being familiar with RX 21 (concerning Applicant's daughter). *Id.* at 537. In addition, he testified that he reviewed the ''Georgia Professional Conduct Rule,'' ''the control [sic] substance guidelines and the pain management rule, I guess that would be called,'' a letter from a patient, the OSC, and Applicant's ''summaries.'' [36] *Id.* at 545–46.

Dr. Downey testified that he knows of Applicant because they practice in the same community and Applicant has referred patients to him over the years. *Id.* at 546. He referred to Applicant as a ''colleague in a sense, yes. Consulting.'' *Id.* at 547. Dr. Downey stated that he had the occasion to review the medical records for Applicant's patients who were referred to him for a pain consultation or an electrodiagnostic study, or who became his patients after Applicant closed his practice. *Id.* According to Dr. Downey, ''as a general rule,'' his medical record review of Applicant's patients did not indicate practice below the standard of care expected of doctors in Georgia. *Id.* at 547–48. ''In fact,'' he testified, ''I looked, with the patients I recall, no changes were made in their pain regimen.'' *Id.* at 548. Dr. Downey did not explain why ''no changes were made in their pain regimen'' necessarily meets the applicable standard of care. Dr. Downey admitted that he did not know if the medical records on which he based this assessment had been prepared by Applicant or by the physician Applicant hired to write all of the controlled substance prescriptions after Applicant voluntarily surrendered his registration. *Id.* at 608–12.

In Dr. Downey's opinion, Dr. Kaufman's evaluation was ''a little overly critical, because Dr. Kaufman and I are both pain specialists and critiquing a primary care physician . . . it was a little bit of an overstep to be so critical, I think.'' *Id.* at 549. Dr. Downey did not testify that Applicant was exempt from complying with GA Pain Management Rule, GCMB Rule 360–3–.02, or the Ten Steps, for example, because he is a primary care physician, not a pain specialist.

Dr. Downey stated that, taking ''as a whole'' the medical records for Applicant's patients that he reviewed for this proceeding, he ''was impressed with the care. The multiple medical conditions, managed the consultations, the bracing, the referrals to physical therapy, . . . hospitalization, post-hospitalization management. I was impressed. I would say they stack up highly.'' *Id.* at 569. He did not explain whether ''stack up highly'' meets the applicable standard of care and he did not address the standard of care for medical record required by the GA Pain Management Rule, the GCMB Rule 360–3-.02, or the Ten Steps.

Dr. Downey testified that he found, in Applicant's medical records, mentions of urine drug screens, office visits, referrals, medical testing, counseling, and pain contracts. *Id.* at 577–78. He stated that he found documentation of health, physicals, labs, x-rays, prior medical records, records from and consultations with other doctors, and ongoing evaluation and treatment. *Id.* at 580. Dr. Downey opined that Applicant treated pain diagnoses appropriately.[37] *Id.* at 579. He did not present persuasive elaboration on the connection among what he ''found'' in Applicant's documentation, his opinion that Applicant treated pain diagnoses appropriately, and the applicable standard of care.

During his testimony, Dr. Downey offered his opinion and evaluation of electronic medical records. *Id.* at 537–45. According to Dr. Downey, electronic medical records are ''one of the worst things to happen to medical practice that I can recall in my experience since 1983. . . . Being an old doctor that can't type, a lot of the things get left out.'' *Id.* at 538–39. Dr. Downey testified that electronic medical records ''took the physician contact with the patient out of the picture, put the physician's head and face and fingers into a computer, and poor records result[ed].''

[35] The RD does not address Applicant's credibility in one spot.

[36] There is no indication of the content of Applicant's ''summaries,'' and there is no admitted exhibit with this title.

[37] During his testimony, Dr. Downey offered his views, that he developed since 1995, on treating pain patients —specifically that there is ''outside pressure'' to reduce the amount of pain medicine given to legacy patients, and that treating pain patients has turned doctors into being ''almost policemen'' due to urine drug screen and prescription drug monitoring program requirements. Tr. 549–61.

Id. at 538; *see also id.* at 542. He recounted an experience he had to make the point that a Post-it note ''with just a few chicken scratches on it . . . told us more . . . than ten pages of electronic medical records that say nothing.'' *Id.* at 538–39.

Dr. Downey testified that both his and Applicant's practice used ''AdvantaChart.'' *Id.* at 539. According to Dr. Downey, this electronic medical record software has ''limited space to put physical examinations. If you're typing or trying to put in a physical examination, even with voice-activation, you'll get the 50 characters, and it stops. So you just—you give up. I gave up on it.'' *Id.* Dr. Downey also testified that ''[i]t's very common to see an error'' in electronic medical records. *Id.* at 540. About ''some of the records I saw for review of this case,'' he testified, ''obviously, the wrong button was pressed.'' *Id.* According to Dr. Downey, ''the history is somewhat reliable because that's typed in, . . . and in most of the time the plan is somewhat reliable because it's typed in. But anything between . . . is just kind of well, let's see if we can get something out of it.'' *Id.* at 540–41. Handwritten records are ''much easier'' and ''much more accurate,'' according to Dr. Downey, because ''you can write what you're thinking.'' *Id.* at 542. Dr. Downey concluded that ''records before were handwritten and you couldn't read them. . . . [T]he records now are typed . . . and . . . they tell you nothing.'' *Id.* at 541.

Whether doctors handwrite or type their medical records, Dr. Downey agreed that they ''are still required to properly document patient visits.'' *Id.* at 606. To ensure a complete medical record, Dr. Downey supplemented the electronic AdvantaCharts record with his handwritten notes. *Id.* at 607. ''Well, when I had the AdvantaCharts . . . , because I couldn't put enough information [in electronically], . . . we had a separate sheet, separate office visit sheet.'' *Id.* During cross-examination, Dr. Downey did not answer when asked whether he saw that Applicant had supplemented his AdvantaCharts electronic medical records with handwritten notes. *Id.*

Dr. Downey compared the medical records he has reviewed, apparently during his work for the GCMB physician investigations committee, with Applicant's medical records. *Id.* at 531–32, 543. According to his analysis, ''actually, [Applicant's medical records are] better than most that I see at the record requests for the Georgia Board, because there's a paragraph at the front that's the beginning. It says what's going on. There's a paragraph, again, of what's the plan, and a lot of medical records don't even have that.'' *Id.* at 543–44; *see also id.* at 578. Dr. Downey continued by stating that, although ''you can't find what the result of that office visit is going to be . . . [a]t least . . . [Applicant's] records have a plan, have a start, and that's really what you need.'' *Id.* at 544. He concluded that Applicant's records are not ''outside the usual standard of care or course of professional practice in Georgia,'' explaining his conclusion as ''that's comparing medical records across multiple specialties, over three years of doctors that received complaints, either erroneous complaints, or hassle complaints, or genuine complaints,'' and that Applicant's records are ''not unprofessional.'' *Id.* at 544–45. In other words, Dr. Downey's conclusion that Applicant's records are not ''outside the usual standard of care or course of professional practice in Georgia'' is based on his comparison of Applicant's records with the records of Georgia physicians whom the GCMB is investigating due to complaints.[38]

Dr. Downey testified that Dr. Kaufman ''implied'' that Applicant ''would be expected'' to conduct a urine drug screen, possibly referring to Applicant's legacy patients when he stated that ''[t]here was no concept of a urine drug screen back in those days.'' *Id.* at 584. Dr. Downey stated his disagreement with what he characterized as Dr. Kaufman's implication. *Id.* ''A urine screen 18 years after the first office visit,'' Dr. Downey testified, ''[i]t didn't make sense to me for that to be a criticism.'' *Id.* According to Dr. Downey, ''there is no law or regulation that says . . . [a urine drug screen] needs to be done, but it's kind of filtering through the literature. And that's what it is, it's to say what's in the system the first day they come in the office.'' *Id.; but see id.* at 624–25 (Dr. Downey's testimony that GCMB investigations of physicians inquire whether they are checking urine drug screens. ''And the answer is yes, and then they go back down to the next question. . . . [T]hey don't really delve into the . . . [urine drug screen] result. They look at are you . . . performing . . . [urine drug screens]? Are you meeting the checkmark.''). Despite his criticism of Dr. Kaufman, though, Dr. Downey admitted that the GA Pain Management Rule applies to Applicant's controlled substance prescribing since the Rule's enactment in 2012, including to the controlled substance prescriptions that Applicant subsequently wrote for patients he had been treating for years before the Rule's enactment. *Id.* at 602; *see also id.* at 600–03 (Dr. Downey's agreement that Applicant must comply with the GA Pain Management Rule (GX 4) and GCMB Rule 360–3–.02 (GX 5)).

Dr. Downey stated that he and the other members of the GCMB would be ''concerned'' if they were presented with evidence of a doctor's ''ongoing practice for a number of years . . . [of] prescribing to an immediate family [member] over and over and over, over again for prescriptions such as Adderall and Vyvanse.'' *Id.* at 613–14. He agreed that such a scenario ''starts to look less like an emergency.'' *Id.* at 614. He stated that he does not believe he would consider a doctor's seeking insurance preapproval for prescribing to a family member for an entire year to be a demonstration of emergency prescribing. *Id.*

I agree with the RD that Dr. Downey, as one of Applicant's experts, ''offered more summary opinions or assessments, and less frequently tied . . . [his] conclusions directly to specific regulatory provisions.'' RD, at 76. I also agree with the RD that Dr. Downey ''appeared to be influenced by the practicalities and realities of medical practice . . . in evaluating'' Applicant's medical practice and did not elucidate, or tie his opinions or assessments to, the applicable standard of care.[39] *Id.* The record of Dr. Downey's testimony is replete with examples.

For example, concerning electronic medical records in general and Applicant's medical records in particular, the primary focus of Dr. Downey's testimony was his opinion that electronic medical records are ''one of the worst things to happen to medical practice that I can recall in my experience since 1983'' and his self-interested conclusion that ''[b]eing an old doctor that can't type, a lot of the things get left out.'' Tr. 538–39. It is in

[38] Applicant's sixth exception urges me to adopt Dr. Downey's assessment of Applicant's medical records. Applicant Exceptions dated September 10, 2018 (hereinafter, Applicant Exceptions), at 7. I reject Dr. Downey's assessment as it is not an accurate statement of the applicable standard of care. *Accord* Tr. 591–92; *see also infra* n.39.

[39] I do not agree that Dr. Downey always ''presented his testimony in a professional, candid, and straightforward manner.'' RD, at 66; *see, e.g.,* Tr. 590 (Dr. Downey testifying that ''I hate to say this. Could you repeat that question? I forgot how I was supposed to answer that.''); *id.* at 591–92 (ALJ's statements accompanying his sustaining a relevance objection by the Government to Dr. Downey's testimony: ''Dr. Downey, you've been giving your opinion, and you've compared . . . [Applicant's] treatment and whatnot to a lot of the doctors that you've reviewed . . . for possible disciplinary action before the . . . [GCMB], but that's not the standard that we're going to use. We're going to use whether it complied with the regulations of Georgia.'').

this context of derogatory statements about electronic medical records, in general, and the resulting inadequacy of his own medical records that Dr. Downey summarily forgave the deficiencies of Applicant's medical records. While ''you can't find what the result of that office visit is going to be,'' Dr. Downey testified, ''[a]t least . . . [Applicant's] records have a plan, have a start, and that's really what you need.'' *Id.* at 544. Although acknowledging that ''[t]here are some [electronic medical record] software programs that allow a[n] unlimited amount of information,'' Dr. Downey's evaluation of Applicant's medical records did not state the applicable standard of care for medical records or address whether Applicant could have availed himself of one of the software programs with more functionality to assist his compliance with that standard. *Id.* at 539. While he testified that he, himself, resorts to adding handwritten paper records to his electronic medical records, he did not even suggest using handwritten paper records, as he did, as a way that Applicant could bring his medical records up to the applicable standard of care.

By way of further example, while stating that he is ''not complaining,'' Dr. Downey testified that ''the physicians in pain management are now almost policemen'' due to the ''opioid epidemic.'' *Id.* at 552; *see also id.* at 554 (''[T]he patient has to pay for the test that's required to prove that they are taking the medication they're taking and not taking something else, which 70 percent of the people that are in pain are compliant. And sometimes more, 80 percent.''). ''We have to monitor urine drug screens, for example, to make sure there's compliance, which is almost a legal aspect,'' he added. *Id.* at 552. He spoke extensively about his involvement in a proposal that the GCMB ''reduce the urine screen requirement from four per year to one per year because . . . [s]o many doctors are pulling away from taking care of people in pain because of the police aspect.'' *Id.* at 553.

