the following: (1) The date that a controlled substance was administered, or dispensed (whether by prescription or actual delivery of the drug); (2) the name of the patient to whom a controlled substance was administered or dispensed (whether by prescription or actual delivery); (3) the patient's dental complaint; (4) the name, dosage, and quantity of the substance prescribed, dispensed or administered; and (5) the date that the medication was previously prescribed, dispensed or administered to that patient if the medication was prescribed, dispensed or administered in the last year, as well as the amount last provided to that patient. If no controlled substances are prescribed, administered, or dispensed during a given quarter, Respondent shall submit a letter to the DEA office indicating that there was no activity to report during the quarter.

(B) Within 15 days of the event, Respondent shall inform the local DEA office of any proceeding initiated against him by a State licensing board, whether the board regulates his professional practice or his authority to prescribe controlled substances. In addition, within 15 days of the event, Respondent shall inform the local DEA office of any interim or final order of a State licensing board which imposes a sanction, whether the sanction be a reprimand, a fine, a civil penalty, a probationary period, a rejection of a petition for termination of probation, an imposition of a condition, a suspension, or a revocation of any State professional license or authority to prescribe a controlled substance.

(C) In the event that Respondent changes employment during this three-year period, he shall immediately notify the local DEA office that is monitoring his drug activity logs.

To ensure that there is no confusion as to the duration of these conditions, all three conditions shall remain in effect for a period of three years from the date of this Order's publication in the **Federal Register**.

Moreover, because Respondent has not previously appreciated the seriousness of these proceedings and his obligation to comply with the CSA, the Agency's rules, and the conditions imposed pursuant to the 2002 Order, I further conclude that a period of outright suspension of his registration is warranted. Accordingly, while I grant Respondent a new registration, said registration will be suspended outright for a period of three months.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823 and 824, as well as 28 CFR 0.100(b) and 0.104, I hereby order that the application of Gregory D. Owens, D.D.S., to renew his DEA Certificate of Registration, be, and it hereby is, granted subject to the conditions set forth above. I further order that the DEA Certificate of Registration issued to Gregory D. Owens, be, and it hereby is, suspended for a period of three months from the effective date of this Order. This Order is effective August 24, 2009.

Dated: July 16, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–17681 Filed 7–23–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–59]

Roy E. Berkowitz, M.D.; Revocation of Registration

On August 26, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Roy E. Berkowitz, M.D. (Respondent), of Slidell, Louisiana. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BB0492912, as a practitioner, and the denial of any pending applications to renew or modify his registration, on the grounds that Respondent does ''not have authority to prescribe controlled substances in the State of Louisiana,'' and that his ''continued registration is inconsistent with the public interest.'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that as a result of prescriptions for controlled substances which Respondent issued in 2006 and 2007 that were inconsistent with State rules and regulations, Respondent entered into a Consent Order with the Louisiana State Board of Medical Examiners, which ''strips [Respondent] of authority to handle controlled substances in the State of Louisiana, the state in which [he is] registered with DEA.'' *Id.*

Respondent requested a hearing on the allegations, and the matter was assigned to an Administrative Law Judge (ALJ), who commenced pre-hearing procedures. Thereafter, the Government moved for summary disposition on the ground that Respondent ''currently lacks authority to handle controlled substances in the State of Louisiana—his state of registration.'' Gov. Mot. at 1.

In support of its motion, the Government attached a declaration of a DEA Diversion Investigator (DI). Therein, the DI stated that on October 15, 2008, she had queried the Louisiana State Board of Pharmacy's Web site to determine Respondent's license status, and found that ''the Controlled Dangerous Substance license #33853 of Roy E. Berkowitz, M.D. was delinquent, having expired on September 25, 2008.'' *Id.* at Appendix I.

The ALJ allowed the Respondent to file a response to the motion through October 30, 2008. Moreover, on October 29, 2008, the ALJ granted Respondent an extension of the due date until November 6, 2008, on which date Respondent filed his response.

Therein, Respondent noted that while the Show Cause Order had relied on the State Board's Consent Order, the motion for summary disposition relied on a ''declaration * * * asserting that a license issued by the Louisiana Board of Pharmacy to [Respondent] expired on September 25, 2008.'' Resp. at 1. Respondent maintained that the Government was improperly changing its theory of the case, and argued that ''[t]he DEA without leave to amend the Order to Show Cause has sought to change the underlying basis of the case.'' [1] *Id.* at 2–3.

