which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' *Id.* § 802(21). *See also id.* § 824(a)(3) (authorizing the revocation of a registration upon a finding that the registrant ''has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances''). Based on these provisions, the Agency has repeatedly held ''that a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances.'' *James L. Hooper*, 76 FR 71371, 71372 (2011) (collecting cases), *pet. for rev. denied, Hooper* v. *Holder,* 481 F. App'x 826 (4th Cir. 2012).

Here, there is no dispute as to the material fact that Respondent does not hold authority under New Mexico law to dispense controlled substances and is thus not a practitioner within the meaning of the Act. *See* 21 U.S.C. 802(21). Accordingly, his application must be denied. 21 U.S.C. 823(f).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Nicholas J. Nardacci, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: July 11, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–17264 Filed 7–20–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–71]

Turning Tide, Inc. Decision and Order; Procedural History

On August 17, 2010, the former Administrator of the Drug Enforcement Administration issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, Show Cause Order or Order) to Turning Tide, Inc. (Respondent), of Rockland, Maine. Show Cause Order, at 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration RT0370015,[1] which authorized it to dispense controlled substances as a Narcotic Treatment Program pursuant to 21 U.S.C. 823(g)(1), and the denial of any pending applications to renew or modify its registration, on the ground that its ''continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* at 1.

The Show Cause Order specifically alleged that ''Respondent is owned by Angel Fuller-McMahan'' and that its ''registration is conditioned upon a Memorandum of Agreement (MOA) with DEA which prohibits Ms. Fuller-McMahan from (1) having physical access to Respondent's premises; (2) ordering controlled substances on behalf of Respondent; and (3) executing any renewal applications . . . on behalf of Respondent.'' *Id.* at 1–2. The Order then alleged that Ms. Fuller-McMahan had been arrested on July 13, 2010 and charged with unlawful possession of cocaine, and that at the time of her arrest, she had in her possession approximately 25 grams of cocaine and two hypodermic needles.[2] *Id.* at 2. The Order further alleged that Ms. Fuller-McMahan had ''arranged to purchase cocaine'' from both a patient and an employee of Respondent. *Id.* The Order also alleged that ''[w]hile serving as Respondent's Program Director, Ms. Fuller-McMahan approached another patient . . . and offered to trade methadone for cocaine'' by ''creat[ing] a fraudulent order for methadone,'' even though she was then prohibited by the MOA from ordering controlled substances on behalf of Respondent. *Id.* The Order then alleged that Ms. Fuller-McMahan had purchased cocaine in three separate ''illegal drug transactions with another of Respondent's patients.'' *Id.*

Next, the Show Cause Order alleged that notwithstanding the MOA's terms, ''Ms. Fuller-McMahan continues to retain control and have supervisory authority over key aspects of Respondent's operation,'' that she had represented to a patient ''that she has access to controlled substances which are ordered on behalf of Respondent,'' and that she has ''repeatedly violated the terms of the MOA by entering the physical premises of [Respondent] and executing a renewal application on [its] behalf.'' *Id.* Finally, the Order alleged that Respondent ''continued to employ Ms. Fuller-McMahan's husband, Vance McMahan, despite the fact that Mr. McMahan has been convicted of illegal drug possession and has access to Respondent's controlled substances and confidential patient information.'' *Id.*

Based on the above allegations, the former Administrator concluded that Respondent's continued registration during the pending of the proceeding would ''constitute an imminent danger to the public health and safety'' and therefore ordered that its registration be suspended immediately. *Id.* at 3 (citing 21 U.S.C. 824(d)). The former Administrator also authorized the Special Agents and Diversion Investigators who served the Order to either ''place under seal or to remove for safekeeping all controlled substances that [Respondent] possesses pursuant to the registration which [was] suspended.'' *Id.* (citing 21 U.S.C. 824(f) and 21 CFR 1301.36(f)).

Thereafter, Respondent requested a hearing on the allegations and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ). Following the ALJ's issuance of an Order for Pre-Hearing Statements, the Government moved for summary disposition on the ground that on September 7, 2010, the Maine Department of Health and Human Services (MDHHS) had temporarily suspended Respondent's Substance Abuse Treatment license. ALJ Dec., at 3. As support for the motion, the Government attached a letter dated September 7, 2010 from the Director of the MDHHS's Division of Licenses & Regulatory Services to Ms. Fuller-McMahan. Mot. for Summ. Disp., at Ex. 2. Therein, the Director stated that MDHHS was ''revoking on an emergency basis for a period not to exceed thirty days the agency's licenses to operate an Opioid Treatment Program and . . . Outpatient Substances Abuse Services.'' *Id.* (citing 14–118 C.M.R. Ch. 5, § 2.10.9). The letter further stated that ''[t]he Department reserves its right to petition the District Court to extend the period of license revocation in accordance with 4 M.R.S.A. § 184(6) and 5 M.R.S.A. § 10003.'' *Id.* at 2.