Dr. Downey also described point of care urine drug screens as ''disappointingly inaccurate'' and spoke extensively about how the interpretation of results ''can be a challenge.'' *Id.* at 555. ''Has anyone seen one of these cups,'' he asked. *Id.* He elaborated:

> It's a plastic cup, and it's got some stripes on it, some paper stripes with chemicals in there. Urine goes in, and you try to read that chemical. If two lines show up on the paper strip, then that test is negative. If one line shows up, and that little pink line is so subtle that a lot of times three or four people have to look and say is there a line there or not? If it's not there, the test is positive for that substance. If the line is there, this is negative, and it's okay. So it can be some visual acumen challenge to determine whether it's positive or negative . . . for any particular one of those substances that it can test.

Id. at 555–56. He stated that ''[y]ou're taking that urine screen because you have to. It's state law to take it four times a year, so you take it, but the interpretation is almost anybody's guess.'' *Id.* at 557. ''It becomes a, basically, an exercise in frustration,'' he concluded. *Id.* At the forefront of Dr. Downey's testimony were what he considers to be impositions on doctors by medical, legislative, and law enforcement attempts to address the ''opioid epidemic.'' *Id.* at 552–54.

In subsequent testimony, Dr. Downey stated that the GCMB does not ''delve into the . . . [urine drug screen] result'' in evaluating a doctor's prescribing habits. *Id.* at 624–25. ''They look at are you . . . meeting that checkmark,'' he testified. *Id.* at 625. How a doctor deals with multiple, inconsistent urine drug screens is ''not even brought up,'' Dr. Downey stated. *Id.* When asked if the GCMB would intervene regarding how a doctor handles multiple, inconsistent urine drug screens, Dr. Downey answered that ''I wouldn't say never, but it hasn't happened in my three years.'' *Id.* Dr. Downey did not explain the differences between his testimony and section (2)(f) of the GA Pain Management Rule. GX 4, at 2 (360–3–.06(2)(f)) (''The physician shall respond to any abnormal result of any monitoring and such response shall be recorded in the patient's record.'').

I base my Decisions and Orders on the CSA and, as the ALJ indicated during the hearing, on all other applicable authorities. Tr. 591–92. Accordingly, I find that Dr. Downey's testimony is largely not germane and certainly not as germane to my adjudication of this matter as Dr. Kaufman's testimony. In the event of inconsistencies between the testimony of Dr. Downey and the testimony of Dr. Kaufman, I will credit Dr. Kaufman's testimony.[40]

The ALJ certified Applicant's second expert, Dr. Joseph Bailey, as an expert in general medicine after the Government's initial objection. *Id.* at 926–27; RD, at 67. Dr. Bailey retired after a thirty-three year career as Chief of Rheumatology at the Medical College of Georgia. Tr. 920. He stated that the ''loss of . . . [Applicant's] presence . . . has been a major negative,'' that Applicant ''has demonstrated, repetitively in my judgment, the highest quality of the practice of medicine that one could ask out of anyone,'' and that Applicant ''is the kind of physician that I would go to if I had illness and was in need of care.'' *Id.* at 935–36.

Dr. Bailey testified that he spent fifteen to twenty minutes reviewing M.B.'s medical records, and ''did not make an effort to go through every component of that chart. I was unable to.'' *Id.* at 941. Based on his review of the medical records for M.B., he agreed that ''M.B. had complex medical issues . . . , as well as psychiatric issues.'' *Id.*

The RD states that ''Dr. Bailey's limited review of the medical records would limit the weight given to his testimony.'' RD, at 68, n.46. I agree. Further, I find that, given the very limited relevance of Dr. Bailey's testimony to the adjudication of this matter, I see no need to assess Dr. Bailey's credibility.

Applicant also called three licensed practical nurses he employed at his practice to testify. The first one, the nurse manager at his practice (hereinafter, LPN), testified about her education, her employment history, and her current lack of employment due to the closure of Applicant's office. Tr. 637–38, 806–07. When she worked for Applicant as nurse manager, she was responsible for the staff and student schedules, and ''made sure office policies and procedures were handled.'' *Id.* at 639. She described the daily operation of Applicant's office, including Applicant's demeanor with patients and the procedures for new and existing patient office visits. *Id.* at 641–44. LPN testified that, for the six years before the practice closed, Applicant had a nurse with him during patient visits. *Id.* at 647. She testified that the nurse would help Applicant enter information into the electronic medical record. *Id.* If Applicant decided during the office visit to put the patient on a controlled substance, the nurse ''would type it up into the system'' when Applicant was with her. *Id.* The nurse would print the prescription and get it from the printer. *Id.* Applicant ''would make sure that that's exactly what was in the computer, and then he'd sign it and give it to the patient,'' LPN

[40] I do not agree that Dr. Downey's testimony was always ''sufficiently objective, detailed, plausible, and internally consistent to be generally reliable.'' RD, at 66. As already discussed, Dr. Downey's testimony is marked by his personal opinions about matters such as the state of the medical profession and legal and professional requirements currently imposed on doctors who prescribe controlled substances. I find that his reference to, and discussion of, Applicant's controlled substance prescribing documented by Applicant's medical records is virtually non-existent, and that the usefulness of his testimony to evaluate the relevant evidence pales when compared to Dr. Kaufman's testimonial contribution to the adjudication of this matter.

stated.[41] *Id.* LPN testified that Applicant ''would see . . . [patients receiving a prescription] at least once every 90 days.'' *Id.* at 649; *but see id.* at 815–16 (LPN testimony that ''[w]e didn't see . . . [Applicant's daughter] on a regular basis. . . . I wouldn't even say a few times a year. . . . Maybe once her dentist was out of town. . . . It wasn't a regular thing. It was just . . . [e]mergency kind of reasons.''). LPN testified that Applicant ''never'' signed blank prescriptions. *Id.* at 649–50.

LPN testified that the office policy for patients for whom Applicant prescribed controlled substances was a monthly urine drug screen and a visit every three months.[42] *Id.* at 644–45, 773. She stated that a patient would call the office thirty days after Applicant prescribed the controlled substance and say, ''I've had my 30 days, I'm going to come in tomorrow and pick up my prescription.'' *Id.* at 645. Then, according to LPN, ''[w]e would get the prescription ready if, after we looked at the chart and made sure that they did have a visit, and then the patient would come in the next day.'' *Id.* LPN continued to describe the controlled substance refill process by stating that ''[w]e would do a urine drug screen on them, and if they didn't fail the urine drug screen, if it was positive for what they were on and negative for what they weren't, we would get them their prescription.'' *Id.*

LPN's testimony did not explicitly state who interpreted urine drug screens administered before a controlled substance refill prescription could be given out. Her testimony, though, did not describe a role for Applicant or for the practice's Physician Assistant in the process. Her description first advised that ''[w]e would do a urine drug screen on them'' and, after explaining what passing a urine drug screen means (''it was positive for what they were on and negative for what they weren't''), she continued by stating that ''we would get them their prescription.'' *Id.* From LPN's continued use of the pronoun ''we,'' without defining it, and her use of the word ''get,'' I find that the staff, not Applicant or any registrant, interpreted urine drug screen results during the controlled substance refill process implemented in Applicant's practice.[43]

When asked what would happen if there were an abnormal urine drug screen, LPN testified that ''[w]e would send it off for a confirmation.'' *Id.* On follow-up, when asked if the ''patient would have to see anybody if there was an abnormality,'' LPN stated that ''[i]t depended on the abnormality.'' *Id.; see also id.* at 739–40. In other words, LPN did not testify that all abnormal urine drug screens required the immediate attention of a registrant, or at least the attention of a registrant before the controlled substance refill was handed out. ''[S]ay he [Applicant] had given them Klonopin before, and they were negative for Klonopin, then we would go ahead and give them their prescription . . . [and] [w]e would send it off for confirmation,'' LPN testified. *Id.* at 646. In other words, LPN's testimony distinguished between the prior action of Applicant in having prescribed the controlled substance Klonopin and the subsequent unilateral action by the staff (''we would go ahead and give them their prescription''). *Id.* LPN's testimony continued with her stating, ''Klonopin, it's a benzo[diazepine], and it's affected by light . . . [s]o then we may get a negative . . . when they've been on it before. So we would go ahead and continue the Klonopin.''[44] *Id.*

When asked if ''someone like M.B. . . . failed to [sic] test would she have to see somebody,'' LPN responded that ''[s]he would normally see'' Applicant or the Physician Assistant. *Id.* I note that LPN was not asked, and did not state, whether ''someone like M.B.'' would be *required* to see Applicant or the Physician Assistant *before* being given the controlled substance refill prescription. I find, however, that LPN's use of the word ''normally'' means that there were times when ''someone like M.B.'' would not see either Applicant or the Physician Assistant before receiving a controlled substance refill prescription. In addition, according to the ''Office Protocol and Pain Treatment'' that LPN authenticated, ''established patients'' on ''controlled meds'' visit every ninety days ''unless [urine drug screen] failure . . . then sched[ule] visit.'' RX 2, at 1. I find that the language in the Office Protocol and Pain Treatment document, ''then sched[ule] visit,'' makes clear that ''established patients'' are not required to see Applicant on the same day as the urine drug screen failure. The same Office Protocol and Pain Treatment document also instructs that the results of the urine drug screen given at the time of prescription ''pick up'' are ''scanned into chart for review'' and ''notes'' that urine drug screen ''failure, p[atien]t needs app[ointmen]t to discuss. Chart and UDS will be reviewed at time of visit, p[atien]t will be counseled and may be released from our care.'' *Id.* Thus, I find that the Office Protocol and Pain Treatment document does not make a meeting with Applicant or any registrant a prerequisite to the release of a controlled substance refill prescription. I also find that Applicant's Office Protocol and Pain Treatment document does not instruct the staff to withhold a controlled substance refill prescription in the event of an abnormal urine drug screen.

LPN testified that for ''suspicious patients, patients that failed their drug screen,'' or about ten to fifteen times a week, and for new patients, ''[t]here was a DEA website that we . . . would go on . . . [to see] what doctors they had gotten prescriptions from, if they were controlled prescriptions, when those were filled at the pharmacy, [and] what pharmacy filled it.''[45] Tr. 649, 794. I find that this testimony and the portion of the Office Protocol and Pain Treatment document stating that the ''rx website'' is only to be checked if the new patient ''states recently on controlled meds and if the pt does not have records'' are inconsistent. RX 2, at 1.

A patient who received a prescription could fill it at the pharmacy in Applicant's office. A licensed practical nurse (hereinafter, PLPN) on staff ''ran'' the pharmacy, filled prescriptions, and was responsible for maintaining the controlled substance records. Tr. 650, 807. The office manager auto-ordered the medicine for Applicant's office pharmacy. *Id.* at 651. The medicine came in prefilled, sealed, and labeled bottles. *Id.* According to LPN, the office pharmacy was opened to help patients without insurance who could not afford their medication. *Id.* at 662. ''[S]hortly after,'' she added, a ''year, year and a half after we started our pharmacy, big-name pharmacies started doing the $4 plan, where patients could go and get some of their generic medications for $4.'' *Id.* She stated that the office pharmacy ''couldn't beat $4, so we didn't do well with that.'' *Id.* LPN

[41] LPN testified that Applicant used blue watermark prescription paper and signed prescriptions in red ink. Tr. 648.

[42] According to DI, however, a urine drug screen was not required when a family member picked up the controlled substance refill prescription including, possibly, a Schedule II refill prescription. Tr. 131.

[43] The testimony of other witnesses whom Applicant called informs this finding. *Infra* section III.E.

[44] LPN testified that ''also, if you stop Klonopin that patient might have a seizure.'' Tr. 646.

[45] From the description, it appears that LPN is describing the Prescription Drug Monitoring Program, not a DEA website. *See, e.g.,* RX 10; *see also* Tr. 792–95.

continued by stating that ''our pharmacy was on auto-order, so they were automatically just sending us a standard order . . . and we ended up having to dispose of those that were expired'' since ''we didn't sell a lot of medications.'' *Id.*

LPN was at work when DEA inspected Applicant's office on August 11, 2015. *Id.* at 653. She testified that the DEA team arrived ''right after lunch'' and asked to see Applicant, the Physician Assistant, and the pharmacy. *Id.* at 653–54. She stated that she, Applicant, PLPN, and GS went to the office pharmacy. *Id.* at 654. Applicant returned to seeing patients, as permitted by the DEA team. *Id.* According to LPN, the DEA team asked her questions and asked her to get and show them things. *Id.* at 658. LPN testified that the DEA team asked her ''if we had a patient that came in at 2:00 [on August 6, 2015], and who was that patient, and did they get a prescription.'' *Id.* at 738. She reported her response as ''[w]e did not have a patient that came in on 2:00 that Thursday. We closed early that day. It was 12:30 when we closed.'' *Id.* LPN stated that Applicant was in the office on August 6, 2015, ''just to review some paperwork, review some prescriptions, sign some things,'' and that the Physician Assistant was in the office to see all of the patients who came in on August 6, 2015. *Id.* at 738–39. He was also in the office all day on August 7, 2015. *Id.* at 739. On cross-examination, LPN testified that the ''printed'' dates on RX 6 and RX 7 (August 18, 2015) mean that she could not have given the DEA team either of those documents on August 11, 2015. *Id.* at 809. Instead, she stated that the August 6 and 7, 2015 patient schedule reports she handed the DEA team are marked GX 86. *Id.* at 810.

