**Discussion**

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. § 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[4]

According to Florida statute, ''[a] practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.'' Fla. Stat. § 893.05(1)(a) (2025). Additionally, according to Florida statute, ''dispense'' means ''the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.'' Fla. Stat. § 893.02(7) (2023). Further, a ''practitioner'' as defined by Florida statute includes ''an osteopathic physician licensed under chapter 459.'' [5] *Id.* at § 893.02(23).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice as an osteopathic physician in Florida because his Florida osteopathic medical license has been suspended. As discussed above, an individual must be a licensed practitioner to dispense a controlled substance in Florida. Thus, because Registrant lacks authority to practice as an osteopathic physician in Florida and, therefore, is not authorized to dispense controlled substances in Florida, Registrant is not eligible to maintain a DEA registration in Florida. Accordingly, the Agency will order that Registrant's DEA registration 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. FP0455142, issued to Kenneth Pherson, D.O. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Kenneth Pherson, D.O., to renew or modify this registration, as well as any other pending application of Kenneth Pherson, D.O., for additional registration in Florida. This Order is effective September 19, 2025.

**Signing Authority**

This document of the Drug Enforcement Administration was signed on August 11, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

**Heather Achbach,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

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**BILLING CODE 4410–09–P**

by email to the other party and to the Office of the Administrator, Drug Enforcement Administration, at *dea.addo.attorneys@dea.gov*.

[4] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper, M.D.,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton, M.D.,* 43 FR at 27617.

[5] Chapter 459 regulates osteopathic medical practice and applies to Registrant; it defines an ''osteopathic physician'' as ''a person who is licensed to practice osteopathic medicine in this state.'' Fla. Stat. § 459.003(4).

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Andrew Konen, M.D.; Decision and Order

**I. Introduction**

On August 12, 2024, the United States Department of Justice, Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Andrew Konen, M.D., of Dallas, Texas (Respondent). OSC, at 1. The OSC proposes the revocation of Respondent's DEA certificate of registration, BK4924139, (registration) on the ground that his ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4), in conjunction with 21 U.S.C. 823(g)(1)). More specifically, the OSC alleges that Respondent issued ''numerous prescriptions for Schedule II–IV controlled substances outside the course of professional practice and not for a legitimate medical purpose.'' *Id.* at 3.

Respondent timely requested a hearing, and the matter was assigned to an Administrative Law Judge (ALJ). *Infra* section II.D. After Respondent's failures to comply timely with the ALJ's scheduling Orders, and Respondent's failure to show good cause for his noncompliance, the ALJ terminated the proceedings after deeming that Respondent waived his right to a hearing and was in default. *Id.* The matter is before the Agency on the Government's Request for Final Agency Action (RFAA).

After accessing and carefully analyzing the entire record, *infra,* the Agency finds substantial record evidence supporting the conclusion that Respondent is deemed to be in default because he ''failed to . . . otherwise defend.'' [1] 21 CFR 1301.43(c); *infra* sections II.B., II.C., II.D., II.E., and II.F. Accordingly, based on Agency rule, the

[1] As the Government did not include the entire record in its RFAA, the Agency accessed it from the Office of Administrative Law Judges' docket and considered every item in it.

Agency deems that Respondent admits the OSC's factual allegations. 21 CFR 1301.43(e). *Infra* section IV. After analyzing the deemed-admitted facts, the Agency concludes that the Government presented a *prima facie* case that Respondent issued Schedule II through IV controlled substance prescriptions ''outside the course of professional practice and not for a legitimate medical purpose'' from at least January 2016 to July 2020. OSC, at 3–6; *infra* sections IV and V. After concluding that Respondent's unlawful controlled substance prescribing makes his continued registration inconsistent with the public interest, the Agency finds that there is no record evidence that Respondent unequivocally accepts responsibility for the founded violations. *Infra* sections VI and VII. Accordingly, the Agency revokes Respondent's registration and denies all pending applications by Respondent for registration in Texas. *Infra* Section VII and Order.

## II. The Default Rule and Its Application in this Matter

### *A. The Controlled Substances Act*

The Controlled Substances Act (CSA) explicitly authorizes the Attorney General to promulgate rules and regulations to support implementation and enforcement of the statute.[2] First, the Attorney General ''is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.'' 21 U.S.C. 821. Second, the Attorney General ''may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). Consistent with these CSA provisions, the Agency promulgated a default rule. 21 CFR 1301.43.

### *B. The ALJ's Powers and Duties*

The Administrative Procedure Act (APA) and the CSA's implementing regulations address the powers and duties of Agency ALJs. According to the APA, an Agency ALJ, among other things, may ''regulate the course of the hearing,'' ''dispose of procedural requests or similar matters,'' and ''take other action authorized by agency rule consistent with this subchapter.'' 5 U.S.C. 556(c)(5), (9), and (11).

The CSA's implementing regulations clearly state that an Agency ALJ's duty is ''to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order,'' and that the ALJ ''shall have all powers necessary to these ends.'' 21 CFR 1316.52. The salient provision also explicitly states that the ALJ's ''powers'' include ''any action permitted . . . by the provisions of the APA.'' *Id.* Further, it provides a non-exclusive list of powers ''necessary'' to the ''end'' of the ALJ's ''dut[ies],'' powers such as ''rul[ing] on procedural items pending before him'' and ''[r]equir[ing] parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties.'' 21 CFR 1316.52(c) and (g). The Agency notes, as particularly relevant to this adjudication, that the latter is typically done in filings such as Prehearing Statements.

Accordingly, the Agency concludes that the Agency ALJ assigned to this matter clearly has the duty and the power to issue scheduling orders, to rule on matters concerning those scheduling orders, and ''to take all necessary action to avoid delay, and to maintain order.'' 21 CFR 1316.52.

### *C. Procedures Applicable to this Adjudication*

Effective December 14, 2022, pursuant to the provisions of the CSA, the Agency implemented a final rule to increase the efficient execution of its CSA functions relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals. 87 FR 68036 (2022) (amending 21 CFR 1301.37 and 1301.43). The final rule states that the person named in the OSC has thirty days after receiving the OSC to request a hearing and to answer the OSC's allegations. 21 CFR 1301.37(d). It also states that any party's failure to comply with its terms may result in that party's default, unless the party establishes ''good cause'' to excuse the default. 21 CFR 1301.43. An unexcused default, the final rule provides, ''shall be deemed to constitute a waiver of the . . . right to a hearing and an admission of the factual allegations of the order to show cause.'' 21 CFR 1301.43(e). The final rule affords multiple opportunities to establish ''good cause'' to excuse a deemed default. *Id.* As this final rule was in effect when DEA issued the OSC to Respondent, it applies to Respondent's response to the OSC.

Both the default rule's notice of proposed rulemaking (NPRM), 85 FR 61662 (2020), and the final rule use the phrase ''good cause'' throughout.[3] Neither, though, defines ''good cause.''[4] As ''good cause'' is a standard often used in federal legal authorities, the Circuit Courts have addressed and applied it on many occasions in contexts where, like here, there is noncompliance with a scheduling order, a missed deadline, and the like. *Infra* section II.F.

[2] The Attorney General's CSA responsibilities have been delegated to the DEA Administrator. 28 CFR 0.100(b).