Upon reviewing the motion, the ALJ directed Respondent to file a response to the Government's motion, which Respondent did after obtaining an extension.[3] ALJ Dec., at 3. Thereafter, the Government filed a further pleading in which it noted that MDHHS had filed a complaint in state court seeking the temporary suspension and permanent revocation of Respondent's Maine

[1] The Order alleged that Respondent's registration was due to expire on November 30, 2010.

[2] The Order also alleged that on August 31, 2001, Ms. Fuller-McMahan had been convicted in state court of unlawful possession of heroin. Show Cause Order, at 2.

[3] Respondent argued that the proposed revocation of its DEA registration would violate its right to due process because it was based on the MDHHS suspension, which in turn, was based on the DEA Order to Show Cause and Immediate Suspension of Registration. *See* Response In Opposition To The DEA Motion For Summary Disposition, at 2–5.

Alcohol and Drug Treatment Certificate of Licensure. Reply to Opposition to Gov. Mot. for Summ. Disp., at 2. As support for its position, the Government attached a copy of the State's complaint with supporting exhibits, the summons and return of service, and a draft of an order entitled: Order Relating To Plaintiff's Application For Temporary Suspension Of License Pending Judicial Review. However, absent from the evidence was a court order extending the revocation of Respondent's state license.

On October 6, 2010, the ALJ issued her recommended decision. Notwithstanding that the temporary suspension ordered by the Director of the MDHHS was due to expire on the following day and could not be extended without a court order, the ALJ granted the Government's motion for summary disposition on the ground that it was undisputed that Respondent ''lacks the authority to currently handle controlled substances under state law,'' and thus, it was not entitled to maintain its DEA registration. ALJ at 5–6. The ALJ therefore recommended that Respondent's registration be revoked. *Id.* at 10.

On October 27, 2010, the ALJ forwarded the record to the Administrator's Office for final agency action. However, at no time did the Government move to supplement the record with evidence showing that the state court had extended the suspension of Respondent's state license.

Upon review of the record, the former Administrator noted that Respondent's DEA registration had expired on November 30, 2010. A subsequent query of the Agency's registration records determined that Respondent had not filed a renewal application. Moreover, public records of the State indicated that Respondent was no longer in business. Accordingly, the former Administrator directed the parties to address why the case was not moot and to specifically identify what collateral consequence existed which precluded a finding of mootness. Order of the Administrator (Sept. 20, 2011), at 1–2 (citing *RX Direct Pharmacy, Inc.*, 72 FR 54070 (2007)).

Only the Government filed a response. Therein, the Government noted that upon service of the Immediate Suspension Order, it ''seized and placed under seal various controlled substances from Respondent's facility.'' *Id.* at 1 (citing Affidavit of DI). According to the DI, the Agency seized 121 unopened 500 ml bottles of methadone 10mg/ml; 18 opened 500 ml bottles of methadone 10mg/ml ''containing various amounts of methadone''; and 23 individual ''take home'' doses of methadone. GX 10, at 3.

Noting that under the Controlled Substances Act, '' '[a]ll right, title and interest in' any controlled substances seized pursuant to a suspension order 'vests in the United States upon a revocation order being[sic] final' and 'shall be forfeited to the United States,' '' the Government argued that if the case ''is declared moot and dismissed, title to the controlled substances will be left undetermined.'' *Id.* (quoting 21 U.S.C. 824(f)). The Government further noted that '' 'DEA has previously held that ''a litigant cannot defeat the effect of this provision by simply allowing its registration to expire.'' ' '' *Id.* (quoting *East Main Street Pharmacy,* 75 FR 66149 (2010) (other citation omitted)). *Id.* The Government thus maintained that the ''case remain[ed] a live controversy'' and requested the issuance of a final order. *Id.* at 2.