LPN testified that the DEA team asked ''for certain records and patient paper records, which we did not have because . . . we had [electronic medical records].'' *Id.* at 658; *see also id.* at 668–69, 736–37. LPN testified that she offered to show GS the three-ring binders containing the medication information stickers attached to the corresponding filled prescription, but ''he said he didn't want to see that right then.'' *Id.* at 661, 664–65. She said that GS told her, Applicant, and PLPN that ''there were just minor issues, and . . . he would send a letter, and we would have to comply with the letter, you know, fix the issues, and he said other than that, the pharmacy was okay.'' [46] *Id.* at 666. LPN testified that Applicant told the staff that ''DEA threatened to take us all to jail, and he signed over his things.'' *Id.* at 742. She clarified on cross examination that no one on the DEA team told her that she would go to jail, only Applicant. *Id.* at 807.

During LPN's testimony, many Applicant exhibits were admitted into the record.[47] *Id.* at 746–805. LPN described RX 5A as concerning ''patients that we released from our office'' and including a list of ''[m]aybe more'' than 100 names and, annotated by her handwritten notes, ''[l]etters to different patients letting them know that they were released from our care.'' *Id.* at 774, 776, 779; *see* RX 2, at 1 (''Release from our care-pts that have been released will not be allowed to become pts again. Pts can be released for non compliance, deception, . . . [urine drug screen] failures.''); Tr. 814–15 (LPN explaining that ''[t]hings would happen'' such that instructions were not followed and precautions were not taken). I find, from my review of pages in RX 5A containing legible handwritten notes, at least five situations in which Applicant was prescribing controlled substances concurrently with another physician. RX 5A, at 28, 41, 43, 50, and 55; *cf.* Tr. 649. I see nothing in the record that explains convincingly why it took months for Applicant's office to address matters that would appear on a query of the Prescription Drug Monitoring Program. I also find at least nine instances in which Applicant continued to prescribe controlled substances despite abnormal urine drug screens. RX 5A, at 29, 46, 48, 49, 52, 76, 83, 87, and 89; *cf.* RX 2, at 1. Again, I see nothing in the record that explains convincingly the continued controlled substance prescribing.

I agree with the RD that LPN ''presented her testimony in a professional, candid, and straightforward manner'' and, ''[f]or the most part, . . . [her] testimony was sufficiently objective, detailed, plausible, and internally consistent to be reliable.'' RD, at 37. As did the ALJ, I ''merit [LPN's testimony] as generally reliable.'' *Id.* I note, though, that there are discrepancies between the testimonies of LPN and PLPN, particularly regarding the controlled substance refill process.

Applicant also called PLPN, the licensed practical nurse staffing the pharmacy, who testified about her professional education, her lack of a pharmacist license, her past employment, and her current unemployment after working for Applicant since 1999 until he closed his practice in November 2016. Tr. 819–22, 911. PLPN described the pharmacy in Applicant's office, including her duties, and how she dispensed medicine, including controlled substances, from it. *See, e.g., id.* at 820–23. She testified that the office handled the prescriptions for the nursing homes Applicant visited. *See, e.g., id.* at 837–38. She explained how Applicant's practice processed requests for refills, including administered urine drug screens, and the use of a box at the front desk as the repository for signed refill prescriptions. *Id.* at 823–38, 840–69, 889–90, 892–901, 903–12, 914–18.

According to PLPN, the process at Applicant's practice for handling requests for refills of controlled substance prescriptions started with a telephone call requesting a refill. *Id.* at 825. ''As long as it was . . . right there at the 30 days and there's no notation that they had to be seen, . . . then we—the prescription would be printed, it would be put in the folder for . . . [Applicant] to sign, so he always viewed everything, signed everything,'' she testified. *Id.* PLPN's testimony was inconsistent regarding whether Applicant always approved and signed all of the controlled substance refill prescriptions she prepared.[48] *Id.* at 832 (''He always approved them.'') *contra id.* at 826 (''Sometimes . . . [Applicant] would come around and say they need to come in.''). PLPN's testimony is consistent that Applicant did pre-sign controlled substance refill prescriptions. The prescriptions that Applicant signed were ''filed in the prescription pickup bin that we have'' at the front desk, PLPN testified. *Id.* at 827. They were filed alphabetically ''to try to find them easier,'' she added. *Id.*

When refill requesters came to the office to pick up refill prescriptions,

[46] LPN stated that ''[i]n June 2012 the State came in and inspected the pharmacy. We didn't have any problems. . . . We didn't hear anything else back from them after that. They said it was fine when they were there.'' Tr. 667–68.

[47] LPN also testified that the handwriting on one of the medical records for D.C, RX 17, at 64, ''looks like [Applicant's spouse's] handwriting . . . [t]hat was added later. That wasn't part of the patient's record.'' Tr. 805; *see also supra* section III.D. (Dr. Kaufman's testimony that the handwritten statement in DC's medical records about where the Suboxone came from is probably not correct, yet the Suboxone was an illegally obtained substance, a problem that Applicant did not address).

[48] Counsel's question to PLPN was not specific (''We may have covered this in part, but I would like to make sure we cover it in depth. When the patient came to the office to pick up a . . . prescription, what was the procedure that was followed?). Tr. 831–32. Nevertheless, the context of PLPN's testimony makes clear that she was describing the procedure followed for picking up controlled substance refill prescriptions because she stated that, after the pre-signed refill prescription was located in the box up front, ''then they would put into the system for a urine drug screen.'' *Id.* at 832. According to the Office Protocol and Pain Treatment document, it is controlled substance refill prescriptions that involved a urine drug screen. RX 2, at 1.

they would first have a urine drug screen. *Id.* at 826. PLPN described how she and ''the office'' monitored the submission of urine samples. *Id.* at 833. She also described how the staff interpreted the urine sample. *Id.* at 834. ''They would check the temperature. They were also looking at the color, and . . . the panel on the cup would tell them what substance was in the urine, and there's . . . we had a sheet that was a checklist. As to whether it was positive or negative, you would check, you know,'' she testified. *Id.* She testified that ''what they're checking for is to make sure the medications they were prescribed were in the patient's system and nothing else.'' *Id.* at 835. Based on PLPN's testimony, I find that she or other staff in Applicant's practice, not Applicant or a registrant, interpreted and analyzed urine samples and determined if the urine drug screen was normal or abnormal.

PLPN testified that ''[i]f their urine drug screen was good, then they would be able to get their prescriptions.'' *Id.* If the urine drug screen was not good, ''we would take them and put them in a room, so that . . . [Applicant] could see them and discuss the test,'' she stated. *Id.* at 836; *see also id.* at 826 (''[T]hey have to be put in a room and be seen by'' Applicant if the urine drug screen showed the presence of marijuana.).

PLPN's testimony was not internally consistent about Applicant's office policy regarding the release of a controlled substance refill prescription and whether Applicant or any registrant first met with the person who failed the urine drug screen before determining whether the pre-signed refill should be released. On one occasion, PLPN testified that ''if they failed'' the urine drug screen, LPN would say ''you've got to come in and talk to'' Applicant. *Id.* at 828. On another occasion, PLPN testified that if a urine drug screen was bad, such as showing marijuana, ''they have to be put in a room and be seen'' by Applicant). *Id.* at 826; *see also id.* at 836. PLPN's testimony about the process implemented prior to the time Applicant was scheduled to be out of town indicates that the staff was pre-authorized to release a controlled substance refill prescription even when the urine drug screen was abnormal and before a meeting with Applicant or any registrant took place.

The process at Applicant's practice that PLPN testified took place before Applicant went out of town was that ''some of us girls would get together and figure out, okay, we need to look back on the schedule of who come [sic] in 30 days prior on those days.'' *Id.* Based on that research, the ''girls'' identified what prescriptions were needed and who needed to be ''squeezed'' in so that Applicant saw them before he went out of town. *Id.* If someone ''failed a urine drug screen'' when Applicant was out of town, PLPN testified that ''we would defer that to . . . [LPN], and most of the time, you know, it was always sent off for confirmation . . . [a]nd a lot of time she was—you've got to come in and talk to'' Applicant. *Id.* at 828. By testifying that ''a lot of time'' LPN stated ''you've got to come in and talk to'' Applicant, PLPN was stating, at a minimum, that there were times when someone who failed the urine drug screen received the controlled substance refill prescription that Applicant had pre-signed without having to speak with Applicant. *Id.* PLPN's testimony does not address whether those whom LPN told ''you've got to come in and talk to'' Applicant received the pre-signed controlled substance refill prescription before subsequently meeting with Applicant. *Id.*

PLPN testified that the office manager handled ordering for the pharmacy. *Id.* at 901–03. PLPN addressed pharmacy-related documents that Applicant moved into evidence, including interactions with the DEA team about the pharmacy and pharmacy-related documents. *Id.* at 860–68, 873–98.[49]

Applicant also called the licensed practical nurse who staffed him during patient office visits (hereinafter, SLPN). She testified about her professional education, her current employment, and her duties in Applicant's practice. *Id.* at 948–49. She testified that she stayed with Applicant ''during the day to see all of his patients.'' *Id.* at 949. She entered the information into the electronic medical record that Applicant told her as he stood over her shoulder, she stated. *Id.* She added that Applicant also told her things that he wanted her ''to change and always made sure my spelling was correct and things of that nature.'' *Id.*

When asked about ''what appear to be template statements about advice about pain'' in the medical records, SLPN stated that a ''lot of the stuff was very repetitive.'' *Id.* at 954. ''[T]he plan of action for the patients is kind of, you know, the same,'' she testified. *Id.* She stated that Applicant ''always would tell patients to . . . take the least amount of medication possible'' and that ''[i]f they could taper off the medication that would be great. . . . [Applicant] would tell them . . . you can do it as slow as possible, even it [sic] just meant a ½ a pill every other day. . . . He would suggest swimming and stretches and exercises and physical therapy.'' *Id.* at 949–50; *see also id.* at 954–55 (When asked if Applicant ''discussed'' with patients ''every time'' and ''reminded'' them ''of these very basic physical therapy, swimming, . . . all the stuff that is in the pain plans,'' SLPN answered ''Yes. He would encourage them constantly to do those things, yes. Every visit, he would go through the same things, over and over and over with them.'').

According to SLPN, someone whose office urine drug screen was abnormal was not ''allowed to receive their medications unless . . . [Applicant] met with them.'' *Id.* at 956. Applicant would sometimes say ''there's lots of false positives in the cups in the office. False negatives, false positives,'' she testified. *Id.* She continued her testimony by stating that ''[i]f the patient, you know, disagreed with what was being said, . . . [Applicant] might give them one week's worth of medicine, send it to the lab and say, you got [to] come back in a week and we'll review the lab results.'' *Id.; see also id.* at 955–56 (SLPN's agreeing that Applicant met with the patient when the urine drug screen was confirmed.).

On cross-examination, SLPN testified that Applicant used Suboxone ''to help take people off opioids . . . and to treat pain as well.'' *Id.* at 958. On re-direct, however, when SLPN was asked if Applicant ever used Suboxone to treat pain, she did not answer the question directly. *Id.* Instead, she stated that ''sometimes patients would say that they felt like it controlled their pain . . . because you're not going through withdrawals having that pain.'' [50] *Id.*

Applicant also called a member of his office staff whose in-office employment tenure was almost six years. *Id.* at 944. She continued handling medical billing for Applicant's nursing home practice after he closed his office practice. *Id.* at 945. After some questioning, the Government objected to her testimony as being outside the parameters stated in Applicant's Prehearing Statement. *Id.* at 946. As he considered the objection, the ALJ noted that she was the third witness

[49] *See infra* n.50 regarding the reliability of PLPN's testimony.

[50] I do not see in the RD an assessment of the reliability of the testimony of PLPN or SLPN that parallels its assessment of the reliability of LPN's testimony. The topics covered by the testimonies of PLPN and SLPN are similar to the topics covered by LPN's testimony. The RD does not question the general reliability of the testimony of PLPN or SLPN and, based on my review, I find no reason to do so. As such, as with LPN's testimony, I merit the testimonies of PLPN and SLPN as generally reliable. I note again, though, that there are discrepancies among the testimonies of LPN, PLPN, and SLPN, particularly regarding the controlled substance refill process.

describing the same front desk protocols and procedures. *Id.* Before the ALJ ruled on the objection, Applicant's counsel withdrew the witness. *Id.* at 946–47.

