



BILLING CODE: 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

**Thomas Neuschatz, M.D.
Decision and Order**

On July 2, 2013, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Thomas Neuschatz, M.D. (hereinafter, Applicant), of Marysville, California. GX 9. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration as a practitioner, on the ground that his "registration would be inconsistent with the public interest." Id. (citing 21 U.S.C. 823(f)).

The Show Cause Order specifically alleged that on April 29, 2011, Applicant had surrendered his DEA registration, and that on May 30, 2011, Applicant applied for a new registration as a practitioner. Id. Next, the Order alleged that a DEA investigation had found that Applicant "prescribed and dispensed inordinate amounts of controlled substances . . . under circumstances where [he] knew or should have known the prescriptions were not for legitimate medical purposes." Id.

Next, the Show Cause Order alleged that a medical Expert had reviewed the medical records of three of Applicant's patients (E.G., R.E., and J.G.) and concluded that he "prescribed controlled substances to those patients without a legitimate medical purpose and/or outside the usual course of professional practice." Id. at 1-2. More specifically, with respect to E.G., the Order alleged that over the course of E.G.'s first five visits, Applicant escalated the daily dose of medication from 22.5 mg of hydrocodone to 80 mg of hydrocodone and 320 mg of oxycodone. Id. at 2. The Order further alleged that "[f]rom approximately January 4, 2011 through April 16, 2011, [Applicant] prescribed Dilaudid to E.G. without conducting an in-person physical

examination” and during this period, E.G. made a single office visit. Id. The Order then alleged that based on Applicant’s “prescribing of high dosages of opioid medications and failing to perform a diagnostic evaluation of E.G.’s pain complaints,” the Expert concluded that Applicant’s “treatment of E.G. fell outside the usual course of professional practice.” Id. at 2.

After alleging that R.E. died of “acute poisoning by multiple pharmaceuticals and illegal substances,” the Show Cause Order alleged that Applicant had failed to inquire into the patient’s history of drug abuse, notwithstanding that R.E.’s intake forms had suggested that such history existed, and that R.E. “provided no medical records and was unable to list previous physicians or pharmacies.” Id. The Order further alleged that Applicant “performed limited physical examinations of R.E. over the course of approximately 11 office visits.” Id. Based on Applicant’s alleged “failure to confirm R.E.’s medical history, [his] failure to determine R.E.’s source of pain, and” that he “escalated dosages of highly addictive pain medications despite an unconfirmed . . . diagnosis,” the Order further alleged that the Expert had concluded that Applicant acted “outside the usual course of professional practice” in prescribing controlled substances to R.E. Id.

With respect to J.G., the Show Cause Order alleged that Applicant violated federal law by prescribing methadone to treat J.G.’s “opioid dependence” because he was “not authorized to prescribe [s]chedule II controlled substances to treat narcotic dependent patients.” Id. (citing 21 U.S.C. 823(g)(1); 21 CFR 1306.07(a)). The Order further alleged that “J.G. died of an apparent overdose of prescription medications” after his last visit with Applicant. Id.

The Show Cause Order, which also notified Applicant of his right to request a hearing on the allegations or to submit a written a statement regarding the allegations while waiving his right to a hearing, the procedure for electing either option, and the consequences for failing to

elect either option, id. at 3, was served on Applicant by certified mail addressed to him at the address of his proposed registered location. GX 10, at 1. As evidenced by the signed return receipt card, service was accomplished on July 10, 2013. Id. at 2.

On August 13, 2013, the Government submitted a Request for Final Agency Action. Therein, the Government noted that since the date of service of the Show Cause Order, Applicant had not requested a hearing. Request for Final Agency Action, at 4. The Government thus contends that Applicant has waived his right to a hearing and requests the issuance of a final order denying the application. Id. at 4, 7.

Subsequently, on August 22, 2013, the Government filed an addendum to its Request for Final Agency Action. Therein, the Government noted that on July 23, 2013, the Medical Board of California (MBC) adopted a Stipulated Surrender of License and Order (hereinafter, Stipulated Surrender), pursuant to which Applicant surrendered his California Physician's and Surgeon's Certificate, and that the MBC's Order "became effective on August 22, 2013." Addendum to Request for Final Agency Action, at 1-2. The Government attached a copy of the MBC's Decision, the Stipulated Surrender of License and Order, and the Accusation, which alleged forty-nine (49) causes for discipline. The Government also served a copy of the addendum on Applicant.