[3] Indeed, ''good cause'' was the standard in the prior iteration of 21 CFR 1301.43(d) (''If any person entitled to a hearing or to participate in a hearing pursuant to . . . 1301.32 or . . . 1301.34–1301.36 fails to file a request for a hearing or a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.''). The prior iteration of 21 CFR 1301.43 does not include the deemed admission of the OSC's factual allegations.

[4] The NPRM and final rule cite *Kamir Garces Mejias, M.D.,* 72 FR 54931 (2007), an Agency decision issued under the last version of the default rule. In that decision, DEA charged the doctor with issuing controlled substance prescriptions in the absence of a legitimate physician-patient relationship. *Id.* at 54931. When the doctor failed to file a Prehearing Statement in timely compliance with the ALJ's scheduling Order, the ALJ issued another Order establishing a second deadline for that filing. *Id.* The doctor, though, did not comply with the ALJ's second deadline. *Id.* The ALJ issued a third Order setting another deadline and giving ''notice that . . . [the doctor's] failure to comply could be deemed a waiver of her right to a hearing.'' *Id.* The doctor, again, did not comply with the ALJ's deadline. *Id.* The Government then filed a motion asking the ALJ to find that the doctor ''waived her right to a hearing'' and to terminate the proceeding. *Id.* The ALJ granted the Government's motion and terminated the proceeding on March 7, 2007.

On March 12, 2007, Respondent's counsel moved for reconsideration, arguing that he is a solo practitioner, that he had ''an extremely busy Court calendar'' since January of that year, and that ''it had not been his 'intention to be disrespectful or to willfully disobey the orders issued by the ALJ.' '' *Id.* at 54931–32. The ALJ denied the request for reconsideration, stating that Respondent had thus far in the proceedings failed to comply with all of the ordered deadlines, that she had never submitted a written request for an extension of any of the deadlines, and that ''Respondent's failure to pursue her case remains a waiver of her right to a hearing.'' *Id.* at 54932. The ALJ also denied Respondent's second request for reconsideration. *Id.* The Agency agreed with the ALJ's termination of proceedings, writing that ''Respondent has not shown 'good cause' for failing to comply with the ALJ's orders and [the Agency] thus find[s] that Respondent has waived her right to a hearing.''

There are clear fact parallels between *Kamir Garces Mejias, M.D.,* and the instant facts: repeated failures to comply with the ALJ's multiple deadlines for filing a Prehearing Statement, the ultimate failure of Respondent ever to file a Prehearing Statement, and the absence of good cause for the failures. Before issuing this Decision/Order, the Agency read and analyzed the entire record before it. It cites the record in detail in this Decision/Order and explains the significance of its contents. The Agency concludes that it is appropriate to apply the final rule to this record. *Infra* sections II.D, II.E., and II.F.

*D. Respondent's Request For a Hearing and Conduct During Prehearing Proceedings*

As already discussed, Respondent timely requested a hearing.[5] Order for Answer and Prehearing Statements, dated August 29, 2024 (OAPS), at 1. In the OAPS, issued the day after Respondent filed his hearing request, and citing relevant authority, the ALJ points out that the request for hearing ''does not satisfy the requirement of DEA's regulations that the Respondent file an Answer . . . as the Respondent did not answer the allegations contained in the OSC in his [request for hearing].'' *Id.* (citing 21 CFR 1316.47 and 1301.37). The OAPS also cites the default rule references on pages 6 and 7 of the OSC, stating that a respondent's failure to answer timely, to plead, or ''otherwise [to] defend'' may lead to the respondent's being ''deemed to otherwise have waived the right to a hearing and to be in default.'' *Id.* The OAPS orders Respondent to file a compliant answer ''by 5:00 p.m. Eastern Time ('ET')/4:00 p.m. Central Time ('CT') on September 12, 2024.''[6] [7] *Id.* at 1–2.

The OAPS also addresses the filing of Prehearing Statements and the scheduling of the Prehearing Conference. *Id.* at 2–3. As for Respondent, the OAPS states that, ''[t]o the extent the Respondent timely files his Answer,'' he is to file his Prehearing Statement ''no later than 2:00 p.m. ET/1:00 p.m. CT on October 3, 2024.'' *Id.* at 2. It also states that ''[f]ailure to timely file a prehearing statement that complies with the directions provided above may result in a sanction, including (but not limited to) a waiver of hearing and an implied withdrawal of a request for hearing.'' *Id.* at 4.

The Agency finds unequivocal and uncontroverted record evidence that, on October 2, 2024, after 5:00 p.m. ET, Respondent filed a request for an extension of time to file his Prehearing Statement (Respondent's Motion for Time Extension).[8] Order Granting in Part Respondent's Motion for Extension of Time to File Prehearing Statement, dated October 3, 2024 (Order Granting in Part), at 1, n.1. Respondent's Motion for Time Extension, asking that the original October 3, 2024 Prehearing Statement filing deadline be extended to December 15, 2024, is based on three grounds.[9] [10] The first ground is that ''the Government and its expert witness . . . do not have access to the complete medical and prescription records for each of the three named patients in this case'' and, therefore, the Government's expert witness ''cannot opine on the nature, quality, and appropriateness of the patient care and prescribing rendered by Respondent for each patient.'' Respondent's Motion for Time Extension, at 2. The ALJ's responsive Order correctly points out that ''[i]t is unclear why this allegation supports Respondent's request for additional time to file a prehearing statement.'' Order Granting in Part, at 1.

Respondent's second ground for a time extension is that ''there is a parallel criminal case against Respondent.'' Respondent's Motion for Time Extension, at 1. Respondent elaborates that he is ''in the process of preparing a § 41(g) motion to contest a search warrant that was improper in that it failed to authorize a search at the location listed in the warrant, resulting in an improper seizure of property that Respondent is now attempting to reclaim,'' and that he ''is considering whether to enter into a reverse proffer in the near future.'' *Id.* at 3. Concerning Respondent's second ground, the ALJ's responsive Order correctly states that ''[a]s the Agency has previously ruled, a stay of DEA administrative enforcement proceedings based on a parallel criminal proceeding 'is unlikely to ever be justified.' '' Order Granting in Part, at 1.

Respondent's third ground is that he ''has not yet retained an expert to review the patient medical records, the Government's written statement, applicable guidelines and standards, peer-reviewed literature, and other relevant documents because the insurance carrier has not yet approved the costs associated with retaining an expert in this case.'' Respondent's Motion for Time Extension, at 3. Respondent represents that he ''is working with the insurance carrier now to follow up on retaining an expert to review the records and related documents and to prepare expert testimony in this proceeding.'' *Id.*

The ALJ's Order Granting in Part, after noting that the Government timely filed its Prehearing Statement, cites its ''power to 'conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order . . . including . . . [a]rrange and change the date, time and place of . . . prehearing conferences.' '' Order Granting in Part, at 2, citing 21 CFR 1316.52(a). It states that ''[t]he tribunal does not find that a nearly 75-day extension for Respondent to retain the services of an expert witness and file his prehearing statement is warranted,'' but that ''the tribunal will afford the Respondent a 2-week extension of time to file his prehearing statement.'' *Id.* Thus, the Order Granting in Part adjusts the deadline for Respondent to file his Prehearing Statement to October 17, 2024, at 2:00 p.m. ET/1:00 p.m. CT. *Id.*

Respondent did not file his Prehearing Statement on or before the October 17, 2024 deadline. Order Directing Compliance for Respondent to File Prehearing Statement, dated October 18, 2024 (Order Directing Compliance), at 1. As already discussed, the OAPS reminds Respondent that his ''[f]ailure to timely file a prehearing statement that complies with the

[5] Based on the record evidence, the Agency finds that Respondent's request for a hearing is dated August 28, 2024. As August 28th is well within thirty days of the date of the OSC's issuance on August 12, 2024, the Agency finds that Respondent timely filed his request for a hearing. 21 U.S.C. 824(c)(2)(B); 21 CFR 1301.37(d)(1).