Applicant called the Chief Information Officer (hereinafter, CIO) of the software company whose application he used to manage his in-office pharmacy. *Id.* at 671. CIO's testimony described the application's functionalities, including how it is able to interface with external data, how it tracks in real time inputted data and changes, and what reports it can generate. *Id.* at 672–709. The software does not, however, interface with distributor invoices or order forms such as DEA–222s. *Id.* at 710.

According to the RD, CIO ''presented his testimony in a professional, candid, and straightforward manner.'' RD, at 49. In addition, the RD concludes that CIO's testimony was ''impartial, objective, detailed, plausible, and internally consistent.'' *Id.* I agree with the RD and, as the RD did, I merit CIO's testimony as fully credible. *Id.*

The first character witness whom Applicant called was Joseph Newman, a former federal criminal prosecutor for the Southern District of Georgia and, at the time of his testimony, a part-time *pro tem* and substitute Judge in the State Court of Chatham County. Tr. 510. Judge Newman testified that he has known Applicant socially for eighteen years due to the longstanding, since childhood, friendship of their wives. *Id.* at 512–14. While he testified that he is not a member of the Augusta community, he also testified that Applicant's reputation in the community for being truthful and law abiding is ''good'' and, therefore, that he would ''absolutely'' believe him ''under oath.'' *Id.* at 514. He testified that, from his social conversations and dealings with Applicant, that Applicant is ''an extremely knowledgeable doctor with a broad range of medical knowledge . . . [who] has always administered great concern to his patients and the way he goes about practicing medicine.'' *Id.* at 515. He testified that he believes the Augusta community shares his sentiments as he underlined that he is ''not really a member of the Augusta community as such.'' *Id.* The Government did not cross-examine this witness.[51]

The second character witness whom Applicant called was Dr. Paul Allen Biladou, a retired general internist and oncologist who also served on the faculty of the Medical College of Georgia. *Id.* at 721. Dr. Biladou testified that he thinks he knows Applicant ''pretty well personally, and medically.'' *Id.* at 722–23. He stated that the individuals whom he knows whom Applicant ''treated . . . for both general medical conditions, as well as helping people with substance abuse . . . [had] good outcomes . . . [and] spoke highly of him.'' *Id.* at 723. Dr. Biladou testified that he is familiar with Applicant's reputation for truthfulness in the community and in the medical profession, and that reputation is good. *Id.* at 723–24. He stated that Applicant provided an important service to the community when he was practicing and that he would like to see Applicant get his DEA certificate back. *Id.* at 724. The Government did not cross-examine Dr. Biladou.[52] *Id.*

The third character witness whom Applicant called was Dr. Justin Voich Bundy, an orthopedic surgeon in August, Georgia. *Id.* at 725. Dr. Bundy testified that Applicant took care of ''a lot of . . . [his] patients over the past six to seven years'' and ''assume[s he knows Applicant] very well.'' [53] *Id.* at 726. Dr. Bundy testified that he is familiar with Applicant's reputation for truthfulness in the community and in the medical profession, and that reputation is good. *Id.* at 727. He stated that Applicant's practice provided a needed service to the community and that he believes it is in the public's interest for Applicant to get his DEA certificate of registration back. *Id.* at 728–29. The Government did not cross-examine this witness.[54] *Id.* at 730.

The fourth character witness whom Applicant called was Earl Wright, a pharmacist for about forty-eight years who became familiar with Applicant in the mid-1990s. *Id.* at 731, 734. He testified that Applicant double-signed prescriptions in red ink and that he has not seen any other doctor do that. *Id.* at 734. According to Mr. Wright, Applicant and his office ''have always been very receptive to resolving whatever questions we have'' about Applicant's patients and prescriptions. *Id.* at 735. Mr. Wright stated that Applicant's patients ''speak well of him . . . [and t]hat says a lot for him.'' *Id.* He testified that thinks it would be in the public's interest for Applicant to have a DEA certificate of registration. *Id.* The Government did not cross-examine this witness.[55] *Id.*

In addition, RX 22 consists of statements supporting Applicant from about fifty patients, colleagues, and others.

I find that the four individuals who offered verbal character witness testimony and the written statements of support for Applicant in RX 22 provided limited evidence relevant to Applicant's controlled substance prescribing, specifically evidence of his experience in dispensing controlled substances, and to whether I should grant Applicant's request for a registration.[56] 21 U.S.C. 823(f)(2). Heart-felt evidence, if it is not specific or presented in a context that explains it, is of limited value in an adjudication such as this one. I find that the record evidence of multiple controlled substance-related violations outweighs the evidence in the testimonies of the four individuals and in RX 22.

F. Allegation That Applicant Unlawfully Pre-Signed and Pre-Printed Prescriptions

Having read and analyzed all of the record evidence, I find that the Government has not presented a *prima facie* case that Applicant unlawfully pre-signed and pre-printed controlled substance prescriptions due to insufficiently developed record evidence. The fact that I am not sustaining this charge due to insufficient evidence, however, does not allay the concerns raised by evidence in the record.

As already discussed, the OSC charges that Applicant unlawfully pre-signed and pre-printed prescriptions. OSC, at 2. According to the Government's Posthearing Brief, ''[i]n order for a prescription to be valid, it must be signed and dated on the same date.'' Govt Posthearing dated July 30, 2018, at 3. The Government submitted testimonial and documentary evidence to support this allegation. The Government's documentary evidence includes patient sign-in sheets, GX 86, and double signed (computer software and wet signed) and single signed (computer software signed) prescriptions, many of which are for controlled substances, seized from Applicant's office on the inspection date. GX 87 (314 prescriptions) and GX 88 (four prescriptions). According to the

[51] *See infra* n.56 regarding the reliability of Judge Newman's testimony.

[52] *See infra* n.56 regarding the reliability of Dr. Biladou's testimony.

[53] Dr. Bundy testified that he does not have any business relationship with Applicant. Tr. 730.

[54] *See infra* n.56 regarding the reliability of Dr. Bundy's testimony.

[55] *See infra* n.56 regarding the reliability of Mr. Wright's testimony.

[56] The RD does not assess the testimony of Judge Newman. The RD states that the testimonies of Dr. Biladou, Dr. Bundy, and Mr. Wright were candid, straightforward, and ''sufficiently objective and plausible to be reliable.'' RD, at 69–70, 47 (respectively). Given the very limited relevance of these witnesses' testimonies to the adjudication of this matter, I see no need to make a reliability finding.

OSC, GX 86 ''demonstrated that patients received prescriptions authorized and signed by . . . [Applicant] on those days when neither . . . [Applicant or his Physician Assistant] were [sic] present at . . . [his] office.'' OSC, at 2.

Applicant submitted testimonial and documentary evidence to refute this charge. In terms of documentary evidence, Applicant submitted patient schedules for August 6 and 7, 2015. RX 6 and RX 7. During her testimony, LPN confirmed the notations on the face of each page of RX 6 and RX 7 showing that they were printed on August 18, 2015, seven days after the inspection. Tr. 807–08. I agree with the RD that the print date of RX 6 and RX 7, alone, makes them less credible than GX 86. RD, at 73.

I find that the Government's evidence includes circumstantial, but not substantial, evidence supporting this charge. GX 86 consists of seven pages. I find that the only legible date on GX 86, August 5, 2015, is on the top of its first page. GX 86, at 1. Throughout GX 86, I find that there are hours and minutes entered in handwriting under columns labeled ''Arrival Time'' and ''Appt. Time.'' One could infer from these handwritten times under ''Arrival Time'' and ''Appt. Time,'' and from the sequence of those times and any information in the ''Appointment with'' and ''New Patient'' columns, roughly what took place in Applicant's office on August 6 and 7, 2015. One could also infer from the handwriting in the column marked ''Appointment with'' which member of Applicant's office met with the person who filled in that row of the sign-in sheet. If one were to make these inferences, one would first need to be able to read the handwriting on the pages of GX 86, much of which is too light to be seen and illegible. I note that no Government witness testified about the specific content of any line or lines of GX 86 to assist the adjudication of this.

I find, though, that ''Dr Pursley'' is legibly written on the last page of the exhibit in the row stating that the arrival time was ''3:40'' and the appointment time was ''3:45.'' *Id.* at 7. If one were to infer that the last page of GX 86 proves what took place at 3:40 or 3:45 on Friday, August 7, 2015, as the Government's case theory suggests, then one could conclude from the last page of GX 86 that Applicant did, indeed, see a patient after 3:30 on that Friday. Such an inference conflicts with the Government's case theory, and other record evidence, that Applicant was not in the office that Friday.

Further, GX 86 does not contain legible evidence, let alone substantial evidence, that anyone actually received a controlled substance refill prescription on August 6 or August 7, 2015. Thus, I do not see substantial legible evidence in GX 86 that ''patients received [controlled substance] prescriptions authorized and signed by . . . [Applicant] on those days when neither . . . [Applicant nor his Physician Assistant] were [sic] present'' in Applicant's office. OSC, at 2.

Regarding the prescriptions in GX 87 and GX 88, I find that many, but not all of them, are for controlled substances. Of the prescriptions that are for controlled substances, I find that the prescriptions include orders for Schedule II and III controlled substances. *E.g.,* GX 87, at 12 (Schedule II); *id.* at 5 (Schedule III); GX 88, at 2 (Schedule II). I also find that many, but not all, of the prescriptions have Applicant's ''wet'' signature in addition to his computer-generated electronic signature. GX 87, at 214 (prescription for a Schedule II controlled substance bearing Applicant's electronic and ''wet'' signatures and dated August 6, 2015); *id.* at 127 (prescription for a Schedule IV controlled substance bearing Applicant's electronic signature and Physician Assistant's ''wet'' signature and dated August 7, 2020); GX 88, at 1–4 (prescriptions for Schedule II and Schedule IV controlled substances bearing only Applicant's electronic signature and dated August 11, 2015). I do not see substantial evidence in the record, however, explaining why some of the controlled substance prescriptions in these exhibits include both an electronic and a ''wet'' signature while others do not. It could be, for example, that the printed prescription was not accurate and that Applicant did not sign it for that reason. *See* Tr. 647; 21 CFR 1306.05(f) (stating that a secretary or agent may prepare a prescription for the practitioner's signature).

Although I find that the record contains substantial evidence addressing aspects of the controlled substance prescriptions in GX 87 and GX 88, such as what prescriptions were written, and circumstantial evidence, including the testimony of LPN, PLPN, and SLPN, concerning when Applicant may have signed them, I do not find substantial record evidence explicating the prescriptions in GX 87 and GX 88. Further, I find conflicts within the record evidence concerning the prescriptions comprising GX 87. For example, putting aside the record evidence concerning D.C., M.B., and Applicant's daughter, the record does not establish with substantial evidence Applicant's policy or process concerning controlled substance refill prescriptions. It is this policy or process, though, that appears to be at the heart of the Government's theory for the first OSC allegation.[57]

While there is also circumstantial record evidence addressing aspects of the prescriptions in GX 88, I do not find that GX 88 contributes substantial evidence to the establishment of a violation of the first OSC allegation. For example, the four pages of GX 88 consist of controlled substance prescriptions dated August 11, 2015, the date of the inspection, written for two different individuals. Given the date on the prescriptions, the time and location of their seizure could have occurred concurrently with the two individuals' medical visits. *See* Tr. 647 (LPN's testimony that SLPN would print prescriptions she typed into the computer, Applicant would make sure what printed is ''exactly what was in the computer and then he'd sign it and give it to the patient.''). In sum, the record evidence does not substantially illuminate these prescriptions.[58]

For the above reasons, I find insufficient evidence in the record to support my finding that the Government presented a *prima facie* case that Applicant violated 21 CFR 1306.05 or Ga. Code Ann. § 16–13–41(b). On the record before me, therefore, I find an insufficient evidentiary basis to support a founded violation of either of these two provisions.[59]

Regarding the third legal basis of the first OSC allegation, 21 CFR 1306.04(a), the Government's Posthearing Brief does not advocate for it to be sustained. Accordingly, it appears, from the Government's decision not to address this regulation in its Posthearing Brief, that the Government may have

[57] The inclusion of Schedule II controlled substance prescriptions in GX 87, however, might be evidence of a violation of the GA Pain Management Rule requiring physicians to monitor patients receiving Schedule II and Schedule III controlled substance prescriptions for compliance with the therapy, to note abnormal monitoring results, to respond to an abnormality, and to record the response in the patient's record. GX 4, at 2 (360–3-.06(2)(f)).