Based on the Government's submission, I find that since the date of service of the Order to Show Cause, neither Applicant, nor anyone purporting to represent him, has either requested a hearing on the allegations or submitted a written statement in lieu of a hearing. See 21 CFR 1301.43(a) & (c). Accordingly, I find that Applicant has waived his right to a hearing or to submit a written statement. Id. § 1301.43(c) & (d).__I therefore issue this Decision and Final

Order based on the Investigative Record submitted by the Government. Id. § 1301.43(e). I make the following findings of fact.

FINDINGS

Applicant previously held DEA Certificate of Registration BN5628194, which authorized him to dispense controlled substances, as a practitioner, in schedules II-V. GX 2, at 1.

However, on April 29, 2011, Applicant voluntarily surrendered this registration. Id. On May 30, 2011, Applicant submitted an application for a new registration. GX 1, at 1.

Applicant also previously held a Physician's and Surgeon's Certificate which was issued by the MBC. However, on May 23, 2012, the MBC's Executive Director issued a forty-nine (49) count administrative complaint, which sought the revocation of Applicant's state license. See Accusation, In re Thomas Neuschatz, M.D., (M.B.C. 2012) (No. 02-2009-199792). On June 25, 2013, Applicant voluntarily entered into the Stipulated Surrender, and on July 23, the MBC adopted the order, which became effective on August 22, 2013. Accordingly, I find that Applicant no longer possesses authority under California law to dispense controlled substances.

In the Stipulated Surrender, Applicant "agree[d] that, at a hearing, [the MBC] could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline." Stipulated Surrender, at 3. Applicant agreed that if he "should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in [the] Accusation . . . shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure." Id. at 4-5.

With respect to E.G. (Show Cause Order, at 2), the MBC alleged that Applicant “prescribed excess quantities of controlled substances and dangerous drugs” to her. Accusation, at 18. More specifically, the MBC, after noting the large doses that Applicant had prescribed to her, found that he:

- (1) “failed to make a specific diagnosis regarding E.G.’s pain”;
- (2) never evaluated “her psychological status”;
- (3) “never followed up on x-rays that he ordered”;
- (4) never documented whether E.G. had complied with the exercise and stretching program he had recommended;
- (5) never specified the functional goals of treatment in the pain treatment plan;
- (6) increased her medications but never provided clear reasons for doing so in the medical record and found that the increases were “never based on [her] functional status”;
- (7) never documented that she brought in her pain medication bottles even though this was required by her pain contract;
- (8) ordered an x-ray for E.G., but there was no x-ray in E.G.’s chart and no further reference to the x-ray in “later progress notes”;
- (9) never spoke with other physicians who had ordered various tests nor “formally requested the results of these studies”;
- (10) found that “[t]he only treatment [he] employed for E.G. was opiate medications, the doses of which were increased with alarming rapidity[,] [and that] [d]uring the initial months of treatment[,] [he] doubled her opiate doses every month until at one point E.G. was receiving a mixture of opiate medications equal to 1,035 mg a day of oral

morphine,” which compares with “the average dose . . . for patients with cancer pain [of] between 100 mg to 200 mg per day”;

(11) “failed to document that he informed E.G. about the risks of opiate medications”;
and

(12) “failed to document that E.G. was ever referred to physical therapy or any physician specialist for evaluation or treatment of her chronic pain condition.”

Id. at 17-18. Based on the above findings, the MBC concluded that Applicant’s conduct “constitute[d] excessive prescribing of controlled substances and dangerous drugs in the care and treatment of E.G.” Id. at 18.