Upon review of the matter, the former Administrator agreed with the Government that the case was not moot. Order Remanding for Proceedings, at 6 (May 20, 2013). She concluded, however, that a final order based on Respondent's lack of state authority could not resolve the issue of title to the drugs that were seized for two reasons. First, she explained that the Immediate Suspension Order, which provided authority for the seizure, was not based on Respondent's lack of state authority. *Id.* at 6. Second, she observed that ''even if a subsequent loss of state authority could be used to support the forfeiture of drugs which have been seized based on entirely different factual allegations and legal grounds, the Government [was] not entitled to prevail'' because the ''contention that Respondent lacked state authority was not supported by substantial evidence.'' *Id.* at 7. The former Administrator then observed that the MDHHS' suspension order was due to expire the day after the ALJ issued her recommended decision (and even before the record was forwarded to the Administrator's Office) and that while the Government had submitted a copy of the State's complaint which sought to extend the suspension, a summons, and an unsigned proposed order extending the suspension, the Government produced no evidence ''that the state court had continued the suspension past the initial thirty days imposed by the MDHHS.'' *Id.* Because the record did not support the finding required under 21 U.S.C. 824(a)(3), the former Administrator remanded the case for further proceedings consistent with her opinion. *Id.* at 8.

On remand, the ALJ ordered the parties to file and serve their respective prehearing statements. Order for Prehearing Statements (GX 11), at 1. The Government timely complied. Termination Order (GX 12), at 1. Thereafter, Respondent moved to enlarge the time for filing its prehearing statement. *Id.* While the ALJ granted the motion and extended the due date of Respondent's statement by three weeks, Respondent failed to comply. *Id.* Accordingly, twelve days later, the ALJ held, *sua sponte,* that ''Respondent ha[d] constructively waived its right to a hearing'' and ordered that the hearing be terminated. *Id.* at 2.

Thereafter, the Government submitted a Request for Final Agency Action along with the investigative record to the Administrator's Office. Upon review of the record, the former Administrator adopted the ALJ's finding that Respondent had waived its right to a hearing as to the validity of the Immediate Suspension Order and the seizure of the controlled substances. However, the former Administrator denied the Government's Request for Final Agency Action, reasoning that the public interest provisions of 21 U.S.C. 823(f) and 824(a)(4), which the Government relied on as the source of its authority to immediately suspend Respondent's registration, do not apply to a Narcotic Treatment Program. Order Denying Government's Request for Final Agency Action, at 9 (May 11, 2015).

As the former Administrator explained, Respondent was registered under 21 U.S.C. 823(g)(1). Under this provision, ''[t]he Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance [and/] or detoxification treatment'' if the following three conditions are met:

> (A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;
>
> (B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and
>
> (C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

21 U.S.C. 823(g)(1).

The former Administrator explained that in contrast to every other category of registration set forth in section 823, this provision does not grant the Attorney General authority to deny an

application upon a determination ''that the issuance of such registration . . . would be inconsistent with the public interest.'' Order Denying Govt.'s Req., at 9 (*comparing* 21 U.S.C. 823(g)(1) *with id.* § 823(f); *see also id.* § 823(a), (b), (c), (d), (e), and (h). The former Administrator also observed that, in contrast to every other category of registration set forth in section 823, Congress did not characterize these three provisions as ''factors'' to be considered and given discretionary weight ''[i]n determining the public interest.'' Order Denying Govt.'s Req., at 9 (*comparing* § 823(g) *with id.* § 823(f); *see also id.* § 823(a), (b), (c), (d), (e), and (h). Rather, the three subparagraphs of section 823(g)(1) are conditions for registration.

With respect to the Agency's authority to revoke a registration, the former Administrator noted that while 21 U.S.C. 824(a) sets forth five different ground for revoking a registration, it also contains a specific provision which governs the Agency's authority to revoke a registration with respect to a Narcotic Treatment Program. This provision states that:

> A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

Id. § 824(a). So too, section 824(d) provides that ''[a] failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section.'' *Id.* § 824(d).

The former Administrator noted that section 824(a)(4) authorizes the revocation of a registration upon a finding that a registrant ''has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' Order Denying Govt.'s Req., at 7. However, based on the provisions of section 823(g)(1) and the specific provision governing the revocation of an NTP registration for non-compliance with any standard referred to in 823(g)(1), the former Administrator explained that even assuming that the public interest revocation authority of section 824(a)(4) could be invoked in this proceeding, this provision does not grant the Government any additional authority because the determination must be made by reference to the standards set forth in section 823(g)(1). *Id.* at 8–9.