[58] DI testified that the controlled substance prescriptions gathered into GX 88 ''were the ones that were refills for the next day.'' Tr. 130. The record does not include a foundation for this testimony. As already discussed, all of the prescriptions in GX 88 are for controlled substances and are dated August 11, 2015. GX 88. GX 87, however, also contains several controlled substance prescriptions dated August 11, 2015, the date of the DEA inspection. *E.g.,* GX 87, at 119, 120, 201. The inclusion of those prescription in GX 87 appears to be inconsistent with this portion of DI's testimony. The record does not explicate these facts. The insufficient evidence in the record about these exhibits limits the weight I afford them.

[59] I acknowledge the RD's recommendations to the contrary. RD, at 90–92.

abandoned this theory. Regardless, there is extensive circumstantial evidence in the record supporting a violation of this regulation. While this evidence falls short of the substantial evidence needed to sustain the allegation, the evidence raises concerns about Applicant's office process and procedures regarding controlled substance prescription refills.

The testimony of LPN, PLPN, and SLPN about the process Applicant implemented in his office regarding controlled substance prescription refills raises concern about whether Applicant improperly delegated his controlled substances-related responsibilities to his licensed practical nursing staff. For example, the weight of the record evidence suggests that neither Applicant nor the Physician Assistant always analyzed, reviewed, or responded to the results of office-administered urine drug screen monitoring before the office LPN staff released a controlled substance refill prescription.[60] *Supra,* section III.E. Instead, based on the record evidence, Applicant apparently ceded to the LPN staff the analysis of urine drug screen samples. *Id.* Further, Applicant apparently delegated to the LPN staff the responsibility of determining who, after having submitted to a urine drug screen, receives and who does not receive a controlled substance refill prescription. *Id.* Indeed, Applicant's LPN staff testimony admitted to their handing out controlled substance refill prescriptions even when the in-office urine drug screen results were abnormal. *Id.* I note that there is no affirmation in the LPN staff testimony that their handing out a controlled substance refill prescription never occurred before Applicant or the Physician Assistant evaluated the urine drug screen sample results, responded to an abnormal urine drug screen result, and recorded in the medical record his response to the abnormal urine drug screen. *Id.; contra* 21 CFR 1306.12(b) (leaving it to individual practitioners' ''sound medical judgment and in accordance with established medical standards, whether it is appropriate to issue multiple [Schedule II] prescriptions and how often to see their patients when doing so'').[61] While these matters are troubling for their consistency with core CSA principles, they played no role in my decision to deny Applicant's request for a registration.

G. Recordkeeping Allegations

The OSC charges Applicant with violating federal and Georgia controlled substance recordkeeping requirements. OSC, at 2. Regarding this charge, the testimony of Applicant's licensed practical nursing staff and the testimony of GS are in conflict.[62] According to Applicant's licensed practical nursing staff, GS was shown the two pharmacy notebooks, RX 11I and RX 11J (Pharmacy Invoices for 2013 and 2014, respectively). Tr. 860–61 (PLPN testifying that, when a DEA agent asked for the invoices for the medications in the pharmacy on August 11, 2015, she showed him the two pharmacy notebooks); *see also id.* at 890–92 (PLPN testifying that she showed GS the pages consisting of RX 11I and RX 11J on August 11, 2015); and *id.* at 664–65 (LPN testifying that ''[w]e showed'' GS the pharmacy's notebooks containing medication bottle ''stickers'' and the ''patient's prescription''). According to both LPN and PLPN, the DEA agent looked at the two pharmacy notebooks and stated that ''he didn't need to see that right now.'' *Id.* at 665 (testimony of LPN); *see also id.* at 861 (PLPN testifying that she showed the DEA agent the two pharmacy notebooks and that he ''picked it up, he opened it, flipped a couple of pages, and said I don't need it right now and sat it down.'').

GS, on the other hand, testified that he asked PLPN if she had the ''records for any controlled substance that you might have on hand.'' *Id.* at 138, 140; *see also id.* at 141–42 (GS testifying that he specifically asked Applicant's office staff for ''any initial inventory, the bi-annual inventory, the purchasing records, the dispensing records, any type of destruction records''). GS explained that the controlled substance-related records that registrants are required by federal and Georgia law to maintain include an initial inventory, a bi-annual inventory, dispensing records, purchasing records, return records, and destruction records. *Id.* at 138–41. According to GS, Applicant's staff was not able to produce any of the records he requested. *Id.* at 142; *see also id.* (GS testifying that ''[t]hey never provided . . . [the bi-annual inventory]. They never said they had one. They never showed me one.''). GS also testified that ''at no point in time did anyone from . . . [Applicant's] staff nor . . . [Applicant] say that they maintain controlled substance records electronically . . . [n]or was I shown a data base that would indicate that they possibly maintained controlled substance records electronically.'' *Id.* at 144; *see also id.* at 143; *id.* at 169 (GS testifying that the computer PLPN showed him ''was in the nurse's station hallway . . . [and] was the electronic medical record.'').

As already discussed, GS testified that Applicant's office did not produce any of the controlled substance records that the law requires Applicant to maintain. *Id.* at 141 (required by federal and Georgia state law); *see also id.* at 168 (GS testifying that he ''[n]ever received one controlled substance record while we were on site.''). Further, GS enumerated Applicant's recordkeeping violations during his testimony. *Id.* at 155. He testified that Applicant had no bi-annual inventory, no purchasing records on site, no invoices, and no records showing the destruction of controlled substances. *Id.* at 155–56. GS explained that he would have accepted the required controlled substance records even the next day, had Applicant provided them at that time. *Id.* at 156 (''On site, even the next day, if they came to us and said hey, we found these records, was this what you were talking about? We probably would have been like, yes, that's what we're looking for. . . . But that all became a moot point, once it went to Surrender for Cause.'').

Regarding Applicant's hearing exhibits, GS testified that, had he been

[60] The weight of Applicant's testimonial evidence is that a urine drug screen was a prerequisite to receipt of a controlled substance refill prescription. *See, e.g.,* Tr. 826 (PLPN's testimony that release of a methadone refill prescription required a urine drug screen); *id.* at 832 (PLPN's testimony that a urine drug screen was administered before the release of a controlled substance refill prescription). The apparent exception, gleaned from the Government's testimony, is that a urine drug screen was not a prerequisite to the release of a controlled substance refill prescription when, for example, a family member picked up the refill. *Id.* at 131 (DI testimony).

[61] The location and contents of the plastic tub raise diversion concerns. The record testimony seems to place the plastic tub that held the prescriptions making up GX 87 at the prescription desk, the front desk, and the nurse's station. Tr. 831–32, *id.* at 903. Wherever its location actually was, PLPN answered ''no'' when asked if a patient ''could . . . reach around and grab a stack [of prescriptions from the plastic tub] and take off'', and if ''anybody, other than staff, . . . [had] access to the prescriptions.''1 *Id.* at 837. PLPN's testimony does not provide detail about these two ''no'' answers.

Further, regarding the risk of diversion due to the location of the plastic tub holding signed controlled substance (refill) prescriptions, PLPN answered ''no'' when asked whether, ''in the entire 17 years . . . [she was] there, ever have an issue with loss . . . [or] theft of prescriptions from this—from the storage'' [tub]. *Id.* She also testified that she would ''purge'' the plastic tub when she was not busy. *Id.* What the record evidence does not address is the meaning of PLPN's testimony and the bases for that testimony.

[62] Even if I were to credit the testimony that the DEA investigative team did not ask to see specific records during the inspection, my finding, *infra,* that Applicant never retrieved and provided to DEA any legally required controlled substance records even after Applicant knew from this proceeding which records DEA requires, renders irrelevant. *See, e.g.,* Applicant Posthearing, at 12.

shown RX 11F, ''Inventory,'' he would not have ''taken this anyway because of the dates.'' *Id.* at 163; *see also id.* at 166 (GS testifying about RX 11F that ''You see the problem is, Your Honor, . . . when I'm looking at them, there's clearly violations of the recordkeeping requirements.''); *id.* at 172 (GS testifying about RX 11F that ''[s]ome of the records appear to be non-control. Some were, you know, like in 2009. Some of those records were just on a piece of paper, that had no DEA number. No date it was taken. If that was a record that was provided to me, and they said this is the controlled substance binder, and the inventory required for the two-year timeframe . . . [w]e wouldn't have taken that, because it doesn't have . . . a DEA number on it. You don't know whose records these are for controlled substances. It doesn't have whether it was taken at the beginning of business or the close of business. . . . That was just some of the stuff I gleaned just from the short time that I had a chance to review those.''); *id.* at 167 (GS testifying about RX 11G, agreeing that ''Images Pharmacy Stickers/Records'' would be one form of recording exactly what got dispensed where ''[i]f it was within the timeframe.''); *id.* at 167–68 (GS testifying about RX 11I that ''I can't see what's behind it . . . [and] it's not controlled substances . . . so those wouldn't fall within our purview.''). When asked whether the evidence that Applicant submitted for the proceeding ''meet the federal recordkeeping requirements for controlled substances,'' GS responded that ''there were some in there that appeared, just from looking at it. But there were several in there that there was no quantity that was dispensed, no balance or anything like that. There was just a date and name on there. That was it.'' *Id.* at 172–73.

After testifying that the Georgia recordkeeping requirements ''almost mimic[ ] what federal regulations are,'' GS summarized his analysis that Applicant ''absolutely'' would still have been cited for recordkeeping violations if he had presented his hearing exhibits to GS on August 11, 2015, ''[b]ecause . . . [Applicant's hearing exhibits] are not in compliance with the federal regulations.'' *Id.* at 173. I credit the testimony of GS on this matter and, having reviewed Applicant's record evidence, agree with his assessment of Applicant's admitted exhibits. *See, e.g.,* RX 11I (Applicant's ''Pharmacy Invoices 2013'') and RX 11J (Applicant's ''Pharmacy Invoices 2014''). Both RX 11I and RX 11J are one page each. Three quarters of the exhibits' only page shows a large portion of a single piece of paper labeled ''invoice'' (RX 11J) or ''inv'' (RX 11I). This piece of paper includes an affixed hand-written label stating a month and year (''March 2013'' on RX 11I and ''Jan 2014'' on RX 11J). At the top quarter of the exhibits' only page are snippets of similarly looking affixed hand-written labels stating a month and year and paper on which ''invoice'' or some letters from that word appear. For both RX 11I and RX 11J, the lower three quarters of the exhibits' only page describes one or more medicines, such as ''Celexa'' (RX 11I) or ''Lexapro'' (RX 11J). All visible medicines are listed as non-scheduled substances. In other words, nothing visible on the one page of either RX 11I or RX 11J pertains to a controlled substance.

Further, I note that Applicant called CIO who, as described above, is the Chief Information Officer of the company whose electronic clinical dispensing software application Applicant chose for his practice. Tr. 671–720. I interpret CIO's testimony to state that Applicant's first use of this software was in about March of 2013, including a training period. *Id.* at 700. CIO testified that the company software was ''up and running in Applicant's practice on August 11 of 2015.'' *Id.* at 703. According to CIO, the company's software manages medication inventories and dispensing activities. *Id.* at 672. ''We track everything,'' CIO testified, and represented that the company software is capable of producing all of the controlled substance records required by federal and Georgia law. *Id.* at 672, 704–05.

The record does not address why Applicant or his staff did not contact CIO or his company for assistance with the requests of the DEA investigative team on August 11, 2015. *See id.* at 704–06 (CIO testifying that the company ''usually'' receives calls from customers seeking help in pulling information from the software when DEA is at the customer's site asking for required records and ''[w]e point them to run specific inventory reports or dispensing reports and be able to walk them through pulling up patient records and showing where that information is stored.''). Further, assuming the accuracy of CIO's testimony, the record leaves open the question of why Applicant did not offer into evidence, for incorporation into this proceeding's record, all of the required controlled substance records that the DEA investigative team sought on August 11, 2015.[63] Perhaps the conclusion I could reach that is most favorable to Applicant is that neither he nor his staff understood what records the DEA investigative team was requesting on August 11, 2015.[64] With or without this assumption, the record is clear: Applicant did not provide the legally required controlled substance records to DEA on, or after, August 11, 2015. *See also* RD, at 73–74, 94–95.