Next, Respondent argued that the Agency lacks authority to revoke his registration because in his view, 21 U.S.C. 824(a)(3) requires *both* a suspension, denial or revocation of the state license or registration, and that the practitioner no longer be authorized by state law to handle controlled substances. *Id.* at 3–4. In support of his contention, Respondent attached his declaration in which he stated that he submitted his application for renewal of his Louisiana Controlled Dangerous Substance License in July 2008, and that he was ''advised by the Louisiana Board of Pharmacy that this agency was unable to process'' his application. *Id.,* Ex. A at 1. The declaration further asserted that the Louisiana Board of Pharmacy ''did not enter an order'' denying, suspending or revoking Respondent's application. *Id.* at 1–2. Thus, Respondent argued that the Government's motion should be denied ''[b]ased upon a failure to establish the elements required under 21 U.S.C. 824(a)(3) and 21 U.S.C. 824(a)(4).'' Resp. at 5.

On January 27, 2009, the ALJ issued her Opinion and Recommended

[1] Respondent also invoked the ''mend the hold doctrine,'' an obscure common law rule which prohibits a party to a contract from changing its position on the contract's meaning during the course of litigation over it. *Id.* at 3 (citing *Utica Mut. Ins. Co.* v. *Vigo Coal Co., Inc.,* 393 F.3d 707, 716 (7th Cir. 2004)). Specifically, Respondent contended that the Government's reliance on the expiration of Respondent's lack of a state controlled substance license was ''analogous to an attempt to mend the hold,'' presumably because the Show Cause Order had cited the consent agreement rather than the expiration. *Id.* at 3 (citation omitted). Respondent did not renew this argument in his exceptions, and in any event, the analogy is misplaced.

Decision. Therein, the ALJ granted the Government's motion for summary disposition and recommended that I revoke Respondent's registration and deny any pending applications. The ALJ rejected Respondent's argument that his due process rights were violated by the Government's reliance on the expiration of his state's dangerous substances license, as Respondent was ''advised * * * of the grounds on which the Government relied in seeking to revoke his registration and * * * addressed those grounds in his response.'' ALJ at 4.

The ALJ also rejected Respondent's argument that the Government had failed to show that his continued registration was inconsistent with the public interest, reasoning that the ''subsections of 21 U.S.C. 824(a) are to be considered in the disjunctive.'' *Id.* Framing the issue as ''whether Respondent is currently authorized to handle controlled substances in Louisiana,'' the ALJ noted Respondent's contention that he had applied for a new state controlled substance registration, but that the State Board of Pharmacy had advised him that it could not act on his application. *Id.* at 5. The ALJ then rejected Respondent's argument, reasoning that Respondent did not dispute that his state registration ''is expired, and although he asserts that there should be a hearing on whether his filing of a renewal application extends his authority to handle controlled substances in Louisiana, he makes no showing that he has applied for and been granted the requisite authority.'' *Id.*

The ALJ thus concluded that there was no dispute over the material fact ''that Respondent is currently not authorized to handle controlled substances in Louisiana, the State in which he is registered with the DEA.'' *Id.* Applying the Agency's settled rule that ''[b]ecause Respondent lacks this state authority * * * he is not currently entitled to a DEA registration in Louisiana,'' the ALJ granted the Government's motion and recommended that Respondent's registration be revoked and that any pending application be denied. *Id.*

Thereafter, on February 13, 2008, Respondent submitted his Exceptions to the ALJ's decision, and on March 9, 2009, the ALJ forwarded the record to me for final agency action. Having considered the entire record including Respondent's exceptions, I adopt the ALJ's finding that Respondent currently lacks authority to handle controlled substances in Louisiana, and therefore, is not entitled to maintain his DEA registration. I also adopt the ALJ's recommendation that Respondent's registration be revoked and that any pending application be denied.

I find that Respondent currently holds DEA Certificate of Registration, BB0492912, which authorizes him to dispense controlled substances in Schedules II through V, as a practitioner, at the registered location of 1632 Marina Drive, Slidell, Louisiana. Respondent's Registration does not expire until July 31, 2009. I further find that Respondent Louisiana Controlled Dangerous Substance (CDS) License expired on September 25, 2008.