With respect to R.E. (Show Cause Order, at 2), the MBC alleged that Applicant “prescribed excess quantities of controlled substances and dangerous drugs” to him. Id. More specifically, the MBC found that he:

- (1) failed to comment on R.E.’s history of drug abuse (which included one hospitalization and three rehabilitation programs) during any of “R.E.’s 11 office visits, or on the ‘opiate risk tool’ that [Applicant] used to evaluate his patient’s risk of prescription misuse”;
- (2) prescribed controlled substances after performing a “limited physical examination” and without requesting previous medical records;
- (3) failed to document prescriptions in the medical records;
- (4) prescribed increased doses of opiates without any explanation in the medical records;
- (5) prescribed a muscle relaxer to R.E. despite his “occupational function and physical improvement”;

- (6) prescribed 300 tablets of hydromorphone 8 mg and 150 tablets of methadone 10 mg to R.E. on April 23; then, only 14 days later, prescribed 128 tablets of oxycodone 30 mg and 80 tablets of methadone 10 mg;
- (7) increased the dose of methadone from 50 mg to 70 mg per day “because his pain control is slightly down”;
- (8) prescribed controlled substances when the patient was in a detoxification program;
- (9) failed to document in the medical record any of the prescriptions he provided R.E. while he was in the detoxification program;
- (10) failed to address the patient’s recent inpatient treatment for drug detoxification, and instead refilled all medications without adjusting the dosage;
- (11) increased the doses of opiate medications to a point where R.E. was receiving 740 mg of oral morphine every day, when “the average dose of oral morphine required by patients with cancer pain is between 100 to 250 mg per day”;
- (12) failed to question R.E. when he “should have suspected that R.E. was using the medications for a non-medical purpose”;
- (13) failed to record any formal referral to physical therapy; and
- (14) failed to order any traditional diagnostic tests, including laboratory studies, MRIs, or x-rays.

Id. at 19-23. Based on the foregoing, the MBC concluded that Applicant’s conduct “constitute[d] excessive prescribing of controlled substances and dangerous drugs.” Id. at 24.

With respect to J.G. (Show Cause Order, at 2), the MBC alleged that Applicant prescribed excess controlled substances to her. Id. at 29. More specifically, the MBC found that he:

- (1) knew that J.G. was receiving methadone from a drug treatment clinic, yet failed to document any substance abuse history for J.G.;
- (2) failed to order any diagnostic tests, such as laboratory studies, x-rays, or MRIs;
- (3) falsely documented that J.G. attended the methadone treatment clinic for chronic right shoulder pain and back pain instead of for her addiction;
- (4) began treating J.G.'s anxiety with narcotics instead of the previously prescribed non-habituated medications;
- (5) assumed responsibility for treatment of J.G.'s known addiction, "but inaccurately represented this as a treatment for a chronic pain condition";
- (6) failed to discuss the care of J.G. with her primary physician or with any of the addiction specialists at the methadone clinic she was attending;
- (7) "assumed the methadone maintenance of a known opiate addict despite his lack of qualification and without the guidance of qualified addiction specialists"; and
- (8) failed to document all of the medications J.G. was taking.

Id. at 25-28. Similarly, the MBC found that Applicant "prescribed excess quantities of controlled substances and dangerous drugs to" J.G. Id. at 29.

The MBC relied on a medical report prepared by an Expert, who, after reviewing the medical files for E.G., R.E., and J.G., concluded that Applicant's conduct with respect to each patient "reflect[ed] an extreme departure from the usual practice of general medicine."¹ Expert Report, at 8-32. With respect to E.G., the Expert noted that Applicant increased the patient's dose of controlled substances from the equivalent of 157.5 mg/day oral morphine to 1,035

¹ In reaching her conclusions, the Expert relied on the "Model Guidelines for the Use of Controlled Substance for the Treatment of Pain." Stipulated Surrender, at 4. California adopted these guidelines in 1994 and later revised them in 2007. See MBC, Guidelines for Prescribing Controlled Substances for Pain, http://www.mbc.ca.gov/pain_guidelines.html.

mg/day oral morphine over a seven month period (constituting a roughly 100% dose increase per month). Id. at 6. The Expert concluded that Applicant’s “conduct reflect[ed] an extreme departure from the usual practice of general medicine, because, of his failure to ever render a diagnosis regarding [E.G.’s] pain complaints or to more thoroughly evaluate her psychological status.” Id. at 8. The Expert noted that “[n]o specific diagnosis corresponding to [E.G.’s] pain complaints was ever made” and “[t]here [was] no specific evaluation of her psychological status other than frequent notations about her anxious affect.” Id. Moreover, the Expert observed that while Applicant ordered an x-ray of E.G.’s lumbar spine, there was no report in E.G.’s record and while E.G. has supposedly undergone x-rays and CT scans which were ordered by her prior physicians, Applicant did not request the results. Id. at 9-10.