H. Allegation That Applicant Unlawfully Prescribed Controlled Substances

Having read and analyzed the record evidence, the parties' arguments, and the RD, I find that the record contains substantial evidence that Applicant prescribed controlled substances beneath the applicable standard of care and outside the usual course of professional practice in Georgia to M.B., D.C., and his daughter. *Supra* sections III.D. and III.E; *see also infra* section IV.B.3 (Applicant's Exceptions). My findings based on the record evidence include that Applicant failed to comply fully with the Georgia requirement to obtain the patient's history, to conduct a physical exam, and to obtain informed consent before prescribing controlled substances. *Id.* (*e.g.,* inadequate documentation of M.B.'s medical history, physical examination, and pain complaints; prescribing controlled substances for M.B. for about eleven

[63] I note that Applicant moved RX 11B, RX 11C, RX 11D, and RX 11E into evidence without objection. Tr. 678–84. While CIO and PLPN addressed these exhibits, neither testified that their contents are the required records that DEA requested on August 11, 2015. CIO testified, however, that ''reports could have been run by users at the practice'' and that his company's software is capable of producing all of the reports required by federal and Georgia authorities. *Id.* at 703, 705. Yet, neither Applicant's closing brief nor his exceptions argues that any of Applicant's exhibits consist of any of the records that DEA requested on August 11, 2015. *See also id.* at 693–95 (CIO's testimony that ''you can export your current inventory as of today, and that would give you a report of what you have on hand,'' ''[r]ight now you can't go back and do a point-in-time inventory,'' ''you can review all the changes . . . if you rolled back all the log entries and applied them to either your beginning inventory or the current inventory. You could work back or forward into it,'' ''[t]here's a screen that . . . gives you the current inventory. Again, you can filter it to show just controls, or you can do a biannual inventory for all medications,'' and there's ''one report that you can set the schedules to show schedule II, schedule III.''); *see, e.g., id.* at 695–701 (CIO's description of RX 11C as manual adjustments made to inventory in March 2015, CIO's description of RX 11D as an order summary report showing ''[b]asically every data point that's collected in the dispensing process,'' and CIO's description of RX 11B and RX 11E as showing all medications added through vendor shipments.).

[64] Both parties' exceptions address the RD's statements about certain witnesses' motivations to fabricate evidence. Applicant Exceptions, at 4; Government Exceptions, dated September 10, 2018 (hereinafter, Govt Exceptions), at 6; RD at 72–73. My findings are not premised on motivation to fabricate evidence, so I need not address these exceptions.

years without a diagnosis that should be treated with a controlled substance; prescribing controlled substances for DC without documentation of a physical examination of the parts of the body about which DC had complained; internal inconsistency in DC's medical records due to the listed diagnosis and the documented maladies). They include that Applicant did not re-evaluate patients, did not always document the changes he made to a patient's therapy, and did not always document the impact of a change in therapy. *Id.* (*e.g.,* failure to re-evaluate the efficacy of controlled substance therapy; failure to obtain a specialist's consult when therapy was ineffective). My findings also include that Applicant's medical records fall beneath the applicable standard of care and outside the usual course of professional practice. *Id.* (*e.g.,* incomplete documentation and explanation in medical records). They include that Applicant prescribed methadone for DC for addiction, not pain. *Id.* My findings include record evidence of dangerous controlled substance prescribing by Applicant that risked the lives of those for whom he wrote the prescriptions. *Id.* (*e.g.,* methadone prescriptions for DC; two short-term opioids prescribed for M.B.). My findings further include that Applicant did not comply with the applicable standard of care when he prescribed controlled substances despite signs of abusing, or being addicted to, controlled substances by the person for whom he wrote the prescription. *Id.* (*e.g.,* prescribing for M.B. despite her exhibiting signs of controlled substance abuse).

Regarding Applicant's daughter, I find that Applicant admitted he unlawfully prescribed controlled substances for her between August 2014 and June 2015. *Id.* I find insufficient evidence in the record to support a conclusion that Applicant's treatment of his daughter was always necessitated by an emergency. *Id.* I further find that Applicant also admitted he did not follow his urine drug screen-related office procedures when treating his daughter. *Id.; see also* RX 4, at 2 (ADD and ADHD patients take a urine drug screen at visits). ''I understand it is wrong in hindsight. And, you know, I'm sorry I did it,'' he stated. Tr. 1038. His testimony was that he understood the GCMB position on treating family members, ''but it's not a perfect world and it's my daughter.'' *Id.* When asked if he was willing to make a condition of being granted a registration that he ''not treat anybody under . . . what is ultimately a Georgia regulation'' about the treatment of family members, Applicant stated, ''Oh, yeah. I mean, I make amends.'' *Id.* at 1040.

I. Allegation That Applicant Did Not Exhibit Candor During DEA's Investigation

In its Supplemental Prehearing Statement, the Government ''gave notice'' that it ''elected to drop the lack of candor charges'' from the OSC. Govt Supp Prehearing dated May 8, 2018, at 1; *see also* Tr. 9–10. Accordingly, I do not address this allegation.[65]

IV. Discussion

A. The Controlled Substances Act and the Public Interest Factors

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

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

(2) The applicant's experience in dispensing . . . controlled substances.

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

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

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

Id.

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each factor, I '' 'need not make explicit findings as to each one,' '' and I '' 'can give each factor the weight . . . [I] determine[ ] is appropriate.' '' *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018), quoting *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *see also MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009) quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005)). In other words, the public interest determination ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Peter A. Ahles, M.D.,* 71 FR 50,097, 50,098–99 (2006).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. Both parties submitted documentary evidence. The admitted documentary evidence implicates Factors Two and Four.[66] In this matter,

[65] Applicant's seventh exception concerns his cooperation with DEA and cites filings he submitted on the matter. Applicant Exceptions, at 7–8. The Government's withdrawal of the lack of candor OSC charge renders moot Applicant's seventh exception and obviates a need for me to address it.

[66] Regarding Factor One, ''[a]lthough statutory analysis [of the CSA] may not definitively settle . . . [the breadth of the cognizable state 'recommendation' referenced in Factor One], the most impartial and reasonable course of action is to continue to take into consideration all actions indicating a recommendation from an appropriate state.'' *John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 (2020). Applicant's Second Motion for Leave to Supplement Evidence Post-Hearing dated February 7, 2020 (hereinafter, Second Supplement Evidence Motion), at 2, seeks to supplement the record with evidence that Applicant's Georgia and South Carolina medical licenses were renewed after the record was certified and transmitted to me. Second Supplement Evidence Motion, at 2. Without explication, Applicant cites 21 CFR 1316.57 as authority for his Motion. His reliance on this provision, however, is misplaced.

While the title of the regulation, ''Submission of documentary evidence and affidavits and identification of witnesses subsequent to prehearing conference,'' may suggest that it supports the Second Supplement Evidence Motion, the text of the regulation makes clear that it applies to evidence a movant had good cause not to identify or submit ''at the prehearing conference,'' when the movant is able to submit the evidence ''sufficiently in advance of the . . . hearing to avoid prejudice or surprise to the other parties.'' 21 CFR 1316.57. Due to this authority's irrelevance, I do not grant Applicant's Motion.

Nevertheless, if the record evidence were to have included the content of the Second Supplement Evidence Motion concerning Applicant's Georgia and South Carolina medical license renewals, I would consider those license renewals under Factor One. *John O. Dimowo, M.D.,* 85 FR 15,800, 15,810 (2020). Further, I would have afforded the evidence minimal weight because Applicant's submission includes no evidence that the Georgia and South Carolina medical licensing authorities were aware of the allegations being adjudicated in this proceeding, considered them, and determined that they would not be an impediment to the renewal of Applicant's medical licenses. *Id.*

As to Factor Three, there is no evidence in the record that Applicant has a ''conviction record under Federal or State laws relating to the

while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four. I find that the Government's evidence with respect to Factors Two and Four, as to the recordkeeping and unlawful controlled substance prescribing, satisfies its *prima facie* burden of showing that Applicant's having a registration would be ''inconsistent with the public interest.'' [67] 21 U.S.C. 823(f). I further find that Applicant failed to produce sufficient evidence to rebut the Government's *prima facie* case.

B. Factors Two and Four—Applicant's Experience Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

1. Allegation That Applicant Unlawfully Pre-Signed and Pre-Printed Controlled Substance Prescriptions

The OSC allegation that Applicant unlawfully pre-signed and pre-printed controlled substance prescriptions cites three authorities. As already discussed, the Government's Post Hearing brief does not address the first authority, 21 CFR 1306.04(a), and the Government, therefore, apparently has abandoned it.

The second cited federal regulation, 21 CFR 1306.05, states that all controlled substance prescriptions ''shall be dated as of, and signed on, the day when issued'' and lists the information they must ''bear.'' 21 CFR 1306.05(a). As already discussed, *supra* section III, I find that the record includes circumstantial, but not substantial, evidence that Applicant violated this regulation.

The cited provision of the Georgia criminal code, Ga. Code Ann. § 16–13–41(b), is similar to 21 CFR 1306.05 but only concerns prescriptions for Schedule II controlled substances. It states, in salient part, that such an order ''shall include the name and address of the person for whom it is prescribed, the kind and quantity of such Schedule II controlled substance, the directions for taking, the signature, and the name, address, telephone number, and DEA registration number of the prescribing practitioner.'' Ga. Code Ann. § 16–13–41(b). It further states that ''[s]uch prescription shall be signed and dated by the practitioner on the date when issued.'' *Id.*

The Georgia Supreme Court analyzed this statute, including the cited subsection, in *Raber* v. *State,* 285 Ga. 251 (2009). In that decision, the Georgia Supreme Court determined that, pursuant to Ga. Code Ann. § 16–13–41(b), a '' 'prescription' is 'issued' only when both the signature mandate and the other contemporaneous requirements are fulfilled.'' [68] 285 Ga. at 253. Based on the Georgia Supreme Court's interpretation of the OSC-cited subsection, I do not find substantial evidence in the record that Applicant violated Ga. Code Ann. § 16–13–41(b).[69]

For all of the above reasons, I find that the Government did not present a *prima facie* case that Applicant unlawfully pre-signed and pre-printed controlled substance prescriptions.[70]

2. Recordkeeping Allegations

The second allegation in the OSC, concerning recordkeeping, consists of two paragraphs. The first paragraph alleges that, ''when asked to produce the required records necessary to maintain controlled substances,'' Applicant was ''unable to produce any records.'' OSC, at 2. This paragraph does not cite a legal basis for its allegation against Applicant. *Id.* Applicant's Posthearing Brief, however, makes clear that he understood the requirement that ''records . . . be readily available'' and is aware of the authority for the requirement, 21 CFR 1304.04.[71] Applicant Posthearing Brief dated July 30, 2018, at 23. As such, I find that Applicant understood the basis of the second OSC allegation, had the opportunity to litigate it, and did, in fact, litigate it.[72] Accordingly, I need not address further whether the second OSC allegation was properly noticed.

The second paragraph of the second OSC allegation consists of five subparagraphs listing some of Applicant's alleged recordkeeping violations. OSC, at 2. The cited federal authorities list requirements that applied to Applicant when he was registered. *Id.; see, e.g.,* 21 CFR 1304.04(a) (stating that required inventories and records be kept for at least two years); 21 CFR 1304.04(g) (incorporating 21 CFR 1304.04(f)'s requirements stating that inventories and records of Schedule II controlled substances be maintained separately from other Schedules' records and that Schedule III, IV, and V controlled substance inventories and records be maintained separately or in a form that is readily retrievable); 21 CFR 1304.11 (inventory requirements); and 21 CFR 1304.21 (continuing records requirement). The listed state authorities parallel or incorporate federal recordkeeping requirements. OSC, at 2.

The CSA's recordkeeping requirements are an essential part of the statute's goal of preventing the diversion of controlled substances from legitimate to illicit purposes. *Howard N. Robinson, M.D.,* 79 FR 19,356, 19,370 (2014) (''There is no question that the maintenance of accurate records by registrants is key to the DEA's ability to fulfill its obligations to regulate controlled substances.''). The Supreme Court recognized statutory recordkeeping requirements as part of the ''closed regulatory system'' Congress devised to ''prevent the diversion of drugs from legitimate to illicit channels.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13–14, 27 (2005). As recently as last year, the Eleventh Circuit affirmed that a recordkeeping violation, not having controlled substance prescriptions readily retrievable when DEA asked for them, is a violation of federal law. *Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x 724, 730 (2019). Further, the Eleventh Circuit determined that the violation of the ''readily retrievable'' recordkeeping

manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency decisions have noted, there are a number of reasons why 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, M.D.,* 75 FR 49,956, 49,973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808 (10th Cir. 2011). Agency decisions have therefore noted that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[67] I already determined that the Government did not present a *prima facie* case as to the Unlawfully Pre-Signed and Pre-Printed Controlled Substance Prescriptions allegation due to insufficiently developed record evidence. *Supra* section III.F.

[68] While the Georgia Supreme Court further opined that Ga. Code Ann. ''§ 16–13–41(a) and (d)(1) may also imply that a written prescription is issued only when the 'ultimate user' or someone on his behalf has received it,'' the OSC only cites subsection (b) of Ga. Code Ann. § 16–13–41 as its state law basis. *Raber* v. *State,* 285 Ga. 251, 254 (2009). Ga. Code Ann. § 16–13–41(d) concerns Schedules III, IV, and V.

I note that DI's testimony is consistent with the Georgia Supreme Court's interpretation of the relevant subsection. Tr. 108.