The former Administrator further noted that because Respondent's registration was issued pursuant to section 823(g)(1), it was clear that the public interest standard of section 823(f) has no application in this proceeding. *Id.* at 9. She then held that, consistent with section 824(a), the suspension order could only be sustained if the Government put forward sufficient evidence to support ''a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1).'' *Id.*

The former Administrator noted, however, that the allegations of the Order to Show Cause and Immediate Suspension Order may, if supported by substantial evidence, establish that Respondent failed to comply with the standards of section 823(g)(1). *Id.* However, because in its Request for Final Agency Action, the Government had not addressed which of the standards had been violated and how so, the former Administrator denied the Government's Request for Final Agency Action. *Id.* Analogizing the Government's Request to a motion for summary judgment, the former Administrator then explained that just as the denial of a motion for summary judgment is an interlocutory order and not a final decision, so too the denial of the Government's Request for Final Agency Action is an interlocutory order and not a final decision of the Agency. *Id.* (citing, *inter alia, R.R. Donnelley & Sons Co.* v. *FTC,* 931 F.2d 430, 431 (7th Cir. 1991) (holding that the denial of a motion for summary judgment is an interlocutory order and not a final judgment)). The former Administrator thus provided the Government with the opportunity to file a successive Request for Final Agency Action. *Id.*

Thereafter, the Government attempted to establish that this matter had become moot because there was no need to determine title to the drugs that were seized pursuant to the ISO. The basis for the Government's contention was that: (1) The drugs had since passed their expiration date, (2) Respondent's successor-in-interest (Ms. Fuller-McMahan) had not responded to a letter from the Special Agent in Charge of the local Field Division which offered her the opportunity to make arrangements for the disposal of the drugs, and (3) in a phone call with an Agency Investigator months later, Ms. Fuller-McMahan permitted the Agency to destroy the drugs. I found, however, that Ms. Fuller-McMahan's actions did not relinquish Respondent's title to the property. Order, at 1–2 (Mar. 16, 2016).

Subsequently, the Government again suggested that the case was moot because it had determined that a creditor (Coastal Enterprises, Inc.) had placed a lien against Respondent assets, and that Coastal had executed a release of its claims against the drugs the Agency had seized. I rejected this as sufficient to establish mootness because the Government continued to acknowledge that Ms. Fuller-McMahan is Respondent's successor-in-interest and because the Government produced no evidence that Coastal had foreclosed on its lien and/or obtained a judgment against Respondent. Order, at 1 (May 4, 2016).

Thereafter, the Government resubmitted its Request for Final Agency Action. *See* Second Req. for Final Agency Action. Ms. Fuller-McMahan also submitted a letter to me stating that she has in her ''possession documents and recordings that refute these allegations.'' Letter from Angel Fuller-McMahan to the Acting Administrator (May 20, 2106). However, Ms. Fuller-McMahan did not provide either the documents or the recordings, and in any event, the former-Administrator remanded this matter to the Office of Administrative Law Judges for the express purpose of allowing Respondent to challenge the Suspension Order. While Respondent initially indicated its intent to participate in the hearing, it failed to comply with the ALJ's Order and file a Prehearing Statement. As a result, the ALJ found that Respondent had waived its right to a hearing and terminated the proceeding. Thereafter, the former Administrator adopted the ALJ's waiver finding. Order Denying Government's Request for Final Agency Action, at 6 (May 11, 2015). Ms. Fuller-McMahan has offered no reason to reconsider that finding. Accordingly, based on the Investigative File submitted by the Government, I make the following finding of fact.

Findings

Respondent, an administratively-dissolved corporation, was formerly registered as a Narcotic Treatment Program under 21 U.S.C. 823(g)(1). Ms. Angel Fuller-McMahan was the owner of the corporation.

On August 31, 2001, Ms. Fuller-McMahan, following her entry into a plea agreement, was convicted by the Maine Superior Court of the unlawful possession of heroin and given a suspended sentenced of two years imprisonment and one year of probation. GX 3, at 1. She also enrolled in a methadone maintenance program. *Id.*

On October 18, 2007, Ms. Fuller-McMahan filed a new application on behalf of Respondent for registration as a Narcotic Treatment Program. *Id.* On June 13, 2008, Ms. Fuller-McMahan entered into Memorandum of Agreement (MOA) with DEA's New England Field Division, pursuant to which the Agency granted Respondent's application subject to certain conditions. *Id.* at 1–2. As relevant here, these included that: (1) Ms. Fuller-McMahan ''is prohibited from ordering any controlled substances and will execute a power of attorney authorizing one of her management staff to order the controlled substances''; (2) that ''the same management staff will'' execute Respondent's renewal applications; (3) Ms. Fuller-McMahan ''will not have physical access to the registered location'' or ''any keys or codes to the alarm system''; (4) Ms. Fuller-McMahan ''will not be enrolled as a client of'' Respondent and ''will not guest dose at [it] under any circumstances.'' *Id.* at 1. The MOA further provided that ''[v]iolations of the terms . . . may result in an order to show cause to revoke, or revoke and immediately suspend'' its DEA registration, and that in any such proceeding, ''DEA reserves the right to introduce into evidence . . . this Agreement and violations of this Agreement.'' *Id.* at 1–2. On June 23, 2008, the then Special Agent in Charge of the Field Division approved the MOA, *id.* at 2, and on July 1, 2008, Respondent's application was approved. GX 2, at 2.