[6] The OAPS cites Respondent's ''assert[ion]'' that he was served with the OSC on August 13, 2024, when designating September 12, 2024, as the Answer's due date. OAPS, at 2, n.1.

[7] The Agency finds unequivocal and uncontroverted record evidence that the OAPS specifically sets out the time deadlines in both Eastern Time, the ALJ's time zone, and in Central Time, presumably Respondent's and Respondent's counsel's time zone in Texas. OAPS, at 1–2. The Agency further finds unequivocal and uncontroverted record evidence that the OAPS details the electronic filing process for the parties, including that ''[y]our attention is specifically directed to 21 CFR 1316.45, which provides, *inter alia,* that '''[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk.' . . . The email receipt date reflected by the DEA Judicial Mailbox server shall conclusively control all issues related to the date of service of all filed correspondence, provided however, that correspondence received after 5:00 p.m., local Washington, DC time, will be deemed to have been received on the following business day.'' *Id.* at 3–4.

[8] Although the ALJ's Order in response to Respondent's Motion for Time Extension does not raise it, the Agency notes that the OAPS ''further Ordered'' that ''any requests for extension of time to file must be made by written motion *sufficiently in advance of scheduled deadlines to be considered and ruled upon.*'' OAPS, at 4 [emphasis added]. Respondent filed his motion for an extension of time to file his Prehearing Statement after 5:00 p.m. the day before the deadline for the filing of his Prehearing Statement. Accordingly, as the OAPS states, Respondent's Motion for Time Extension is deemed to have been received on October 3, 2024, the ALJ-ordered deadline for Respondent to file his Prehearing Statement and, therefore, was not filed ''sufficiently in advance of [the] scheduled deadline[ ] to be considered and ruled upon.'' *Id.* at 3–4.

[9] Respondent's Motion for Time Extension, at 1, asserts that Respondent filed his answer timely. The Order Terminating Proceedings, *infra,* confirms Respondent's assertion. Order Termination Proceedings, at 1.

[10] Respondent's Motion for Time Extension, at 3, asserts that the ''Government has been consulted about the continuance and is unopposed to the requested extension of time in which to submit Respondent's written prehearing statement.'' Further, Respondent's Motion for Time Extension includes a ''Certificate of Conference'' stating, among other things, that the ''parties . . . discussed the estimated length of time needed for the hearing'' and the ''situs of the hearing.'' Respondent's Motion for Time Extension, at 5.

directions provided . . . may result in a sanction, including (but not limited to) a waiver of hearing and an implied withdrawal of a request for hearing.'' OAPS, at 4. The Order Directing Compliance, though, does not sanction Respondent. Instead, it affords Respondent an opportunity to file his Prehearing Statement by October 23, 2024, at 2:00 p.m. ET/1:00 p.m. CT, and to ''show good cause why he did not timely file such prehearing statement in accordance with the directions set forth in the Order'' Granting in Part. Order Directing Compliance, at 2. The Order Directing Compliance further states that, if Respondent fails to comply with the extended deadline, the ALJ ''will take appropriate action and the Respondent will face an appropriate remedy (*e.g.,* waiver of his right to a hearing, entry of default, allegations being deemed admitted, and/or dismissal of his request for hearing).'' *Id.*

When Respondent did not file his Prehearing Statement by the October 23, 2024 deadline, the ALJ issued the Order Terminating Proceedings. That Order recounts the requirements of the ALJ's prior Orders about this matter, Respondent's compliance and non-compliance with his Orders, and the ALJ's multiple avisos to Respondent warning that non-compliance with his Orders ''may result in sanction, including (but not limited to) waiver of Respondent's right to hearing, entry of default, admittance of allegations, and implied withdrawal and dismissal of Respondent's request for hearing.'' Order Terminating Proceedings, dated October 23, 2024, at 1–2. Although Respondent was granted two extensions of time to submit his Prehearing Statement, the Order Terminating Proceedings states, Respondent ''failed to so submit'' and ''supplied no good cause for his failure.'' *Id.* at 2. The Order terminates the proceedings after deeming that Respondent waived his right to a hearing and is in default. *Id.* at 3 (citing 21 CFR 1301.43(c)(1) and (e)).

Later on the day of October 23, 2024, Respondent filed his ''Motion for Leave and Request for Reconsideration of Termination of Proceedings and Reinstatement of Proceedings Filed for Good Cause'' (Motion for Leave). Respondent's Motion for Leave does not include a Prehearing Statement, but states that he ''will also file his Prehearing Statement to the best of his ability despite genuine and real problems that Respondent's counsel has experienced that led to the delay and the Judge's order terminating the proceedings against Respondent.'' Motion for Leave, at 1.

According to the Motion for Leave, the ''issue'' is whether ''Respondent can prove that his delay and failure to file the prehearing statement as ordered by the ALJ was not due to neglect or malfeasance but was based on legitimate circumstances beyond counsel for Respondent's control.'' *Id.* The ''issue'' portion of the brief also states that it would be ''unfair'' to Respondent, ''given the totality of the circumstances and the immediate and sudden impact of the ALJ's order terminating the proceedings,'' not to allow Respondent to ''present evidence in this proceeding.'' *Id.* at 1–2. Further, however, the Motion for Leave states that Respondent's counsel ''would be able to file an appropriate Prehearing Statement, despite the deficiencies laid out . . . with respect to the records and timeliness of an expert's retention which would assist the Government in its case.'' *Id.* at 5; *infra* sections II.E. and II.F.

Broadly configured, Respondent's Motion for Leave makes five points. First, it states that the Order to Show Cause ''arises from a criminal investigation involving an active case in the Eastern District of Texas,'' that Respondent ''is also the subject of a target letter and criminal investigation involving others,'' and that the investigation of Respondent has been going on for ''at least'' four to five years. Motion for Leave, at 2. Second, according to the Motion for Leave, Respondent's counsel ''is and has been quite ill, with at that time an undiagnosed systemic infection throughout his body which targeted the skin'' and which ''has made Respondent tired and has forced him to work from home for the last few months.'' *Id.* at 2–3. Further, ''[g]iven the unknown cause of . . . [his symptoms], counsel for Respondent was concerned that his underlying issue may be contagious.'' *Id.* at 3. Respondent's counsel ''was able to obtain an appointment with a specialist for the morning of'' October 22, 2024. *Id.* As Respondent and his counsel were scheduled to attend a ''reverse proffer presented by the Assistant United States Attorneys (AUSAs) handling the criminal investigation'' on that day, Respondent and his counsel contacted the AUSAs ''with sufficient notice and in advance of the meeting to inform them'' of Respondent's counsel's illness and specialist appointment. *Id.* The AUSAs, ''without hesitation,'' rescheduled their meeting and ''wished counsel a successful physician visit and a rapid recovery.'' *Id.*