[69] GX 87, page 183 of 314 is a prescription for Klonopin (Schedule IV). It shows Applicant's computer-generated and wet signatures. This appears on the address line: '',, GA.'' Even though this prescription does not include the ''address of the person for whom it is prescribed,'' it does not violate Ga. Code Ann. § 16–13–41(b) because it is not a prescription for a Schedule II controlled substance.

[70] In reaching this conclusion, I acknowledge and disagree with the RD's conflicting findings and recommendations. *E.g.,* RD, at 90–92. Given my findings, there is no need for me to address Applicant's fourth exception. Applicant Exceptions, at 5.

[71] This regulation is referenced in the second paragraph of the OSC's second allegation. OSC, at 2, subparagraphs 5.d. and 5.e.

[72] The RD reaches the same conclusion for different reasons. RD, at 94.

requirement was supported by substantial evidence and, thus, appropriately used by the Government to meet its *prima facie* burden to show that continued controlled substance registration would be inconsistent with the public interest. *Id.* at 729–30. Thus, the elements of this OSC's second allegation concerning recordkeeping requirements are essential to the CSA's anti-diversion purpose; they are far from mere administrative niceties. *See also Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 224–25 (6th Cir. 2009) (''Volkman did not keep proper records for controlled substances that were ordered and dispensed under his registration. The . . . [CSA] requires all prescription-dispensing entities to conduct a biennial inventory of all of the controlled substances it has on hand and to 'maintain, on a current basis, a complete and accurate record of each [controlled] substance' that it has 'received, sold, delivered, or otherwise disposed of.' '').

As already discussed, I found that Applicant, on August 11, 2015, did not provide the DEA inspection team any of the records he was required to maintain as a registrant. I also found that Applicant did not produce those required records to the DEA inspection team at any time after August 11, 2015, including during this proceeding. Accordingly, I find that Applicant violated the controlled substance recordkeeping requirements of federal and Georgia law.[73] Further, I disagree with Applicant's suggestion that ''this issue is moot.'' [74] *See, e.g.,* Applicant Posthearing, at 6 n.2.

[73] Even if Applicant's required controlled substance records were readily retrievable and available, as CIO's testimony suggested, I already found that Applicant never retrieved or made any of them available to DEA. *Supra* section III.G.

[74] Applicant's argument about 21 CFR 1304.04, that the ''records need only be readily retrievable,'' suggesting that the records need not actually be provided, is without merit. Applicant's Posthearing, at 23. The regulatory definition of ''readily retrievable'' calls for locating the records ''in a reasonable time.'' 21 CFR 1300.01(b). Agency decisions state that ''what constitutes 'a reasonable time' necessarily depends on the circumstances.'' *Edmund Chein, M.D.,* 72 FR 6580, 6593 (2007), *pet. for rev. denied, Chein* v. *Drug Enf't Admin.,* 533 F.3d 828, 832 n.6 (D.C. Cir 2008), *cert. denied,* 555 U.S. 1139 (2009). According to that DEA decision, ''under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request.'' 72 FR at 6593. The decision explained that ''[t]o allow a registrant an even greater period of time to produce the records would create an incentive for those who are engaged in illegal activity to obstruct investigations by stalling for time in the hopes that DEA personnel would eventually give up and leave.'' *Id.* As such, there is no doubt that ''readily retrievable'' encompasses both timely retrieval and the production of the records to DEA.

3. Allegation That Applicant Unlawfully Prescribed Controlled Substances

According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' [75] 21 CFR 1306.04(a). The Supreme Court stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon, supra,* 546 U.S. at 274. The Eleventh Circuit recently noted, in part, that, ''[u]nder the CSA, the responsibility for the proper prescribing and dispensing of controlled substances, which must be for 'a legitimate medical purpose,' is on the prescribing practitioner.'' *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 827.

As already discussed, I found that Applicant prescribed controlled substances beneath the applicable standard of care and outside the usual course of professional practice.[76] *Supra* sections III.D., III.E., and III.H.[77]

[75] The standard of care applicable in this adjudication is set out *supra* section II.

[76] After stating that ''[e]valuation of . . . [Factor Two, experience in dispensing controlled substances] is a mixed bag,'' the RD states, among other things, that the ''prior positive medical experience'' of Applicant ''apparently enjoys the confidence and esteem of his colleagues and the hierarchy of the medical community, as evidenced by the several character witnesses who testified.'' RD, at 109. It states that Applicant ''has recently been elected by his peers to Trustee of . . . a prestigious regional medical society'' and that ''[a]nother indication of his positive experience are the scores of letters of recommendation and of support from former patients.'' *Id.* Without citing any record evidence, the RD states that Applicant's ''experience in prescribing controlled substances is extensive, as reflected by his long career in treating patients and reported willingness to take on difficult and complex patients.'' *Id.* It also asserted, without citation to any record evidence, that Applicant ''has extensive experience in treating patients suffering from alcohol and drug addiction.'' *Id.* It also claimed, also without citation to record evidence, that Applicant had ''enacted various apparently effective policies and procedures to prevent drug diversion and drug abuse at his clinic.'' *Id.* at 109–10. I disagree with these portions of the RD.

Factor Two is the ''applicant's experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). As I indicated, *supra* section III.E., the public interest assessment that the CSA requires me to make does not contemplate my considering the character witness testimony and other forms of adulation that Applicant offered into the record. 21 U.S.C. 823(f). Instead, the CSA requires me to consider Applicant's controlled substance dispensing experience, among other things. 21 U.S.C. 823(f)(2). I find that the record evidence of multiple controlled substance dispensing-related violations is relevant to the public interest inquiry I am charged with undertaking and, therefore, outweighs all of the record evidence that Applicant was respected and may also have dispensed controlled substances in conformity with state and federal law.

[77] I note that there is record evidence suggesting situations when Applicant complied with the applicable standard of care. *See, e.g.,* RX 19, at 185–87 (medical record for M.B. concerning March 2015 stating that ''[w]e will not prescribe narcotic pain medicine unless pain management provides us with a formal letter, on their clinic letterhead and signed by the provider that conducted the patient's exam, stating what medicine, at what dose, and in what manner the medicine should be taken,'' that ''PT statd [sic] she found some pills tucked into a blanekt [sic] in the closet and she assumed that they were her Percocet. She states she had to hide her medicines from herself to keep from taking too much,'' and ''[n]on-compliance is grounds for dismissal from our care.'' Yet, the medical record for three visits later, in June 2015, states that ''PT had hydrocodone and valium in system. PT swears she did not take anthing [sic] other than what we give her. I told her that the mass spectrometry reading illustrates otherwise and that this is what we have to go by. I have instructed the patient t[o] ensure she take [sic] the correct meds, throw away all old meds, and only take what we authorize as we instruc[t] or she could be released from our care.'' *Id.* at 207. In other words, the medical records show that indications of Applicant's compliance with the applicable standard of care involve no follow-up and, therefore, non-compliance.

According to Dr. Kaufman, Applicant did not follow his own protocols. Tr. 312. Regarding M.B.'s medical records from 2013, Dr. Kaufman testified that M.B.'s request for early controlled substance refills ''is an ongoing problem, it hasn't been

Applicant engaged a skillful team and defended himself against all of the OSC's allegations. I read and analyzed every aspect of Applicant's defense.[78]

Applicant argued that Dr. Kaufman should have considered ''M.B.'s mental health issues in making his opinion'' and that, because he did not, he ''could not competently and intelligently analyze M.B.'' Applicant Exceptions, at 3–4. Applicant's argument did not cite any provision of federal or Georgia law that states, or even suggests, that there is a mental health exception to the requirement that controlled substance prescriptions be effective and legitimate. 21 CFR 1306.04(a). I looked for a mental health exception to the applicable standard of care in federal and Georgia law and in Agency decisions. I found none.[79] Accordingly, I reject Applicant's second exception.

Applicant labeled ''clearly erroneous'' the RD's conclusion that Applicant prescribed methadone for D.C. to treat addiction, not pain. Applicant Exceptions, at 5–6. Applicant argued that ''[b]ased purely on . . . [Applicant's] reduction of D.C.'s methadone from the 190 mg received through the methadone clinic to 10 mg immediate [sic] prior to the cessation of methadone by D.C. Kaufman lept to the conclusion that . . . [Applicant] was treating for addiction as opposed to pain.'' *Id.* at 6. Applicant also argued that D.C.'s ''debilitating cluster migraine (mini-seizure) headaches,'' knee osteoarthritis in both knees, and chronic lower back pain ''support'' the conclusion that Applicant was treating D.C. with methadone for pain, not addiction. *Id.* I disagree with Applicant's characterization of the record evidence and, as did the RD, I credit Dr. Kaufman's testimony on this matter and find that Applicant prescribed methadone for D.C. to treat addiction. *See also* RD, at 77–78.

First, the credible record evidence puts in doubt Applicant's diagnoses of pain in DC *E.g.,* Tr. 229–30 (Dr. Kaufman's testimony about Applicant's treatment of D.C.); *see also* RX 17, at 64–68 (Applicant's office notes for D.C.'s visit on June 25, 2013); Tr. 249–50 (Dr. Kaufman's testimony regarding Applicant's methadone prescribing for D.C. stating that ''there's no mention of a back examination. It's not even listed as a possibility. There's no mention of the knee examination. And on the next page, there's further examinations, where again, no back exam, no knee exam. . . . And then the next page is the list of diagnosis. And the first diagnosis is lumbago, which means back pain. And the medicine for that is Tylenol. And it says, 'opioid dependence, counseled patient on the condition, advise him to seek group or individual therapy, anxiety state, take the medicines as prescribed.' And another diagnosis is 'long term use of medications, with a urine drug screen having been performed.' . . . [The methadone is] not being used as a pain reliever, because it's not be[ing] given several times a day, what you notice is the methadone pain effect wears off, so they're going to tell you the pain is much worse at night, because it's worn off. It's not a pain medicine anymore. It will still work to prevent you from being an addict prevent the addictive behavior, but it's not going to work for the pain.'').

Second, as Applicant admitted, it is significant that D.C.'s 190 mg. of methadone was prescribed by a methadone clinic before Applicant took it over. Applicant Exceptions, at 6; Tr. 1009 (Applicant's testimony that a methadone clinic prescribed methadone to D.C.). The credible record evidence is, in Georgia, that methadone clinics treat addiction, they do not treat pain, and that only methadone clinics may prescribe methadone to treat addiction. Tr. 498 (Dr. Kaufman confirming that, in the state of Georgia, methadone treatment for addiction can only be given by a narcotic treatment clinic); *see id.* at 233–34 (''If you were to go to a methadone clinic and say, I have chronic knee pain. Could you give me methadone? They would turn you down. It's not their expertise. . . . So, anybody who is going to a methadone clinic is a person who has an addiction issue.''); *see also id.* at 605 (testimony of Applicant's expert, Dr. Downey, that, in Georgia, only specially licensed narcotic treatment programs are authorized to issue methadone for addiction). Thus, if a methadone clinic initially prescribed methadone for D.C., the prescription was clearly to treat addiction. When Applicant took it over, even when he reduced the amount over time, he was prescribing methadone to D.C. for addiction.

Third, Applicant's evidence, in the form of office policy, clearly states that Suboxone is prescribed for addiction, not pain. RX 3C, at 11. According to Applicant's own evidence, D.C.'s methadone prescription was being ''tapered down,'' so that it could be replaced by Suboxone. Consequently, it is clear that Applicant prescribed methadone for D.C. to treat addiction. Accordingly, I reject Applicant's fifth exception. Applicant Exceptions, at 6–7.

In sum, I carefully considered all of the record evidence relevant to Factors Two and Four and Applicant's position on that evidence. I applied my credibility assessments to that evidence. I conclude that the Government met its *prima facie* burden of showing that Applicant violated federal and Georgia recordkeeping requirements and prescribed controlled substances beneath the applicable standard of care and outside the usual course of professional practice. I further find that Applicant did not rebut the Government's *prima facie* case regarding these violations. Accordingly, I conclude that it would be ''inconsistent with the public interest'' for me to grant Applicant's application for a registration. 21 U.S.C. 823(f).