The Expert further observed that Applicant failed “to develop a treatment plan with objectives,” and that he rapidly increased the dosage of opioids “with alarming rapidity.” Id. Applicant did not, however, document a justification for the increases, which in the Expert’s observation, were “never based on [E.G.’s] functional status.” Id. Finally, the Expert found that “signs of misuse on the part of [E.G.] did not seem to affect [Applicant’s] prescribing” practices.² Id. at 11. In sum, the Expert found that Applicant’s “prescription treatment of patient [E.G.] fell outside the usual course of the professional practice of medicine.” Id. at 13.

As for R.E., the Expert noted that, notwithstanding that at the first visit, R.E. stated that he had previously taken Norco, OxyContin 40mg, and was currently taking three OxyContin 80mg tablets a day for neck pain, he “claimed not to know the name of his treating physician, the location of any pharmacy[,] nor was he able to produce a prescription bottle.” Id. at 26.

Moreover, the Expert noted that R.E. told Applicant that “[h]e ha[d] no records.” Id. Also, the

² As example, the Expert noted that on November 4, 2008, Applicant increased E.G.’s dose of both OxyContin and Norco because “[s]he would like to go up on the Norco and I said fine.” GX 4, at 9.

Expert observed that on the medical history form which R.E. completed at the initial visit, R.E. had disclosed that in 2004, he had a “drug related” hospitalization. GX 7, at 32; GX 4, at 23.

The Expert explained that under these circumstances, “most clinicians [would] suspect drug seeking for non-medical uses,” and that “when aspects of [a] patient’s case appear suspicious, the standard practice is to request medical records or to speak with the most recent treating physician in order to verify the patient’s history and past treatment.” GX 4, at 26. The Expert then found that there was no evidence in the medical record that Applicant ever confirmed the medical history or prior treatment of R.E. with prescriptions.” Id.

The Expert noted that at R.E.’s first visit, Applicant documented in the medical record that he had prescribed only 45 dosage units of oxycodone 30mg. Id. at 23. Yet, the Expert found that the actual prescription issued by Applicant authorized the dispensing of 240 oxycodone 30mg. Id. at 23; GX 7, at 23 & 45.

The Expert further found that Applicant failed “to evaluate the reason for [R.E.’s] unremitting pain despite high doses of controlled substances.” Id. at 27. Moreover, Applicant committed an extreme departure from the standard of care by failing to develop “a treatment plan with clear functional objective.” Id. at 30.

Moreover, according to the Expert, Applicant failed to address numerous signs that R.E. “was misusing or diverting medication.” Id. The Expert found that at several visits, R.E. requested specific drugs such as oxycodone and methadone, sought an increase in Xanax, and reported that his medications had been stolen. Id. at 24 & 29. Yet the Expert also found that “[a]t no time was laboratory testing done to confirm medication use by the patient and exclude [the] possibility of diversion” [and] [a]t no time did [Applicant] document having performed a random pill count to confirm medication adherence.” Id. at 29. The Expert thus concluded that

Applicant’s continued treatment of R.E. “with rapidly escalating doses of controlled substances despite an unconfirmed medical diagnosis,” fell outside the usual course of the professional practice of medicine. Id. at 32.

Finally, with respect to J.G., the Expert noted that Applicant never documented nor referenced her “substance abuse history, although this was known to him” from prior treatment and it was “also . . . implied given her ongoing treatment at a methadone maintenance clinic.” Id. at 16. The Expert noted that Applicant “assumed responsibility for treatment of this known addict with methadone, but inaccurately represented his prescriptions for methadone as treatment for her chronic pain condition.” Id. at 18; see also id. at 22 (Applicant “knowingly prescribed methadone to prevent opiate withdrawal rather than for the treatment of pain.”). Applicant did this “despite his lack of qualification and without the guidance of a qualified addiction specialist.” Id. at 20. As such, “his misrepresentation that methadone was indicated for the treatment of her chronic pain rather than as treatment for her opioid addiction was patently false.” Id. at 18. The Expert thus concluded that Applicant’s “treatment of [J.G.] fell far outside the usual professional practice of medicine.” Id. at 32.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner’s registration may be denied “if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest.” 21 U.S.C. 823(f). In making the public interest determination, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing . . . controlled substances.

- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). "These factors are . . . considered in the disjunctive." Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors and may give each factor the weight . . . [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied." Id.; see also Kevin Dennis, M.D., 78 FR 52787, 52794 (2013); MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2010).

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for a denial of an application, pursuant to 21 U.S.C. § 823(f), are met. 21 CFR 1301.44(e). This is so even in a non-contested case. Gabriel Sanchez, M.D., 78 FR 59060, 59063 (2013). Having considered all of the factors,³ I conclude that the Government's evidence with respect to factors two and four establishes, prima facie, that the issuance of a DEA Certificate of Registration to Applicant "would be inconsistent with the public interest." 21 U.S.C. 823(f).

Factors Two and Four – The Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

A. The Preclusive Effect of the MBC Order

Under the doctrine of collateral estoppel, the MBC's findings of fact and conclusions of law are entitled to preclusive effect in this proceeding if the parties had an adequate opportunity

³ The Government presented evidence that, as of August 22, 2013, Applicant no longer possessed a state license to practice medicine. Stipulated Surrender, at 4-5. The CSA only permits the Attorney General to 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(f). As such, the CSA requires the denial of an application for registration when the applicant's state license has been suspended or revoked. Sheran Arden Yeates, M.D., 71 FR 39130, 39131 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993). Applicant's loss of his state license thus provides an independent ground to deny his application for a DEA Certificate of Registration.

to litigate the issues. Robert L. Dougherty, M.D., 76 FR 16823, 16830 (2011); Univ. of Tenn. v. Elliot, 478 U.S. 788, 797-98 (1986) (“When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata[.]”) (internal quotations and citations omitted). Moreover, a State Board’s findings may be entitled to preclusive effect even where an Applicant/Registrant chose not to dispute the allegations and entered into a consent agreement or stipulated settlement. David A. Ruben, 78 FR 38363, 38365 (2013) (holding that findings of a consent agreement which supported state board’s disciplinary action were not subject to relitigation before DEA, because, inter alia, physician agreed that he could not contest the findings in any future proceeding involving the Board or other state agency); cf. Jose G. Zavaleta, M.D., 78 FR 27431, 27433-34 (2013) (holding that the findings of a prior DEA proceeding are entitled to preclusive effect in a subsequent DEA proceeding notwithstanding that the Applicant/Registrant waived his right to a hearing in the first proceeding).

Thus, in Ruben, the Administrator held that the findings of a consent agreement were entitled to preclusive effect in a DEA proceeding, even though the registrant had not actually litigated them, noting that under the relevant State’s law, a judgment entered by stipulation or consent ““may be conclusive, with respect to one or more issues, if the parties have entered an agreement manifesting such intention.”” 78 FR at 38366 (quoting Chaney Building Co. v. City of Tucson, 716 P.2d 28, 30 (Ariz. 1986)). Because in Ruben, it was clear that the parties intended that the findings of the consent agreement would be binding between them and could not be relitigated in a subsequent proceeding before the state board (or another state agency), and

under the relevant state law, the agreement was entitled to preclusive effect, the Administrator rejected the contention that the findings were subject to relitigation before this Agency.⁴ Id.

Relevant to the Order at issue here, the Supreme Court of California has held that “a stipulated judgment may properly be given collateral estoppel effect, at least when the parties manifest an intent to be collaterally bound by its terms.” Cal. State Auto. Assn. Inter-Ins. Bureau v. Super. Ct., 50 Cal.3d 658, 665 (1990). The crux of the issue is whether the parties, in agreeing to the settlement order, “manifest[ed] an intent to be collaterally bound by its terms.” Id.; see also Landeros v. Pankey, 46 Cal. Rptr. 2d 165, 167 (Cal. App. 1995) (discussing same).⁵

Here, I conclude that the terms of the Stipulated Surrender and Disciplinary Order manifest that the parties agreed to be bound by the stipulation in subsequent proceedings. Applicant, who was represented by counsel, “voluntarily, knowingly, and intelligently” waived his right to a hearing before the Board, id. at 2, at which he could have “contest[ed] that cause for discipline exists based on” the Board’s charges. Id. at 3.