Third, the Motion for Leave states that Respondent's counsel had been ''attempting to retain co-counsel due to Respondent's counsel's health issues,'' but was not successful at the time. *Id.* Fourth, the Motion for Leave states that Respondent's counsel, ''over the last few days,'' ''prepared and assembled a 'Complaint and Request for Declaratory and Injunctive Relief.' '' *Id.* Respondent's counsel attached the ten-page ''Complaint and Request for Declaratory and Injunctive Relief'' to the Motion for Leave. *Id.* at 11–20. The Motion for Leave explains that, when he tried to file ''this petition as he planned'' on the morning of October 23, 2024, Respondent's counsel, who is ''primarily a healthcare lawyer who does not practice in federal court with regularity,'' learned that his Pacer account was no longer active and, therefore, he could not file the Complaint.[11] *Id.* According to Respondent's counsel, ''Based on the relief requested in the petition, and the orders rendered to the co-Respondents[']similar suits, all orders of this court would have been rendered stayed and the Order Terminating the Proceedings without standing.'' *Id.* The Motion for Leave says nothing else about this assertion. *Id.*

Finally, the Motion for Leave states that Respondent's counsel, because he was not able to ''obtain . . . [co-counsel] assistance'' and ''work efficiently and for a full day without exhaustion,'' ''found himself behind and honestly did not recognize the court's 1:00 p.m. deadline, but rather the date the motions and statements were due.'' [12] *Id.* at 3–4. It states that Respondent's counsel was ''overloaded and non-compliant with the ALJ's very specific order'' due to the ''departure of three attorneys who had been with the firm for ten years or longer,'' causing

[11] Respondent's counsel attached to the Motion for Leave three emails between him and the ''NextGen CM/ECF'' or PACER showing his efforts to gain PACER access. Motion for Leave, at 8–10. The times on the three emails are in the afternoon, between 1:41 p.m. and 3:12 p.m., on October 23, 2024. *Id.*

[12] The Motion for Leave also states that Respondent's insurance company has ''yet to approve his claim for coverage'' and ''as such, Respondent is unable to hire an expert witness to testify after he rendered a consulting opinion.'' Motion for Leave, at 4. It states that ''the records for each patient referenced in the petition by the DEA in most cases triple the size of the files/records noticed as reviewed by the Government's expert in conjunction with his opinion.'' *Id.* The Motion for Leave asks why the government's expert does not ''mention that he was opining on partial treatment records that were missing service dates both before and after'' the dates alleged in the OSC. It further states that ''tracking . . . down and obtaining . . . the statement'' of the ''patients . . . alleged to have not experienced benefit due to treatment . . . has proved timely, especially coupled with Respondent's counsel's recent health experience.'' *Id.*

''administrative chaos and scheduling difficulties.'' [13] *Id.* at 4. Respondent's counsel ''denies that it was with disrespect or improper intent to the ALJ and the proceeding'' that he missed the Prehearing Statement deadline. *Id.* According to the Motion for Leave, Respondent's counsel ''believes'' that the ''factual bases'' in the brief about his being ''overloaded and non-compliant'' with the ALJ's ''very specific order'' are ''sufficient to give the ALJ information to reconsider his order terminating the proceedings.'' He also states that he is ''willing to supply statements from his treating physicians which substantiate [the] . . . disease process.'' *Id.* at 5. The Motion for Leave states, seeming to summarize the thrust of its argument, that ''[h]ealth concerns happen and it would be unfair to Respondent to terminate his rights due to no fault of his own.'' *Id.* at 5.

The ALJ issued his ''Order Denying Respondent's Motion for Leave and Request for Reconsideration of Termination of Proceedings and Reinstatement of Proceedings Filed for Good Cause'' on October 24, 2024 (Order Denying Motion for Leave), appropriately rejecting Respondent's Motion for Leave. *Infra* sections II.E. and II.F. The Order Denying Motion for Leave acknowledges the points in Respondent's Motion for Leave, including its assertions that the failure to file a timely Prehearing Statement was not due to neglect or malfeasance, but to legitimate circumstances beyond Respondent's control, that Respondent's counsel is and has been quite ill, that Respondent's counsel had to reschedule a conference with the prosecutors in the parallel criminal investigation of Respondent, that Respondent's counsel researched, prepared, and assembled, ''over the last few days,'' a complaint for Declaratory and Injunctive Relief that ''would render 'all orders of [this tribunal] . . . stayed and the Order Terminating Proceedings without standing,' '' and that Respondent's counsel ''did not recognize the court's 1:00 p.m. deadline.'' Order Denying Motion for Leave, at 1–2. The Order Denying Motion for Leave finds that the Motion for Leave does not establish the requisite ''good cause,'' and does not include Respondent's Prehearing Statement. *Id.* at 2. It highlights that Respondent's counsel admits to engaging in multiple work efforts during the period leading up to the Prehearing Statement deadline, ''all while seemingly entirely neglecting these administrative proceedings and the directions'' of the ALJ. *Id.*

*E. Application of the Rule to Respondent's Prehearing Proceedings Conduct*

The record clearly shows that Respondent repeatedly failed to comply with the ALJ's scheduling Orders. *Supra* section II.D. The Agency concludes that the content of each of the ALJ's Orders is well within the ALJ's powers and duties, and that the Orders support the conduct of a fair hearing, avoid delay, and maintain order. *Supra* sections II.B. and II.C.

Further, the Agency finds unequivocal and uncontroverted record evidence that, in addition to the OSC, the ALJ's Orders repeatedly include avisos to Respondent of the possible sanctions for failure to comply. *Supra* section II.D. More specifically, the Agency finds unequivocal and uncontroverted record evidence that the ALJ's avisos warn that possible consequences of failure to comply with his Orders include waiver of a hearing, entry of default, and OSC allegations being deemed admitted. *Id.*

*F. Legal Analysis of the Application of the Default Rule in This Matter*

As already discussed, the Agency cited *Kamir Garces-Mejias, M.D.,* a 2007 Agency decision, in the final rule. In *Kamir Garces-Mejias, M.D.,* the Agency agreed with the ALJ that respondent had not shown good cause for her failure to comply with the ALJ's Prehearing Statement filing Order. 72 FR at 54932–33. In other words, for about fifteen years before the formal premiere of the current default rule, the Agency was supporting ALJs' prerogatives to use their statutorily granted power and duties to ensure fair, efficient, and orderly hearings. *Supra,* sections II.B. and II.C. The Agency concludes that this prior Agency decision, among others, supports the ALJ's actions in this matter.

The Agency also examines relevant Supreme Court and Circuit Court case law, including decisions applying ''good cause'' in missed deadline-related situations. Although, as expected, the Agency found no appellate decisions precisely on point, there are several that are quite instructive. The Agency looks to these Article III decisions to guide its application of ''good cause.''