V. Sanction

Where, as here, the Government presented a *prima facie* case that it would be ''inconsistent with the public interest'' to grant Applicant's request for a registration, and Applicant did not rebut the Government's *prima facie* case, the ''burden of proof shifts'' to Applicant ''to show why . . . [he] can be trusted with a registration.'' *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 830; *see also Samuel Mintlow, M.D.,* 80 FR 3630,

resolved and . . . she's addicted to her medication.'' *Id.* at 294. He testified about how Applicant's handling of M.B. measured up against the applicable standard of care in Georgia, stating that ''the Medical Board simply states that when things like this happen, you should document that they've happened, and document what you're thinking. So, if there was a note which had some sort of rational explanation about why you're allowing this to continue, you might allow it to continue forever. I mean there's no set rules, but in this particular patient there's so many other things that are wrong. There's no documentation of a history that should be treated this way. There's no physical exam that justifies this. There were no x-rays or—I mean this is going on for so many years, this type of irresponsible—it's irresponsible. So, I mean, again there's no rules, but this is just not right.'' *Id.* at 296–97. Dr. Kaufman reiterated that Applicant's handling of the situation is outside the applicable standard of care. *Id.* at 297. Thus, I find that what initially appeared to be possible compliant and positive controlled substance dispensing experience turned out, upon examination, to be hollow statements with no compliant follow-up.

My finding does not mean that Applicant's controlled substance-related practice of medicine was always beneath the applicable standard of care and outside the usual course of professional practice. Based on the record evidence before me, I find that Applicant's violations of the applicable standard of care and the usual course of professional practice took place with more than one individual and in more than one context over a period of years and, therefore, were not isolated.

[78] My Decision and Order does not consider and is not based on the fact that PLPN was not registered when she dispensed controlled substance prescriptions from Applicant's in-office pharmacy. Applicant Exceptions, at 2–3 (First Exception).

[79] Consulting with a mental health provider about mental health and addiction issues is the standard of care in states in addition to Georgia. *E.g., Wesley Pope, M.D.,* 82 FR 14,944, 14,956, 14,972 (2017); *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P. and David R. Stout, N.P.,* 80 FR 28,643 (2015).

3652 (2015) (''sufficient mitigating evidence'' must be presented ''to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.''); *Cleveland J. Enmon Jr., M.D.,* 77 FR 57,116, 57,126 (2012) (same); *Robert M. Golden, M.D.,* 61 FR 24,808, 24,812 (1996) (same). Further, past performance is the best predictor of future performance and, when an applicant has ''failed to comply with . . . [his] responsibilities in the past, it makes sense for the agency to consider whether . . . [he] will change . . . [his] behavior in the future.'' *Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x, at 733 (citing *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 831 (citing *MacKay* v. *Drug Enf't Admin.,* 664 F.3d at 820 (''[T]hat consideration is vital to whether continued registration is in the public interest.'') and *Alra Labs., Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995) (''An agency rationally may conclude that past performance is the best predictor of future performance.'')).

Circuit courts have also approved the Agency's acceptance of responsibility requirement. *Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x, at 732; *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 830 (citing *MacKay* v. *Drug Enf't Admin.,* 664 F.3d at 820 (''The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked.''); *see also Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972–73 (2019) (unequivocal acceptance of responsibility); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (collecting cases). The Agency has decided that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases); *Samuel Mintlow, M.D.,* 80 FR at 3652 (''Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction.''). The Agency has also considered the need to deter similar acts by Applicant and by the community of registrants. *Id.*

In terms of egregiousness, the violations that the record evidence shows Applicant committed go to the heart of the CSA—not complying with required controlled substance recordkeeping and not prescribing controlled substances in compliance with the applicable standard of care and in the usual course of professional practice. In addition, the record evidence indicates that Applicant, even though he was registered in the past, lacks familiarity with applicable controlled substance legal requirements. For example, as already discussed, perhaps the conclusion I could reach that is most favorable to Applicant is that neither he nor his staff understood what records the DEA agents were requesting on August 11, 2015. *Supra* section III.G.

Most remarkable, though, are the under-oath statements of Applicant himself during the hearing. The ALJ asked Applicant whether he had changed the way he does business as far as his practices and protocols in response to the OSC allegations and the ''suggestions or the accusations by Dr. Kaufman.'' Tr. 1066. Applicant started his response by stating that he was not going back into his ''ambulatory practice,'' but if he were, he ''would make changes.'' *Id.* He started again to say he was ''not,'' presumably not returning to his ambulatory practice, and then stated: ''I don't desire to not comply with the law. I don't like what I've been through in the last three years.'' *Id.* The ALJ's next question was whether Applicant intended ''to become fully compliant with all of the regulations.'' *Id.* at 1068. Applicant responded: ''Yes, sir.'' The ALJ then asked ''[w]hat about learning any of these regulations. You know, nobody knows them by heart, but you know, you're responsible for knowing . . . both the Georgia regulations as well . . . the DEA regulations if you're going [to] run a doctor's office.'' *Id.* Applicant answered: ''I'm—I'm always willing to learn anything. And I've already learned a lot. And, I think, the one thing, I don't think I left a lot of dead bodies laying around.'' *Id.* at 1069. Applicant's response was an admission of his lack of familiarity with both the applicable federal and Georgia regulations. Further, although Applicant stated that he is ''always willing to learn anything'' and that he's ''already learned a lot,'' his statement about ''dead bodies'' put into question the value he assigned to practicing medicine in compliance with the applicable standard of care, given his belief that his practice, up until this point, had not ''left a lot of dead bodies laying around'' without following that standard of care.

While Applicant took responsibility for unlawfully prescribing controlled substances to his daughter, he did not take responsibility, let alone unequivocal responsibility, for the other allegations I determined to be founded.[80] Indeed, Applicant testified, at the end of the hearing, that he ''still'' believed that his controlled substance prescribing for D.C. and M.B. was within the usual course of professional practice. *Id.* at 1051. He, thus, evidenced no understanding that his controlled substance prescribing fell short of legal requirements. Accordingly, it is not reasonable to believe that Applicant's future controlled substance prescribing will comply with legal requirements, when he was firm in his belief that he did nothing wrong.[81] *Id.*

Applicant's testimony and statements in his briefing that he intended to restrict his medical practice to elderly patients in institutional settings, such as nursing homes, assisted living, and hospice centers, in other words caring for vulnerable individuals who may be isolated from their loved ones, do not advance the approval of his application.[82] Applicant's Amended Response Brief Regarding the 21 U.S.C. 824(c)(3) Corrective Action Plan Provisions dated September 23, 2019, at 5. The recordkeeping and controlled substance prescribing requirements of the CSA and its implementing regulations also apply to practitioners treating the elderly and vulnerable in institutional settings. If I were to grant his application, I would be sending a message to the regulated community that I do not require registrants to know, and conform to, the provisions of the CSA and its implementing regulations. For all of these reasons, I find that it would be against the public interest for me to entrust Applicant with a registration and, therefore, I will deny his application.

Given my decision that it is not in the public interest for Applicant to have a registration at this time, I conclude that Applicant's proposed Corrective Action Plan provides no basis for me to discontinue or defer this proceeding.

Accordingly, I shall order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C.

[80] Although it is not charged in the OSC, Applicant admitted that he also treated his wife. Tr. 1039.

[81] I do not consider remedial measures when an applicant does not unequivocally accept responsibility. Applicant's limited proposed remedial efforts, however, are unpersuasive given the egregiousness and breadth of his violations.

[82] I agree with my predecessors that community impact-type arguments are not persuasive. *Frank Joseph Stirlacci, M.D.,* 85 FR 45,229, 45,239 (2020); *see also Richard J. Settles, D.O.,* 81 FR 64,940, n.16 (2016). Accordingly, I reject Applicant's community impact-type arguments.

823(f), I hereby deny the application submitted by George Pursley, M.D., Control No. W15101573C, seeking registration in Georgia as a practitioner, and any other pending application submitted by George Pursley, M.D. for a DEA registration in the State of Georgia. This Order is effective January 11, 2021.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Poplar Grove Pharmacy Inc.;

Decision and Order

On November 20, 2019, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Poplar Grove Pharmacy Inc. (hereinafter, Registrant) of Baltimore, Maryland. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FP3109027. *Id.* It alleged that Registrant ''has no state authority to handle controlled substances.'' *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that, ''[o]n April 15, 2019, the Maryland State Board of Pharmacy (hereinafter, MBP) . . . issued an Order for Summary Suspension, suspending . . . [Registrant's] Maryland pharmacy permit.'' OSC, at 2. The OSC alleged that ''[c]onsequently, the DEA must revoke . . . [Registrant's] DEA registration based on . . . [its] lack of authority to handle controlled substances in the State of Maryland.'' *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a sworn Declaration, dated May 22, 2020, a DEA Diversion Investigator assigned to the Baltimore District Office (hereinafter, DI) stated that he accomplished personal service of the OSC on Susan Nwoga, Registrant's registration contact, at the Maryland Correctional Institution for Women on December 10, 2019. Request for Final Agency Action (hereinafter, RFAA), EX 4 (DI Declaration), at 1. The DI stated that Ms. Nwoga took the OSC. *Id.*

Further evidence of the adequacy of the Government's service is Registrant's proposed Corrective Action Plan (hereinafter, CAP) dated December 16, 2019. RFAA EX 5 (CAP), at 1. Accordingly, based on the evidence in the RFAA and the Government's representations, I find that the Government's service of the OSC was adequate.

Registrant's Proposed CAP

As already discussed, Registrant timely submitted a proposed CAP. *Id.* In the CAP, Registrant asked that ''DEA begin an internal investigation on it's [sic] failure to provide . . . [Ms. Nwoga] with whistle blower protection and why when big retail pharmacies are met with fines, the DEA set out to entrap . . . [her], a black woman who is an American of Nigerian descent.'' *Id.* at 4. Ms. Nwoga ''denied all charges'' and stated that she is ''entitled to all privileges of a licensed pharmacist.'' [1] *Id.* In the CAP, Registrant did not address the status of its Maryland pharmacy permit, including whether the MBP suspended it.

I find that Registrant waived its right to a hearing and proposed a CAP. I find that the Assistant Administrator, Diversion Control Division, denied ''the request to discontinue or defer administrative proceedings.'' RFAA EX 6 (Letter Denying Proposed CAP), at 1. I also find that the Assistant Administrator concluded that ''there is no potential modification of . . . [the proposed CAP] that could or would alter . . . [his] decision in this regard.'' *Id.* I agree with the Assistant Administrator's CAP-related decisions.

The Government forwarded its RFAA, along with the evidentiary record, to my office on May 28, 2020. In its RFAA, the Government represented that ''Registrant currently lacks authority to handle controlled substances in the state of Maryland, the jurisdiction where it was licensed as a pharmacy and where it is registered with DEA.'' RFAA, at 3. The Government requested ''a Final Order revoking Registrant's DEA registration.'' *Id.* at 4.

I issue this Decision and Order based on the record submitted by the Government in its RFAA, which constitutes the entire record before me.[2] 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FP3109027 at the registered address of 709 Poplar Grove Street, Baltimore, MD 21216. RFAA, EX 1 (Certification of Registration), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V for the business activity of retail pharmacy. *Id.* Registrant's registration ''is in a renewal pending status until the resolution of administrative proceedings.'' *Id.*

The Status of Registrant's State License and Registration

The Government submitted a certified copy of the ''Order for Summary Suspension'' concerning Registrant's pharmacy permit No. P05639 that the MBP issued on April 15, 2019. RFAA, EX 3 (hereinafter, Summary Suspension Order). According to the Summary Suspension Order, Registrant's pharmacist ''pleaded guilty . . . to approximately three hundred (300) counts that included possession with . . . [the] intent to distribute a controlled dangerous substance, Medicaid fraud, and theft.'' *Id.* at 5. The Summary Suspension Order stated that, ''[f]ollowing her conviction, Pharmacist A was ordered held in jail until the date of her sentencing.'' *Id.* It also stated that Registrant ''failed to request or submit to a closing inspection by the . . . [MBP], as required by . . . [MBP] regulations, to ensure the proper transfer of controlled and non-controlled drug inventory and confidential prescription records.'' *Id.* at 6.

After concluding that ''the public health, safety, or welfare imperatively requires emergency action,'' the MBP ''summarily suspended'' the permit issued to Registrant to operate as a pharmacy in Maryland. *Id.* The MBP thus prohibited Registrant from operating as a pharmacy in Maryland and ordered the immediate return of all pharmacy permits to the MBP. *Id.*

The Government also submitted a MBP website screen print showing that Registrant's pharmacy permit is

[1] Most of Registrant's CAP concerned Ms. Nwoga's allegations about ''the DEA's . . . failure to follow their own monitoring policy, thus, allowing the Baltimore city streets to become flooded with controlled narcotics.'' RFAA EX 5, at 2. The CAP stated that she ''satisfied all the requirements of whistle blower,'' but ''[r]ather than protect . . . [her] the DEA began an illegal under cover [sic] operation that spanned many years'' and entrapped her. *Id.* at 2–3. According to the CAP, ''[t]his case is wrought with very ugly racism, anti-feminism, and anti-immigrant overtones in the Baltimore City DEA. The criminal case is under appeal and when reviewed by legal experts, the experts say I will absolutely be released from prison.'' *Id.* at 3.

[2] The RFAA includes Registrant's proposed CAP.