On December 11, 2008, J.C., a pharmacist, executed a state board application to become Respondent's new Pharmacist-in-Charge. GX 16, at 1. On the application, J.C. listed Ms. Fuller-McMahan as an ''authorized person.'' *Id.* at 6. According to a regulation of the Maine Board of Pharmacy, ''[a]n 'authorized person' is a person other than a pharmacy technician (*e.g.,* computer technician, bookkeeper) who the pharmacist in charge has designated to be present in the prescription filling area in the absence of a pharmacist.'' GX 17, at 1 (copy of 02–392 CMR Ch. 1, § 1).

According to the affidavit of a Supervisory Special Agent with the Maine Drug Enforcement Agency (MDEA), on November 3, 2009, he ''interviewed M.K., a former patient'' of Respondent. GX 15, at 2. The Agent further explained that M.K. had called him ''and requested to speak to [him] in exchange for consideration with M.K.'s pending drug charges.'' *Id.* The Agent further explained that an interview was arranged and that ''no promises were made to M.K. in exchange for any information she might divulge.'' *Id.*

According to the Agent, during her interview, M.K. stated that Ms. Fuller-McMahan had ''approached her and asked her to procure cocaine for which [Fuller-McMahan] would be willing to trade methadone purchased on behalf of'' Respondent. *Id.* M.K. further stated that Ms. Fuller-McMahan had said ''that she intended to create a falsified order for methadone to be purchased by'' Respondent for the purported use by prisoners at the county jail ''for drug treatment,'' and that she would trade this methadone for cocaine. *Id.*

The Agent also averred that M.K. had named two other persons who were obtaining methadone at Respondent for drug treatment and selling it. *Id.* According to the Agent, ''M.K. stated she had purchased controlled substances from these'' two persons. *Id.* The Agent did not, however, clarify whether M.K. had purchased methadone from these persons. While according to the Agent, M.K. offered to perform undercover buys from these persons, the Agent offered no evidence that any such buys were performed. Moreover, no further evidence was provided establishing that Respondent was improperly dispensing methadone to these two persons. *See* 42 CFR 8.12(i) (regulations governing ''[u]nsupervised or 'take home use' '').

In his affidavit, the Agent testified that on July 13, 2010, Ms. Fuller-McMahan was arrested and charged with Possession of Cocaine, a felony offense under Maine Law. *Id.* at 1 (citing 17–A M.R.S.A. § 1107–A). The Agent further stated that Ms. Fuller-McMahan was in possession of ''approximately 25 grams of powdered cocaine'' and two syringes which she had obtained from J.R., a patient of Respondent, who performed an undercover sale for the MDEA. *Id.*

After her arrest, Ms. Fuller-McMahan waived her Miranda rights and was interviewed by the Agent; a video recording of the interview was provided by the Government. During the interview, Ms. Fuller-McMahan stated that she intended to deliver the cocaine to C.G., a drug and alcohol counselor employed by Respondent. *Id.* She also ''admitted that she was using cocaine and had ingested cocaine in the last three weeks.'' *Id.* During the interview, Ms. Fuller-McMahan asked the Agent: ''can you charge me with something else? Less? . . . If I agree to not go into Turning Tide . . . or to fight it, ever . . . back out completely?'' *Id.* at 2.

Thereafter, the State charged Ms. Fuller-McMahan with two counts of unlawful possession of a scheduled drug. GX 4, at 1. Ms. Fuller-McMahan pled guilty to one of the counts, and on October 28, 2010, Ms. Fuller-McMahan was convicted by the Superior Court of a single count of unlawful possession of a scheduled drug. *Id.* The court sentenced Ms. Fuller-McMahan to 364 days in the county jail, but suspended all but 30 days of the sentence; the court also placed her on probation for a period of one year. *Id.*

On some date which is not clear from the evidence, Respondent, through its attorney, surrendered its state licenses to operate an Opioid Treatment Program and Outpatient Substance Abuse Services; Respondent also surrendered its pharmacy license. GX 5. Respondent also allowed its registration to expire.[4]

Discussion

As previously held, because Respondent's registration has expired, and there is no application to act upon, the only issue remaining in the proceeding is whether the Government can claim title to the controlled substances it seized pursuant to the authority granted by the Immediate Suspension Order. *See S & S Pharmacy, Inc.,* 78 FR 57656, 57659 (2013); *RX Direct Pharmacy, Inc.,* 72 FR 54070, 54072 (2007). Pursuant to 21 U.S.C. 824(f),

> In the event the Attorney General suspends or revokes a registration under section 823 of this title, all controlled substances . . . owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. . . . Upon a revocation order becoming final, all such controlled substances . . . shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances . . . in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances . . . shall vest in the United States upon a revocation order becoming final.