The Supreme Court issued a decision in 1993 reaffirming its holding in ''other contexts'' that ''clients must be held accountable for the acts and omissions of their attorneys.'' *Pioneer Investment Services Co.* v. *Brunswick Assocs. Ltd, P'ship.,* 507 U.S. 380, 396 (1993). In addition to stating that this holding applies in ''other contexts,'' the Court explains that ''[a]ny other notion would be wholly inconsistent with our system of representative litigation, in which each party is deemed bound by the acts of his lawyer-agent and is considered to have 'notice of all facts, notice of which can be charged upon the attorney.' '' *Id.* at 397 (citing *Link* v. *Wabash R. Co.,* 370 U.S. 626, 633–34 (1962)). The Supreme Court concludes that ''a client may be made to suffer the consequence of dismissal of its lawsuit because of its attorney's failure to attend a scheduled pretrial conference.'' 507 U.S. at 396. Accordingly, the Agency rejects Respondent's argument that he should not suffer the consequence of his attorney's having missed the third deadline for filing his Prehearing Statement. Motion for Leave, at 1–2.

While, again, the Agency found no Fifth Circuit decision exactly on point, the Agency researched Fifth Circuit decisions interpreting the scope of ''good cause'' in the contexts of a missed litigation deadline, a failure to comply with a scheduling order, and the like, to conduct another level of analysis for this adjudication. In *Texas Indigenous Council* v. *Simpkins,* for example, the Fifth Circuit explained, in the context of Federal Rule of Civil Procedure 16, that ''good cause'' requires a party to show that a deadline ''cannot reasonably be met despite the diligence of the party needing the extension.'' 544 F. App'x. 418, 420 (5th Cir. 2013) (citing *S & W Enters., L.L.C.* v. *Southtrust Bank of Ala.,* 315 F.3d 533, 535 (5th Cir. 2003)). In this adjudication, Respondent's Motion for Leave shows the opposite when, despite its listing of personal, health, and professional commitment challenges, it recites the legal work Respondent's counsel did accomplish ''over the last few days'' immediately before the third ALJ-ordered Prehearing Statement deadline. Those listed work accomplishments include contacting AUSAs and negotiating the rescheduling of a ''reverse proffer,'' and researching, preparing, and assembling a ''Complaint and Request for Declaratory and Injunctive Relief'' related to this matter. Motion for Leave, at 2–3.; *supra* section II.D. In other words, Respondent's Motion for Leave demonstrates that the ALJ's already thrice ordered Prehearing Statement deadline *could reasonably have been met* had Respondent's counsel not chosen to prioritize other matters, the apparently more time-consuming one of

[13] The Motion for Leave also ''grant[s]'' that ''counsel took on more than he should have, but it is arguably a lawyer's nature to think they can accomplish more than may be reasonable given the circumstances.'' Motion for Leave, at 5.

which had no ALJ- or Court-ordered deadline. *Supra* section II.D.

There are many contexts in which the Fifth Circuit rejected attempts to demonstrate ''good cause'' for extensions of time sought after a deadline had passed. For example, in *In re OHT Hawk AS* v. *Offshore Heavy Transport AS,* the Fifth Circuit found that ''good cause'' did not excuse the late filing of a claim because notice of the deadline was published in a Harrison County, Mississippi newspaper and the claimant lived in New Orleans, Louisiana, ''just over seventy miles'' away and in ''adjacent metropolitan regions.'' 2022 WL 1486778, at *3 (5th Cir. 2022). Here, Respondent does not claim, or even suggest, that he did not have actual notice of the ALJ-ordered Prehearing Statement filing deadline that Respondent's counsel de-prioritized for other legal work. After all, other than the first missed deadline, the deadlines that Respondent ignored were set as a result of Respondent's request for an extension of the ALJ's original Prehearing Statement filing deadline. *Supra* section II.D (Respondent's Motion for Time Extension). The Fifth Circuit found that claimant in *In re OHT Hawk AS* failed to show ''good cause'' when notice was publicized in the press, ''just over seventy miles'' away and in ''adjacent metropolitan regions,'' and not directly to the claimant. Similarly, the Fifth Circuit's analysis would conclude here that Respondent failed to show ''good cause'' for failing to meet the first extended Prehearing Statement filing deadline that he himself obtained from the ALJ, as well as the subsequent deadline that the ALJ unilaterally afforded him.

By way of further example, in *T.O., a child; Terrence Outley, et al.* v. *Fort Bend Independent School District,* 2 F.4th 407 (5th Cir. 2021), *cert. denied,* 142 S.Ct. 2811 (2022), the Fifth Circuit addressed whether there was good cause to excuse the plaintiffs' failure to submit a timely amendment to their complaint.[14] 2 F.4th at 418. The Fifth Circuit's analysis was done in the context of Federal Rule of Civil Procedure 15(a)(2)'s provision that ''[t]he court should freely give leave when justice so requires,'' and of Federal Rule of Civil Procedure 16(b)'s provision that a ''schedule may be modified only for good cause and with the judge's consent.'' *Id.*

In *In re T.O.,* the Fifth Circuit examined the matters that the Plaintiffs-Appellants sought to add to their second amended complaint and concluded that the Plaintiffs-Appellants knew those matters when they filed their original complaint. *Id.* Accordingly, the Fifth Circuit ruled that the Plaintiffs-Appellants did not show good cause to support their filing a second amended complaint because, ''[s]imply put, it is difficult to conceive of a reason why Plaintiffs-Appellants would not have been able to amend their complaint to include these various allegations in a timely manner.'' *Id.* Similarly, in the instant matter, Respondent is not claiming that he did not receive the ALJ's Orders setting the deadlines for the filing of his Prehearing Statement, one of which he, himself, instigated with his Motion for Time Extension.[15] *Supra* section II.D. Rather, the best Respondent offers is to assert that he ''will also file his Prehearing Statement to the best of his ability;'' but he never did. Respondent's Motion for Leave, at 1.

In sum, the Agency finds that the ALJ faithfully carried out his duties and acted within his statutorily granted powers leading up to, and concluding in, his entry of his Order Denying Motion for Leave. He afforded Respondent three deadlines to file a Prehearing Statement. Not only did Respondent never file a Prehearing Statement, his asserted ''good cause'' bases for failing to do so are belied by the tasks that Respondent's attorney admits to completing instead of the Prehearing Statement in the days before the third, and final, Prehearing Statement deadline. The Agency concludes that the ALJ did not err in finding that Respondent waived his right to a hearing, in ruling that Respondent was in default, and in ordering the termination of proceedings.

## III. The CSA and the Texas Physician Standard of Practice

The main objectives of the CSA, according to the Supreme Court, are to ''conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Gonzales* v. *Raich,* 545 U.S. 1, at 12 (2005). Given these objectives, the Supreme Court states, particular congressional concerns included ''the need to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–13. Further, according to the Supreme Court, to accomplish these goals in the CSA, ''Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by'' the statute.[16] *Id.* at 13. Accordingly, the Supreme Court states, the ''CSA and its implementing regulations set forth strict requirements regarding registration . . . and recordkeeping.'' *Id.* at 14.

As for a practitioner, such as Respondent, a medical doctor, ''[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(g)(1). The section 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.* Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[17] It also directed the Attorney General to consider the same five factors when determining whether to suspend or revoke the registration of a practitioner, such as Respondent, due to the practitioner's commission of ''such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest.'' 21 U.S.C. 824(a)(4), *infra* section VI.A.

According to the CSA's implementing regulations, 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

[14] Plaintiffs-Appellants had already filed an amended complaint, but it did not include the further factual allegations that they sought to include in a second amended complaint. 2 F.4th at 418.