Most significantly, Applicant “agree[d] that, at a hearing, [the MBC] could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline.” Stipulated Surrender, at 3. The Order further provided that “if [Applicant] should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in [the] Accusation . . . shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny

⁴ The Administrator also rejected the contention that the parties could, by their agreement, prevent DEA, as an Agency of the United States, from “giv[ing] the same effect to the factual findings and legal conclusions as would exist in a subsequent state administrative proceeding.” 78 FR at 38367 (citing U.S. Const. art. VI, cl.2; Howlett v. Rose, 496 U.S. 356, 371 (1990) (citing FERC v. Mississippi, 456 U.S. 742, 776 n.1 (1982) (opinion of O’Connor, J.) (“State may not discriminate against federal causes of action”))).

⁵A “stipulated judgment” is akin to a stipulated settlement, as a stipulated judgment arises when “parties to [a] pending litigation stipulated . . . for settlement of the case.” Cal. State Auto. Assn., 50 Cal.3d at 665.

or restrict licensure.” Id. at 4-5.⁶ Accordingly, because Applicant and the MBC manifested their intent to be bound by the terms of the Stipulated Surrender, the Board’s findings are entitled to preclusive effect in this proceeding. Ruben, 78 FR at 38366.

(A) Analysis of the Public Interest Factors

Under a longstanding Agency regulation, “[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [his] professional practice.” 21 CFR 1306.04(a). This regulation further provides that “an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” Id. See also Cal. Health & Safety Code § 11153(a) (a “prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice,” and “an order purporting to be a prescription which is issued not in the usual course of professional treatment” is not a legal prescription).

As the Supreme Court has explained, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the

⁶ It is noted that the Stipulated Surrender contains a provision which states that “[t]he admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Medical Board of California or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.” Stipulated Surrender, at 3.

Under the Controlled Substances Act, “[t]o issue lawful prescriptions” for any controlled substance, a “physician[] must ‘obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.’” Gonzales v. Oregon, 546 U.S. 250-51 (2006) (quoting 21 U.S.C. 822(a)(2)). Thus, DEA is a professional licensing agency with respect to the dispensing of controlled substances. Moreover, even if Applicant and the MBC intended to limit the preclusive effect of the Stipulated Surrender to proceedings involving other California health care licensing agencies, they cannot prevent an Agency of the United States from giving preclusive effect to the proceeding when they have agreed that such effect shall be given in a subsequent proceeding between Applicant and the State. See supra n.4.

drugs for those prohibited uses.” Gonzales, 546 U.S. at 274 (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)); United States v. Alerre, 430 F.3d 681, 691 (4th Cir. 2005), cert. denied, 574 U.S. 1113 (2006) (prescription requirement stands as a proscription against doctors acting not “as a healer[,] but as a seller of wares”).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act “in the usual course of . . . professional practice” and to issue a prescription for a “legitimate medical purpose.” Zavaleta, 78 FR at 27440. What constitutes a legitimate doctor-patient relationship is generally determined by the applicable state law. Id.

Under California law, a physician must first conduct “an appropriate prior examination,” and determine that there is “a medical indication” for prescribing a controlled substance. Cal. Bus. & Prof. Code § 2242(a); see also id. §725(c). Moreover, as the Expert explained, the MBC has issued extensive guidelines setting forth the standards of professional practice in prescribing controlled substances for the treatment of pain. Expert’s Report, at 4. These standards provide that:

A medical history and physical examination must be accomplished. This includes assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

MBC, Guidelines for Prescribing Controlled Substances for Pain. As also set forth in the Expert’s Report, the Guidelines also address such other areas as the development of a treatment plan, the need to obtain informed consent for treatment, the importance of conducting periodic review of a patient’s response treatment, the need to refer a patient for additional evaluations and consultation, especially where a patient presents the “risk for misusing [his] medications,” the

obligation to keep complete and accurate records, and the obligation to comply with both federal and state controlled substances laws and regulations. Id.

With respect to patients E.G. and R.E., the MBC found that Applicant overprescribed controlled substances without documenting a medical necessity, thereby practicing outside the usual course of professional practice. See Cal. Bus. & Prof. Code § 725(c) (requiring a medical basis for prescribing controlled substances); 21 CFR 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose”). Applicant only treated the patients with controlled substances, failed to document treatment plans, failed take into account the patient’s past history of drug abuse, and continuously prescribed high doses of opiates without documenting any explanation for doing so in their medical records. Stipulated Surrender, at 17-23.

Moreover, as the Expert explained, Applicant ignored signs of misuse with respect to E.G., and signs of misuse and diversion with respect to R.E. Expert’s Report, at 11 (“signs of misuse on the part of [E.G.] did not seem to affect [Applicant’s] prescribing practices”); id. at 29-30 (noting that R.E. requested specific controlled substances, reported stolen opioids, and “reported persistent or increased pain at almost every visit” notwithstanding that “the opioid . . . doses had been significantly increased” and that Applicant “fail[ed] to respond to clues that [R.E.] was misusing or diverting medication”). Most significantly, with respect to both E.G. and R.E., the Expert concluded that Applicant’s treatment “fell far outside the usual professional practice of medicine.” Id. at 32.

I therefore find that Applicant violated the CSA’s prescription requirement when he prescribed controlled substance to E.G. and R.E. 21 CFR 1306.04(a). I also find that Applicant unlawfully distributed controlled substances to E.G. and R.E. See 21 U.S.C. 841(a)(1); see also

Moore, 423 U.S. at 142-43 (noting that evidence established that physician “exceeded the bounds of ‘professional practice,’” when “he gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,” and “took no precautions against . . . misuse and diversion”).

Finally, with respect to patient J.G., the evidence shows that Applicant “assumed the methadone maintenance of a known opiate addict despite his lack of qualification and without the guidance of qualified addiction specialists.” Id. at 28. Applicant did so notwithstanding that he did not hold the registration required by the CSA to dispense narcotic drugs for the purposes of providing maintenance or detoxification treatment. See 21 U.S.C. 823(g)(1) (“practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose.”) (emphasis added); George C. Aycock, M.D., 74 FR 17529, 17543 n.32 (2009) (“Under federal law, a practitioner must meet extensive requirements and be separately registered to lawfully dispense narcotic drugs for maintenance or detoxification treatment.”).

Applicant further violated federal law when he prescribed methadone, a schedule II narcotic, for the purpose of treating J.G.’s opioid dependency. Expert Report, at 22. Under a DEA regulation, a practitioner (who is properly registered), “may administer or dispense (but not prescribe) a narcotic drug . . . to a narcotic depend[e]nt person for the purpose of maintenance or detoxification treatment.” 21 CFR 1306.07(a). Applicant thus also violated this provision when he prescribed methadone to treat J.G.’s opioid dependency.⁷

⁷ To similar effect, California law provides that a physician cannot “administer dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a nonmedical purpose.” Cal. Bus. & Prof. Code § 2241(b). Thus, “an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances,” is illegal. Cal. Health & Safety Code § 11153(a)(2); People v. Gandotra, 14 Cal. Rptr. 2d 896, 901 (Cal. Ct. App. 1992) (“[S]ection 11153 . . .

Accordingly, I hold that the evidence with respect to factors two and four supports the conclusion that Applicant's registration "would be inconsistent with the public interest." 21 U.S.C. 823(f). Because Applicant waived his right to a hearing or to submit a written statement in lieu of hearing, there is no evidence to the contrary. See, e.g., Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (internal quotation marks omitted). Accordingly, I will deny Applicant's application.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 0.104, I hereby order that the application of Thomas Neuschatz, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective immediately.

Dated: December 6, 2013.

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2013-29956 Filed 12/16/2013 at 8:45 am; Publication Date: 12/17/2013]

. . . prohibits practitioners from writing controlled substance prescriptions that . . . are outside the course of their usual professional practice.”).