DEA has previously held that a registrant, whose property has been seized pursuant to an Immediate Suspension Order, cannot defeat the effect of this provision by allowing its registration to expire. *See, e.g., Meetinghouse Community Pharmacy, Inc.,* 74 FR 10073, 10076 n.5 (2009).

[4] The Government put forward no evidence in support of the allegation that Respondent ''continues to employ Ms. Fuller-McMahan's husband . . . despite the fact that [he] has been convicted of illegal drug possession and has access to Respondent's controlled substances and confidential patient information.'' GX 1, at 2. Nor did it put forward any evidence as to the allegations that she had engaged in three other illegal purchases of cocaine with another of Respondent's patients.

As explained above, section 824(a) sets forth a specific provision which grants the Agency authority to suspend or revoke the registration of a Narcotic Treatment Program. This provision states that:

> A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

Id. § 824(a). So too, section 824(d) provides that ''[a] failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section.'' *Id.* § 824(d). Thus, consistent with section 824(a), the former Administrator held that the suspension order can only be sustained if the Government puts forward sufficient evidence to support ''a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1).''

Of the three standards for registration as an NTP set forth in 21 U.S.C. 823(g)(1), the Government invokes only subparagraph B. It authorizes ''the Attorney General [to] determine[] that the applicant will comply with *standards established by the Attorney General* respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs.'' 21 U.S.C. 823(g)(1)(B) (emphasis added).

The Government argues that ''Ms. Fuller-McMahan's conduct demonstrated that she was a security threat to [Respondent] and, accordingly, a security risk to its stocks of controlled substances.'' Second Request for Final Agency Action, at 10. It further argues that her ''continued ownership and control over Respondent's clinic constituted an imminent danger to the public health or safety.'' *Id.* (citing 21 U.S.C. 824(d)). And it argues that ''[b]y permitting Ms. Fuller-McMahan to act as Turning Tide's director and continue to have control over the drug treatment facility, Respondent failed to comply with standards respecting the 'security of stocks of narcotic drugs for . . . treatment,' '' and thus violated section 823(g)(1)(B). *Id.* at 11.

Invoking the terms of the MOA, the Government argues that ''the evidence paints a far different picture of Ms. Fuller-McMahan's involvement in [Respondent] than that contemplated by'' the MOA. *Id.* First, the Government argues that Ms. Fuller-McMahan admitted that she remained Turning Tide's director. *Id.* The Government does not, however, point to any provision of the MOA which prohibited Ms. Fuller-McMahan from acting as Turning Tide's director.

Stronger is the Government's claim that Ms. Fuller-McMahan violated the MOA because she was entering its physical premises. The MOA specifically prohibited her from ''hav[ing] physical access to the registered location,'' GX 3, at 1; and as found above, during the interview which followed her arrest, Ms. Fuller-McMahan clearly tried to negotiate a lesser charge for agreeing not to go into the clinic. *See id.* Moreover, the Government produced the application filed by Respondent's PIC, in which he designated her as an ''authorized person,'' GX 16, at 4; which under Maine's regulation authorized her ''to be present in the prescription filling area in the absence of a pharmacist.'' GX 17.

Yet there is no evidence that Ms. Fuller-McMahan ever actually entered the pharmacy or that she possessed the keys or the alarm code for the pharmacy.[5] *See, e.g.,* 21 CFR 1301.72(d) (''The controlled substances storage areas shall be accessible only to an absolute minimum of specifically authorized employees.''). Thus, while the evidence supports a finding that Ms. Fuller-McMahan had access to the clinic and thus violated the MOA, by itself, this conclusion does not support a finding that Respondent posed ''an imminent danger to the public health or safety,'' 21 U.S.C. 824(d), as is required to support the Order of Immediate Suspension.