I also find that while Respondent has applied for a new State CDS license, he has provided no evidence that Board of Pharmacy has issued one to him. Moreover, Respondent cites to no authority establishing that under Louisiana law, his filing of the application extended his CDS license past its expiration date. *Cf.* 5 U.S.C. § 558(c). I thus adopt the ALJ's conclusion that Respondent does not possess authority to dispense controlled substances under Louisiana law, and therefore does not meet an essential prerequisite for holding a registration under Federal law. ALJ at 5.

Respondent nonetheless excepts to the ALJ's decision on various grounds. First, Respondent contends that the ALJ erred in granting the Government's motion for summary disposition because it relied on an issue (the expiration of his State CDS license) which was not raised in the Show Cause Order. In Respondent's view, a motion for summary disposition in an administrative proceeding should be treated analogously to a motion for summary judgment, and that the ''[p]leadings may not be disregarded in ruling on a motion for summary judgment in Federal court.'' Exc. at 2. According to Respondent, ''if the *pleadings,* depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law,'' then the motion should be granted. Exc. at 2–3 (emphasis in original). By emphasizing, ''pleadings,'' Respondent apparently wished to emphasize his position that the Show Cause Order should have contained all the grounds on which the revocation was ultimately based.

This Agency's proceedings are not, however, governed by the Federal Rules of Civil Procedure. And while those rules (and the judicial decisions interpreting them) may be a useful guide, they are not binding on the Agency. Instead, what is binding on the Agency is the Due Process Clause, the Administrative Procedure Act, and the Agency's regulations.

Contrary to Respondent's understanding, to decide this matter on the grounds asserted in the Government's motion does not violate his right to due process. As the Federal Courts have recognized, '''[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.''' *Citizens State Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (quoting *Aloha Airlines, Inc.,* v. *CAB,* 598 F.2d 250, 262 (DC Cir. 1979)). An agency is not required ''to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront.'' *Boston Carrier, Inc.* v. *ICC,* 746 F.2d 1555, 1560 (DC Cir. 1984); *see also Paul H. Volkman,* 73 FR 30630, 30641 n.35 (2008). Indeed, the Federal Courts routinely uphold agency adjudications which are based on matters which were not initially raised in a charging document but which were nonetheless litigated in a proceeding. *See, e.g., Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 137 (2d Cir.1990) (no due process violation where NLRB did not cite in complaint specific provision of NLRA which Board ultimately relied on in its order because the employer ''was not kept in the dark [and] was aware of and actively litigated'' the relevant issue); *Facet Enters., Inc.,* v. *NLRB,* 907 F.2d 963, 972 (10th Cir. 1990) (''A material issue which has been fairly tried by the parties * * * may be decided by the Board regardless of whether it has been specifically pleaded.''); *Citizens State Bank,* 751 F.2d at 213; *Kuhn* v. *CAB,* 183 F.2d 839, 842 (DC Cir. 1950)((''If it is clear that the parties understand exactly what the issues are when the proceedings are had, they cannot thereafter claim surprise or lack of due process because of alleged deficiencies in the language of the particular pleadings.'').

Notably, in the Show Cause Order, the Agency notified Respondent that it was seeking the revocation because he ''do[es] not have authority to prescribe controlled substances in the State of Louisiana,'' and that as a consequence, ''DEA must revoke your DEA registration based upon your lack of authority to handle controlled substances in the State of Louisiana.'' Show Cause Order at 1. The Government thus provided Respondent with notice as to the legal basis for the proceeding.

Moreover, even though the Government relied on the expiration of Respondent's State CDS license rather

than the Consent Order to support its motion, Respondent had an ample and meaningful opportunity to present evidence refuting the Government's evidence and creating a triable issue and/or to make argument (were there any viable ones to be made), regarding the legal effect of his filing of the State renewal application. While Respondent further argues that if the Agency ''was going to place in issue allegations that were not named in the Order to Show Cause, the proper course of action would have been to move to amend the Order to Show Cause,'' he does not identify how he has been prejudiced by the Government's failure to amend the Order. Exc. at 4; *cf. Facet Enterprises,* 907 F.2d at 972 (''In determining whether a respondent can be held liable for an unfair labor practice not charged in the complaint, the central inquiry is fairness: considering the circumstances of the case, did the respondent know what conduct was being alleged and have 'a fair opportunity to present [its] defense?''') (quoting *Soule Glass & Glazing Co.* v. *NLRB,* 652 F.2d 1055, 1074 (1st Cir. 1985)).[2]

The rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence. The Government's failure to file an amended Show Cause Order alleging that Respondent's state CDS license had expired does not render the proceeding fundamentally unfair.