[15] Respondent's Motion for Leave states that his counsel ''honestly did not recognize the court's 1:00 p.m. deadline [to file his Prehearing Statement], but rather the date the motions and statements were due.'' Motion for Leave, at 4. The Agency notes, however, that, despite this statement and others in his Motion for Leave, Respondent did not file his Prehearing Statement with his Motion for Leave as the ALJ's Order Directing Compliance requires. Order Directing Compliance, at 2.

[16] 21 U.S.C. 841(a)(1) (''Under the CSA, it is ''unlawful for any person knowingly or intentionally . . . to . . . distribute[ ] or dispense, or possess with intent to . . . distribute[ ] or dispense, a controlled substance'' ''[e]xcept as authorized'' by the Act.). The CSA defines ''dispense'' to include ''prescribing'' a controlled substance. 21 U.S.C. 802(10).

[17] The five factors of 21 U.S.C. 823(g)(1)(A–E) are:

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

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

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

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

professional practice.'' 21 CFR 1306.04(a). As the Supreme Court explained in the context of the Act's requirement that Schedule II controlled substances may be dispensed only by written prescription, ''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,* 546 U.S. 243, 274 (2006), *see also United States* v. *Hayes,* 595 F.2d 258 (5th Cir.), *cert. denied,* 444 U.S. 866 (1979).

The OSC is addressed to Respondent at his registered address in Texas. Therefore, the Agency also evaluates Respondent's actions according to Texas law, including the applicable Texas physician standard of care. *Gonzales* v. *Oregon,* 546 U.S. at 269–71. As the posture of this matter is Respondent's default and, therefore, there was no opportunity for the parties to litigate legal theories not in the OSC, the Agency confines its analysis of Texas law to the legal provisions cited in the OSC.

According to Texas law applicable during the time period alleged in the OSC, a ''practitioner . . . may not prescribe, dispense, [or] deliver . . . a controlled substance . . . except for a valid medical purpose and in the course of medical practice.'' Tex. Health and Safety Code Ann. § 481.071(a) (2025).[18] Texas law elaborates on the meaning of a ''valid medical purpose'' and ''in the course of medical practice.'' For example, Texas law states that the ''treatment of pain is a vital part of the practice of medicine,'' that ''[p]hysicians should be able to treat their patients' pain using sound clinical judgment without fear . . . [of] disciplinary action,'' and that ''[s]ound clinical judgment results from the use of generally accepted standards of care, which include evidence-based medicine, when available.'' 22 Tex. Admin. Code § 170.1 (2016–2020). ''[T]o protect the public and give guidance to physicians,'' this Texas authority continues, it ''sets forth minimum requirements related to the proper treatment of pain.'' *Id.* For example, it states that a ''license to practice medicine gives a physician legal authority to prescribe drugs for pain,'' and the ''duty'' to ''help, and not to harm patients and the public.'' *Id.* § 170.1(3). The provision elaborates further, stating that ''[h]arm can result when a physician does not use sound clinical judgment in using drug therapy,'' such as either causing the patient to suffer continued pain if the drug therapy is not sufficient, or ''lead[ing] to or contribut[ing] to abuse, addiction, and/or diversion of drugs.'' *Id.* § 170.1(4).

Texas law further specifies that the ''extent of medical records must be legible, complete, accurate and current for each patient,'' and that the treatment of chronic pain ''requires a reasonably detailed and documented plan to assure that the treatment is monitored and evaluated on an ongoing basis.'' [19] *Id.* § 170.1(5) and (6). In sum, the ''intent'' of these provisions is to ''set forth those items expected to be done by any reasonable physician involved in the treatment of pain.'' *Id.* § 170.1(7).

In another provision, Texas law sets out ''minimum requirements for the treatment of chronic pain'' that, along with compliance with the generally accepted standard of care, are how the physician's treatment of a patient's pain will be evaluated.[20] *Id.* § 170.3. Those ''minimum requirements'' include evaluating the patient by obtaining a medical history and a physical examination ''that includes a problem-focused exam specific to the chief presenting complaint of the patient.'' *Id.* § 170.3(1)(A). They state that a ''medical record shall document the medical history and physical exam,'' and, in the case of chronic pain, must document the ''nature and intensity of the pain,'' ''current and past treatments for pain,'' ''underlying or coexisting diseases and conditions,'' the ''effect of the pain on physical and psychological function,'' ''any history and potential for substance abuse or diversion,'' and the ''presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.'' *Id.* § 170.3(1)(B).

Further, the Texas minimum requirements for physicians' treatment of chronic pain under Texas law explicitly include having a written treatment plan that addresses specified elements and that is documented in the medical record; obtaining and documenting the patient's informed consent for the use of controlled substances for chronic pain treatment; and having a written pain management agreement with the patient that covers patient responsibilities regarding physician-ordered laboratory tests, physician-limited refills, and the involvement of only one physician and one pharmacy for the drug dispensing, and that states the reasons why the drug therapy may be terminated. *Id.* § 170.3(2), (3), and (4). Texas law's minimum requirements for physicians treating chronic pain also include the physician's seeing the patient for periodic reviews at ''reasonable intervals,'' during which the physician assesses progress toward treatment objectives and contemporaneously documents, in the medical record, the visit and any adjustments to the treatment plan. *Id.* § 170.3(5)(A–D). The minimum requirements in Texas law also state that a physician treating chronic pain must base any continuation or modification of the use of ''dangerous and scheduled drugs for pain management'' on an ''evaluation of progress toward treatment objectives.'' *Id.* § 170.3(5)(E). They specifically address how the physician is to evaluate the patient's progress toward treatment objectives, requiring that progress or the lack of progress in relieving pain ''must be documented in the patient's record,'' stating that ''[s]atisfactory response to treatment'' may be indicated by the ''patient's decreased pain, increased level of function, and/or improved quality of life,'' calling for the physician to monitor ''[o]bjective evidence'' of the patient's improved or diminished function, including information ''offered or provided'' by family members or other caregivers, and requiring the physician to ''reassess the current treatment plan and consider the use of other therapeutic modalities'' if the patient's progress is unsatisfactory. *Id.* § 170.3(5)(E)(i–iv). The physician's evaluation of progress toward treatment objectives, according to the Texas minimum requirements, must also involve reviewing the ''patient's compliance with the prescribed treatment plan and reevaluat[ing] for

[18] This Texas authority was not amended during the time period alleged in the OSC.

[19] The definition of ''chronic pain'' changed during the period covered by the OSC. 22 TAC § 170.2. The first definition during the relevant time period was ''a state in which pain persists beyond the usual course of an acute disease or healing of an injury. Chronic pain may be associated with a chronic pathological process that causes continuous or intermittent pain over months or years,'' (eff. through July 12, 2020). It changed to ''pain that is not relieved with acute, post-surgical, post-procedure, or persistent non-chronic pain treatment parameters and persists beyond the usual course of an acute condition typically caused by, or resembling that caused by, actual or potential tissue injury or trauma, disease process, or operative procedure or the healing or recovery of such condition with or without treatment. This type of pain is associated with a chronic pathological process that causes continuous or intermittent pain for no less than 91 days from the date of the initial prescription for opioids,'' (eff. through Jan. 18, 2025). These changes do not impact this Decision/Order.

[20] During the time period addressed in the OSC, 22 Tex. Admin. Code § 170.3 was amended several times. Those amendments, elaborating on existing minimum requirements for the treatment of chronic pain, do not impact this Decision/Order.

any potential for substance abuse or diversion.'' *Id.* § 170.3(5)(E)(v).

Finally, the Texas minimum standards also address ''consultation and referral'' and ''medical records.'' Regarding ''consultation and referral,'' Texas law states, among other things, that patients ''who are at-risk for abuse or addiction require special attention,'' and that patients ''with chronic pain and histories of substance abuse or with co-morbid psychiatric disorders require even more care.'' *Id.* § 170.3(6). According to the Texas minimum standards, a ''consult with or referral to an expert in the management of such patients must be considered in their treatment.'' *Id.*

Texas law has a separate provision addressing medical records.[21] *Id.* § 165.1. According to that provision, a licensed physician shall maintain an ''adequate medical record'' for each patient that is complete, contemporaneous, and legible. *Id.* § 165.1(a). The statement of the standards that an ''adequate medical record'' should meet, as particularly applicable to this adjudication, includes the date of the encounter, documentation of the patient's noncompliance, identification of relevant risk factors, and written consents for treatment. *Id.* § 165.1(a)(1)(D), (a)(4), (a)(5), and (a)(7).

## IV. The Deemed-Admitted Facts

As Respondent defaulted, he is deemed to admit the facts alleged in the OSC. 21 CFR 1301.43; *supra* section II.C. Accordingly, the Agency finds, due to Respondent's deemed admissions, the OSC-alleged facts to be uncontroverted and proven unequivocally, as follows:

1. Respondent is registered with the Agency as a practitioner authorized to handle controlled substances in Schedules II through V under Certificate of Registration No. BK4924139. OSC, at 3;

2. Respondent is a licensed physician under Texas license number K0506. *Id.;*

3. From at least January 2016 through July 2020, Respondent issued numerous prescriptions for Schedule II through IV controlled substances, but:

a. failed to conduct or document adequate patient evaluations and histories necessary to establish a medical diagnosis justifying the necessity for the prescriptions,

b. failed to monitor patient progress adequately, and

c. prescribed dangerous combinations of controlled substances.

*Id.*

4. As for individual L.G., on a near monthly basis between at least August 26, 2016, and July 1, 2020, Respondent issued prescriptions for oxycodone 30 mg (a Schedule II opioid) and methadone 10 mg (a Schedule II opioid) although he failed to establish a medical condition sufficient to support the long-term use of opiates by, among other things,

a. Failing to establish an objective diagnosis adequately supported by physical examination, history of present illness, past medical history, or imaging to medically justify the continued prescribing of controlled substances. *Id.* at 3–4;

b. Continuing to prescribe a Morphine Milligram Equivalent (MME) as high as 680;

c. Treating L.G. for several years despite L.G.'s not showing clinical signs of functional improvement or reduction in pain, illustrating a failed opioid regime;

d. Failing to address adequately, and assess, L.G.'s aberrant behaviors, such as inconsistent urine drug screens and illicit drug use;

e. Failing to address adequately L.G. co-morbidities, including hypertension, altered mental status, and insomnia;

f. Prescribing a dangerous combination of methadone, oxycodone, and Ambien for L.G., thus increasing L.G.'s risk of opioid harm.

*Id.* at 4.

5. As for individual E.C., on a near monthly basis between at least January 18, 2016, and June 1, 2020, Respondent issued multiple prescriptions for hydromorphone 8 mg (a Schedule II opioid), oxycodone 60 mg (a Schedule II opioid), morphine 30 mg (a Schedule II opioid), and carisoprodol (a Schedule IV muscle relaxant) although he failed to establish a medical condition sufficient to support the long-term use of opiates by, among other things,

a. Failing to establish an objective diagnosis adequately supported by physical examination, history of present illness, past medical history, or imaging to justify medically the continued prescribing of controlled substances;

b. Continuing to prescribe a MME as high as 312;

c. Treating E.C. for several years despite E.C.'s not showing clinical signs of functional improvement or reduction in pain. *Id.;*

d. Failing to address adequately E.C's aberrant behaviors, such as at least four inconsistent urine drug screens;

e. Failing to address adequately E.C. co-morbidities, such as depression, anxiety, and pulmonary status;

f. Failing to address adequately, and assess, E.C.'s aberrant behaviors, such as clear indications of abuse and past overdoses and inability to self-administer medications;

g. Failing to address adequately with E.C. the risks associated with long-term opioid use;

h. Failing to maintain adequate medical charts related to the treatment of E.C.;

i. Prescribing for E.C. a combination of opioids, a benzodiazepine, and a muscle relaxant, specifically carisoprodol, constituting a highly-addictive ''drug cocktail'' known as the ''Holy Trinity,'' putting E.C. at increased risk for harm, including overdose or death.

*Id.* at 5.

6. As for individual D.S., on a near monthly basis between at least October 19, 2016, and July 17, 2020, Respondent issued multiple prescriptions for controlled substances hydromorphone 4 mg and fentanyl 25 mg (a Schedule II opioid) although he failed to establish a medical condition sufficient to support the long-term use of opiates by, among other things,

a. Failing to establish an objective diagnosis adequately supported by physical examination, history of present illness, past medical history, or imaging to justify medically the continued prescribing of controlled substances. *Id.* at 5–6;

b. Continuing to prescribe an MME as high as 156;

c. Treating D.S. for several years despite D.S.'s not showing clinical signs of functional improvement or reduction in pain;

d. Failing to address adequately, and assess, D.S.'s aberrant behaviors, such as at least four inconsistent urine drug screens;

e. Failing to address adequately D.S. co-morbidities, including hypertension, altered mental status, and insomnia;

f. Failing to maintain adequate medical charts related to the treatment of D.S., specifically, detailing office visits and evaluations with D.S. when no such visits occurred; and

g. Prescribing a combination of opioids, a benzodiazepine, and a muscle relaxant, specifically carisoprodol, the Holy Trinity drug cocktail, putting D.S. at increased risk for harm, including overdose or death. *Id.* at 6.

7. The independent medical expert with whom the Government consulted about Respondent's medical files concluded that Respondent's issuance of the above-described controlled substance prescriptions ''fell outside the standard of care applicable to the

[21] The amendments made to this Texas law section during the period covered by the OSC do not impact this Decision/Order.

practice[ ] of . . . medicine in the State of Texas.''

Given these ''deemed-admitted'' facts due to Respondent's default, the Agency now determines whether they constitute a *prima facie* case that Respondent's continued registration is inconsistent with the public interest. OSC, at 1. The Agency conducts this analysis based on the federal and Texas law applicable during the timeframe of Respondent's OSC-alleged violations: January 2016 through July 2020. *Id.* at 3; *see also id.* at 4, 5; *supra* section III.

**V. Allegation That Respondent Illegally Prescribed Controlled Substances**

According to the OSC, Respondent ''issued numerous prescriptions for Schedule II–IV controlled substances outside the course of professional practice and not for a legitimate medical purpose.'' OSC, at 3. The facts deemed admitted due to Respondent's default establish that Respondent violated multiple provisions of the applicable Texas standard of practice and, thus, that he prescribed controlled substances outside the course of professional practice and not for a legitimate medical purpose. 21 CFR 1306.04(a). For example, under Texas law, a ''practitioner . . . may not prescribe . . . a controlled substance . . . except for a valid medical purpose and in the course of medical practice.'' Tex. Health and Safety Code Ann. § 481.071(a). Further, according to Texas law, a physician is to use ''sound clinical judgement,'' resulting from the use of ''generally accepted standards of care,'' in prescribing controlled substances, so that patients use those substances in a ''therapeutic manner'' to ''relieve'' pain, and so that the physician uses his medical licenses to ''help, and not to harm patients and the public.'' 22 TAC § 170.1.

The deemed-admitted facts establish that Respondent prescribed ''dangerous combinations'' of controlled substances to three persons, thus increasing the risk of harm to them and to the public. OSC, at 4–6. Also pursuant to the deemed-admitted facts, Respondent continued to prescribe controlled substances to three persons for ''several years'' even though the drug therapies he prescribed did not bring about signs of functional improvement or reduction of pain for any of them. For the above reasons, the Agency concludes that Respondent violated applicable Texas law on all of these occasions.

In addition, the applicable Texas standard of practice states that the physician is responsible for obtaining and documenting a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint, and that the rationale for and results of diagnostic and other ancillary services should be included in the medical record. 22 TAC § 165.1(a), *see id.* 170.3(1)(B) (Minimum Requirements for the Treatment of Chronic Pain). According to the deemed-admitted facts, though, Respondent failed to establish an adequately supported diagnosis to justify the prescribing of controlled substances for three persons. OSC, at 3–5. As such, the Agency concludes that Respondent's failures are a violation of the applicable Texas standard of practice.

Also, the applicable Texas standard of practice requires that, to be considered an ''adequate medical record,'' the medical record includes the date of the patient encounter. 22 TAC § 165.1(a)(1)(D). The deemed-admitted facts establish, though, that Respondent's medical records for D.S. ''detail[ ] office visits and evaluations . . . when no such visits occurred.'' *Id.* at 6; *see also* OSC, at 5 (''inadequate medical chart'' for E.C.). Accordingly, the Agency concludes that, under Texas law, Respondent's medical record about a visit that never occurred is not an ''adequate medical record'' and, therefore, that Respondent violated applicable Texas law.

By way of further example, the applicable Texas standard of practice states that the minimum requirements for a physician's treatment of chronic pain include obtaining and documenting the patient's informed consent for the use of controlled substances. 22 TAC § 170.3(3). The deemed-admitted facts, however, establish that Respondent failed to address adequately with E.C. the risks of long-term opioid use. OSC, at 5. The Agency thus concludes that Respondent violated the applicable Texas standard of practice concerning informed consent.

Also, according to the Texas minimum requirements, a physician's continuation of the use of scheduled drugs for pain management must be based on an evaluation of progress toward treatment objectives and must be reevaluated periodically for any potential for substance abuse or diversion. 22 TAC § 170.3(5). The deemed-admitted facts, however, establish that three individuals for whom Respondent prescribed controlled substances for several years showed no functional improvement or reduction in pain, and that the three individuals exhibited aberrant behaviors, such as multiple inconsistent urine drug screens, indications of abuse, and illicit drug use. OSC, at 4–6. Thus, the Agency concludes that Respondent violated the applicable Texas minimum requirements for controlled substance prescribing on multiple occasions.

In sum, based on the deemed-admitted facts and applicable law, the Agency concludes that Respondent prescribed controlled substances on multiple occasions outside the course of professional practice and not for a legitimate medical purpose and, thus, in violation of applicable law. 21 CFR 1306.04(a); Tex. Health and Safety Code Ann. § 481.071; 22 TAC §§ 170.1, 170.3, 165.1.

**VI. Discussion**

*A. The CSA and the Public Interest Factors*

As already discussed, Congress directed the Attorney General to consider five factors in making the determination of whether to suspend or revoke a registration due to the registrant's commission of such acts as would render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4), *supra* section II.A., *supra* n. 17 (public interest factors). The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. at 292–93 (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' citing *In re Arora,* 60 FR 4447, 4448 (1995)); Robert *A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (DC Cir. 2005). Any one factor, or combination of factors, may be decisive. *Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (DC Cir. 2007); *Morall,* 412 F.3d at 185 n.2; *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

The Agency ''may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate. *Morall,* 412 F.3d at 185 n.2*; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (*citing Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016)); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while the Agency is required to consider each of the factors, it ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 *(quoting Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . 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.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

While the Agency considered all of the 21 U.S.C. 823(g)(1) factors in this matter, the Agency finds that the Government's *prima facie* case is confined to factors B and D. The Government has the burden of proof in this proceeding. 21 CFR 1301.44(e). The Agency finds that the deemed-admitted facts with respect to Factors B and D satisfy the Government's *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

*B. Factors B And D—Respondent's Experience Dispensing Controlled Substances and Compliance With Applicable Laws Relating to Controlled Substances*

Allegation That Respondent's Registration Is Inconsistent With the Public Interest

As detailed above, the Agency concludes that Respondent violated the applicable Texas standard of practice on multiple occasions over the course of several years while prescribing controlled substances for three individuals. *Supra* sections IV and V. Thus, the Agency further concludes that Respondent issued prescriptions that lacked a legitimate medical purpose outside the usual course of his professional practice contrary to 21 CFR 1306.04. Accordingly, the Agency finds that the Government presented a *prima facie* case for which the Agency may impose a sanction on Respondent, and that Respondent, due to his default, did not rebut the Government's *prima facie* case. 21 U.S.C. 824(a)(4).

## VII. Sanction

Where, as here, (1) Respondent is deemed to have admitted the factual allegations in the OSC, (2) the deemed-admitted facts are substantial evidence proving the legal violations alleged to support revocation based on acts inconsistent with the public interest, (3) the Government met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to his experience dispensing controlled substances and his numerous failures to comply with laws relating to controlled substances, and (4) Respondent did not rebut the Government's *prima facie* case, the burden shifts to Respondent to show why he can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy,* 881 F.3d at 830; *Garrett Howard Smith, M.D.,* 83 FR 18,882 (2018).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency has required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833 (citing authority including *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.'')), *MacKay,* 664 F.3d at 820 (''[Whether the registrant will change his behavior in the future] is vital to whether continued registration is in the public interest.''). A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy,* 881 F.3d at 830–31.

Further, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. The Agency has also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Regarding these matters, there is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations. As such, Respondent has not presented any evidence showing that he can be entrusted with a registration. Accordingly, the record supports the imposition of a sanction.

The interests of specific and general deterrence weigh in favor of revocation given the egregiousness of the founded violations, violations that go to the heart of the CSA and of this Agency's law enforcement mission. *E.g., Jones Total Health Care Pharmacy,* 881 F.3d at 834 and n.4; *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases), *supra* sections IV and V. In addition, as Respondent has not unequivocally accepted responsibility for the founded violations, it is not reasonable to believe that Respondent's future controlled substance prescribing will comply with legal requirements. *Supra.* Further, given the foundational nature and vast number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not essential to maintaining a registration.

Accordingly, the Agency shall order the revocation of Respondent's registration.

## Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. BK4924139 issued to Andrew Konen, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending application of Andrew Konen, M.D., to renew or modify this registration, as well as any other pending application of Andrew Konen, M.D., for registration in Texas. This Order is effective September 19, 2025.

## Signing Authority

This document of the Drug Enforcement Administration was signed on August 13, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

**Heather Achbach,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

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