The Government further argues that ''[b]y executing a renewal application in direct violation of the MOA . . . Ms. Fuller-McMahan also provided herself with the legal means to order controlled substances . . . and therefore carry out the scheme she had proposed to M.K.'' *Id.* at 11 (citing 21 CFR 1305.11(c); other citations omitted). While the Government then acknowledges that ''there is no evidence that this particular transaction took place,'' *id.,* it notes that Ms. Fuller-McMahan was arrested and convicted for possessing cocaine which she had obtained from a patient and intended to deliver to an employee. *Id.* at 11–12.

The Government then argues that ''Ms. Fuller-McMahan was predisposed to continue to engage in drug trafficking which *could have involved* trading Respondent's stocks of narcotic substances for cocaine'' and that ''[h]er behavior in this regard independently confirms her intent to purchase illegal substances with narcotic drugs slated for legitimate drug treatment.'' *Id.* at 12 (emphasis added). And arguing that her ''past performance is the best predictor of future performance,'' the Government asserts that Ms. Fuller-McMahan's conduct ''demonstrated a high likelihood that she would find a way to divert Respondent's supply of methadone in exchange for illegal drugs[,]'' and ''[t]hus, her continued access, ownership, and control over Respondent's business constituted an imminent threat to the public health or safety.'' *Id.* (int. quotations and citation omitted).

Under DEA's regulation which is applicable to ''all registrants,'' Respondent was required to ''provide effective controls and procedures to guard against theft and diversion of controlled substances.'' 21 CFR 1301.71(a). *See also* 21 CFR 1301.72(d). Thus, substantial evidence that Ms. Fuller-McMahan was obtaining methadone from Respondent's stocks and trading it for other drugs would clearly establish Respondent's non-compliance with a standard established under 21 U.S.C. 823(g)(1)(B) and would clearly support the requisite finding that its continued registration posed an imminent danger to public health or safety as required by 21 U.S.C. 824(d). The Government, however, has not produced such evidence.

The Government points to Ms. Fuller-McMahan's execution of the renewal application. It argues that Ms. Fuller-McMahan did this to ''provide[ ] herself with the legal means to order controlled substances.'' Second Request, at 11. Yet the Government has not produced a single order form (DEA–222) that Ms. Fuller-McMahan executed on behalf of Respondent or any other evidence that she was ordering methadone.

The Government also points to Ms. Fuller-McMahan's alleged proposal to provide methadone to M.K. in exchange for cocaine as support for its assertion that she ''was predisposed to continue to engage in drug trafficking which could have involved trading Respondent's stocks of narcotic substances for cocaine.'' *id.* at 12. This fails too, as notwithstanding Respondent's waiver of its right to challenge the Immediate Suspension Order, the Agency's Order in this matter must be supported by ''reliable, probative, and substantial evidence.'' 5 U.S.C. 556.

Under the Agency's rules, Respondent's waiver of its right to a hearing does not constitute an

[5] The record contains no evidence of interviews of any employees who might have observed her entering the pharmacy.

admission of the allegations. Thus, the Government had the burden of proving its claim that Ms. Fuller-McMahan was likely to trade Respondent's methadone for cocaine.

However, the Government's evidence as to the alleged proposal of Ms. Fuller-McMahan to trade methadone to M.K. in exchange for cocaine is so lacking in indicia of reliability that it does not support the requisite finding under section 823(g)(1). Notably, M.K.'s statement is hearsay,[6] and there is no evidence that M.K., who has not been identified, was under oath when she provided the statement. Also, the MDEA Agent acknowledged that M.K. had offered ''to speak to [him] in exchange for consideration with M.K.'s pending drug charges.'' GX 15, at 2. Notwithstanding that the MDEA Agent further explained that ''no promises were made to M.K. in exchange for any information she might divulge,'' informants typically do not provide information without some expectation of receiving favorable treatment and have ample motive to shade their statements. Nor did the MDEA Agent's affidavit provide any additional facts tending to establish that M.K. had provided reliable information in other matters, or that the information M.K. provided regarding Ms. Fuller-McMahan was otherwise corroborated.[7]

In short, this type of statement has been traditionally viewed by the courts as inherently unreliable, and as such, M.K.'s statement cannot be given any weight in this decision. *See, e.g., Carlos Gonzales,* 76 FR 63118, 63119–20 (2011). And even if the Government had established that M.K.'s statement was reliable, this interview, which occurred more than nine months prior to the issuance of the Immediate Suspension Order, could not support a finding of imminent danger and the subsequent seizure of the drugs.[8] *See, e.g., Norman Bridge Drug Co.* v. *Banner,* 529 F.2d 822, 829 (5th Cir. 1976).

Thus, the only evidence which arguably supports the Immediate Suspension Order and seizure of Respondent's methadone stock is the arrest of Ms. Fuller-McMahan for the possession of cocaine and the syringes, which she had received from J.R., a patient at Respondent, and which Ms. Fuller-McMahan admitted she intended to provide to C.G., a counselor at Respondent. Yet even here, there is no evidence that Ms. Fuller-McMahan either traded methadone for the cocaine she received from J.R. or that she intended to provide the cocaine to C.B. for methadone.

Moreover, notwithstanding M.K.'s allegation, there is no evidence that the Government ever audited Respondent's recordkeeping to determine whether Respondent's methadone was missing or that it developed any reliable evidence that Ms. Fuller-McMahan was diverting methadone. *See* 21 U.S.C. 823(g)(1)(B). Nor did the Government produce any evidence that Respondent's recordkeeping was inadequate.[9] *Id.* In short, while the Government has established that Ms. Fuller-McMahan violated the MOA and this would have supported the issuance of an Order to Show Cause, the Government's principal justification for immediately suspending Respondent's registration and seizing the drugs is not supported by substantial evidence but rests on a hunch. Accordingly, I hold that the Immediate Suspension Order is *ultra vires* and the resulting seizure of Respondent's methadone was unlawful. *See Norman Bridge,* 529 F.2d at 828 (''Such a suspension, or such a seizure, may be invoked *only* to avoid imminent danger to the public health and safety. In the absence of that factor there can be no suspension and no seizure without notice and an opportunity to be heard.'').[10]

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and (d), I hereby declare the Order of Immediate Suspension issued to Turning Tide, Inc., *ultra vires.* This Order is effective immediately.

Dated: July 15, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–17245 Filed 7–20–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 16–12]

James Dustin Chaney, D.O.; Decision and Order

On November 13, 2015, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to James Dustin Chaney, D.O. (Respondent), of Hazard, Kentucky. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration BC8483430, pursuant to which he is authorized to dispense controlled substances in schedules II through V, and the denial of any pending applications to renew or modify his registration or for any other registration, on the ground that he does not have authority to handle controlled substances in Kentucky, the State in which he holds his DEA registration. Show Cause Order, at 1 (citing 21 U.S.C. 823(f); 824(a)(3)).

The Show Cause Order alleged that Respondent is registered as a practitioner with authority to dispense schedule II through V controlled substances at the registered location of 1908 North Main Street, Hazard, KY. *Id.* The Order further alleged that while Respondent's registration was due to expire on August 31, 2015, on August 25, 2015, he filed a timely renewal application and thus, his registration

[6] While M.K.'s statement is actually hearsay within hearsay, I have no reason to question the MDEA Agent's recounting of the facts surrounding M.K.'s agreeing to provide the statement or that he has accurately testified as to the substance of M.K.'s statement.

[7] Likewise, the Government did not produce the entirety of M.K.'s statement and thus, there is no way to evaluate the internal consistency of the statement.

[8] The record does not establish when the MDEA Agent first told DEA about M.K.'s allegations.

[9] The Government also argues that ''there was no evidence that Respondent's employees . . . were taking any steps to minimize that risk,'' *i.e.,* the risk that Ms. Fuller-McMahan was diverting Respondent's methadone. Second Req. for Final Agency Action, at 14. However, the Government has the burden of proving that Respondent's methadone was being diverted. Moreover, it bears noting that under the Maine Board of Pharmacy's rules, Respondent was required to have a licensed pharmacist overseeing its pharmacy, and ''[t]he pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the opioid treatment program for which the licensee is registered as pharmacist in charge, and for the opioid treatment program's compliance with . . . federal and state laws and rules,'' including the CSA and DEA regulations. 02–392 CMR 36 § 4; *see also* 02–392 CMR 29 § 1.

[10] In a June 29, 2015 letter, the Special Agent in Charge of the New England Field Division wrote to Ms. Fuller-McMahan that ''[a]lthough the controlled substances were seized pursuant to an Immediate Suspension Order, they are also being held by virtue of the fact that your registration expired on November 30, 2010, resulting in your not having any authority to handle controlled substances.'' However, to the extent the Government retained possession of the controlled substances based on the expiration of Respondent's registration, 21 U.S.C. 824(g) provides that:

[s]uch controlled substances . . . shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance . . . seized or placed under seal of the procedures to be followed to secure the return of the controlled substance . . . and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance . . . seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance . . . was seized or placed under seal.

21 U.S.C. 824(g). The Government has provided no evidence that it complied with the procedures required by this subsection. Accordingly, the propriety of the seizure must be evaluated under the standards of subsection 824(d) and (f).