Respondent also argues that the ALJ's ruling on the summary disposition motion ''should have been stayed pending disclosure of evidence.'' Exc. at 5. Respondent analogizes the prehearing statements to civil discovery and argues that ''the usual prehearing procedures for exchanging information was [sic] not completed.'' *Id.* There is, however, no general right to discovery under either the APA or DEA regulations, but rather only a limited right to receive in advance of the hearing the documentary evidence and summaries of the testimony which the Government intends to rely upon. *Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000) (citing *McClelland* v. *Andrus,* 606 F.2d 1278, 1285 (DC Cir. 1979)); *see also* 21 CFR 1316.54(e) & 1316.57. Nor, given the narrowness of the issue upon which the motion for summary disposition was based—whether Respondent has authority under state law to dispense a controlled substance—has Respondent shown what material evidence he might have obtained from the Government which he could not have obtained from another source such as the State itself. The contention is therefore without merit.

Respondent also argues that the ALJ unlawfully shifted the burden of proof to him. According to Respondent, ''[t]here is an issue of disputed fact as to whether there has been [a] suspension[,] revocation[,] or denial of [his] state authority to prescribe controlled substances or merely [a] delay in processing his renewal application.'' Exc. at 6. Respondent further claims that the ALJ did not require the DEA to show that the license was ''pending,'' and placed on him the burden of ''show[ing] that he had been granted the requisite authority.'' *Id.* at 7. Relatedly, Respondent maintains that the Government cannot revoke his registration under 21 U.S.C. 824(a)(3) because it has not shown that his registration has been suspended, revoked, or denied by competent authority. *Id.*

Respondent ignores, however, that Congress has made the possession of state authority a prerequisite for obtaining a DEA registration. *See id.* Section 823(f) (''The 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.''). In addition, the CSA defines the term ''practitioner'' to ''mean[] a physician * * * or other person licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to dispense [or] administer * * * a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). A physician who no longer holds authority under State law to dispense a controlled substance is therefore not a practitioner within the meaning of the CSA and cannot lawfully dispense.

DEA has therefore consistently held that a practitioner may not maintain his registration if he lacks state authority to dispense controlled substances. This rule has been applied to revoke the registration of a practitioner even when the practitioner's loss of state authority was based on the expiration of a state license rather than a formal disciplinary action of a state board. *See William D. Levitt,* 64 FR 49822, 49823 (1999); *see also id.* at 49822 (collecting cases). As the Agency explained in *Levitt,* because state authorization was clearly intended to be a prerequisite to DEA registration, Congress could not have intended for DEA to maintain a registration if a registrant is no longer authorized by the state in which he practices to handle controlled substances due to the expiration of his state license. Therefore, it is reasonable for DEA to interpret that 21 U.S.C. § 824(a)(3) would allow for the revocation of a DEA * * * Registration where, as here, a registrant's state authorization has expired.

Id. at 49823. *See also Chevron, Inc.,* v. *NRDC, Inc.,* 467 U.S. 837, 843 (1984) (where Congress is silent on a question, courts defer to an agency's reasonable interpretation of the statute it administers).

Accordingly, in relying on the undisputed fact that Respondent's State CDS license had expired, the ALJ did not erroneously shift the burden of proof from the Government to him. Rather, she correctly applied the Agency's settled precedent that because Respondent clearly lacks authority to dispense controlled substances in the State in which he holds his DEA registration and practices medicine, he is not entitled to maintain his registration. Respondent's registration will therefore be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as by 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BB0492912, issued to Roy E. Berkowitz, M.D., be, and it hereby is, revoked. I further order that any pending application of Roy E. Berkowitz, M.D., for renewal or modification of his registration be, and it hereby is, denied. This order is effective immediately.[3]

Dated: July 17, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–17714 Filed 7–23–09; 8:45 am]

BILLING CODE 4410–09–P

[2] Likewise, the Administrative Procedure Act requires only that ''[p]ersons entitled to notice of an agency hearing shall be timely informed of * * * the matters of fact and law asserted.'' 5 U.S.C. 554(b). He was.

[3] Because of the importance of the legal issues raised by Respondent, I conclude that the public interest necessitates that this Order be made effective immediately.

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

July 20, 2009.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable