clear, Respondent is not entitled to “an opportunity to demonstrate that he can responsibly handle controlled substances” through the issuance of even a restricted registration unless and until he accepts responsibility for his misconduct.18

It is acknowledged that fifteen years have passed since the first Agency Order. See ALJ at 20–21. 28. However, way " * * * " using (his son’s problems) as an excuse for bad behavior or to rationalize it away " * * * " as being justified.” Id. Moreover, in discussing the public interest factors and whether the respondent had rebutted the Government’s prima facie case, the decision made no reference to the medical issues of his son. See 63 FR at 11909–10. It is thus inaccurate to say that the Agency “considered the effect a relative’s medical issues can have on his practice of medicine” when those stresses are taken out of the picture, it is less likely that the circumstances will ever be repeated.” ALJ at 23.

Most significantly, the Agency’s decision in Oakes noted in at least three different places that the respondent had expressed remorse and accepted responsibility for his misconduct. See 63 FR at 11909 noting the evidence in favor of denial of Respondent’s application is overcome by " * * * " his expressions of remorse and acceptance of responsibility for his actions”); id. at 11910 (noting that while the respondent’s misrepresentation on a state application “is troublesome, it does not warrant the denial of Respondent’s application in light of his expressions of remorse and acceptance of responsibility for his actions”); id. at 11911 (noting that while the respondent had not received a legitimate physical examination). Thus, contrary to the ALJ’s reasoning, Oakes provides no comfort to Respondent. Moreover, even giving weight to Respondent’s testimony that he is not likely to again invite a patient to live with him, his testimony does not address his misconduct with respect to Patients #2 and 3.

18 The ALJ also noted that since the revocation of his registration, "Respondent has had no further problems related to his practice of medicine." ALJ at 20. Given that DEA does not regulate the practice of medicine, it is an open question whether such evidence is even relevant in assessing whether an applicant’s registration would be consistent with the public interest. See Edmund Chein, 72 FR 6580, 6590 (2007) (declining to decide "whether a registrant’s unwillingness to comply with State rules that are unrelated to controlled substances can be considered [in a revocation proceeding] when the registrant maintains a valid State license").

What is noteworthy, however, are the State ALJ’s extensive findings regarding Respondent’s dispensing of controlled substances to Patient #1, not only during the period following the issuance of the first Order to Show Cause on July 29, 1993, but also after the DEA ALJ’s issuance of his recommended decision on January 12, 1995. While the DEA ALJ’s decision was not a final decision of the Agency, it found that Respondent dispensed controlled substances to Patient #1 “on demand,” "virtually upon request," with “virtually no scrutiny,” that his “prescribing and dispensing to [Patient #1] was outside of the context of the Respondent’s usual professional practice” and thus violated 21 CFR 1306.04(a), and that the Government had “established a prima facie case under factor (2).” GX 6, at 20. Yet thereafter, Respondent engage in what the State ALJ “characterized as irrational polyparmacy”; the State ALJ further noted that “[t]otally absent from his care and treatment of [Patient #1] was control, monitoring and periodic assessment” and that “[f]rom 1990 to 1996, almost all of respondent’s prescribing to [Patient #1] took place in the absence of a legitimate physical examination.” GX 8, at 15–16.

DEA has long held that “[t]he paramount issue is not how much time has elapsed since [his] unlawful conduct, but rather, whether during that time. * * * * * * *” Respondent has learned from past mistakes and has demonstrated that he would handle controlled substances properly if entrusted with a new registration. Leonardo v. Lopez, 54 FR 36915 (1989); see also Leslie, 68 FR at 15227 (revoking registration issued through administrative error on ground that practitioner still refused to acknowledge misconduct which he committed seventeen years earlier notwithstanding that there was no evidence that he had mishandled controlled substances under the erroneously issued registration).

Moreover, it should be noted that neither the 1995 Order, nor any Agency rule, barred Respondent from re-applying at an earlier date. What does bar his obtaining of a new registration is his failure to fully acknowledge his misconduct. Absent Respondent’s acknowledgment of the full scope of his misconduct, I am compelled to conclude that issuing him a new registration would be “inconsistent with the public interest.” 21 U.S.C. 823(f). Accordingly, I reject the ALJ’s recommended ruling and will deny Respondent’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 order that the pending application of Robert L. Dougherty, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: March 11, 2011.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Erwin E. Feldman, D.O.; Revocation of Registration

On May 29, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Erwin E. Feldman, D.O. (Respondent), of Madison Heights, Michigan. The Show Cause Order alleged that on January 18, 2005, Respondent had prescribed controlled substances on ten occasions to undercover agents without performing a medical examination, and that he had issued prescriptions for Suboxone “to treat opiate addiction without having obtained” certification from the Michigan Center for Substance Abuse Treatment and a separate DEA registration to prescribe controlled substances for “maintenance and detoxification treatment of opiate addiction as required by 21 U.S.C. 823(g).” Id. at 1–2.

Next, the Show Cause Order alleged that on April 4, 2007, Respondent entered into a Memorandum of Agreement (MOA) with the Agency to resolve the allegations of the 2005 Show Cause Order, which was to remain in force through May 2010. Id. at 2. The Show Cause Order then alleged that under the MOA, Respondent agreed that he would prescribe controlled substances for only a thirty-day supply with one refill; that he would not prescribe controlled substances to persons who were not residents of the State of Michigan; that he would not prescribe controlled substances to family members; that he would maintain a log of all controlled substance prescriptions he issued; that he would maintain in patient charts, reports from the Michigan Automated Prescriptions System (MAPS) for all patients who received controlled substances from him for “in excess of six months”; and that he would notify DEA “in writing, within twenty days of the initiation of any proceedings which impacted [his] ability to handle controlled substances, including the initiation of any action by a state entity to restrict, deny, rescind, suspend, revoke or otherwise limit [his] authority to handle controlled substances.” Id.

Finally, the Show Cause Order alleged that Respondent had violated the MOA. Id. The Order specifically alleged that “on several occasions,” Respondent had issued controlled substance prescriptions “with as many as seven refills”; that he had prescribed controlled substances to residents of Florida and Colorado; that he had prescribed Phenobarbital, a schedule IV
respondent’s registration was due to controlled substance, to his wife; that he had failed to maintain an accurate log of his controlled substance prescriptions; that he had failed to maintain MAPS reports for those patients he prescribed controlled substances to for more than six months; and that he had “failed to notify DEA in writing” that on November 3, 2008, the Michigan Board of Osteopathic Medicine and Surgery had filed an administrative complaint against his medical license. *Id.*

Respondent requested a hearing on the allegations, and the matter was placed on the docket of the Agency’s Administrative Law Judges (ALJs). Thereafter, the ALJ ordered the parties to file pre-hearing statements. Ex. 6. On July 27, 2009, the Government filed its pre-hearing statement; on August 17, Respondent’s counsel filed a notice of appearance and requested a two-week extension to file Respondent’s pre-hearing statement. *Id.* The record does not disclose what action the ALJ took in response to Respondent’s request for an extension. However, on September 4, the ALJ issued a “Notice to Show Cause Why the Proceeding Should Not Be Terminated” and gave Respondent “until September 18 to respond.” *Id.* On September 21, Respondent’s counsel faxed a document which bore the caption of Respondent’s Pre-Hearing Statement. *Id.* However, when several pages appeared to be missing, the ALJ’s office left telephone messages on September 21, 22 and 23 with Respondent’s counsel, notifying him that the entire document had not been received.

On September 28, the ALJ issued another “Notice to Show Cause Why the Proceeding Should Not Be Terminated” and gave Respondent until October 1 to file a response. *Id.* However, on October 20, 2009, the ALJ ordered that the proceeding be terminated, noting that Respondent had not filed a response to the order. *Id.* The ALJ further “conclude[d] that Respondent has waived his right to a hearing.” Order Terminating Proceedings, at 1.

Thereafter, the Investigative Record was forwarded to this Office for final agency action. Having reviewed the entire record in this matter, I adopt the ALJ’s finding that Respondent has waived his right to a hearing. *See 21 CFR 1301.43(d).* I make the following findings of fact.

Findings

Respondent is the holder of DEA Certificate of Registration, AF9086415, which authorizes him to dispense controlled substances in schedules II through V as a practitioner. Respondent’s registration was due to expire on September 30, 2008; however, on September 22, 2008, Respondent submitted a renewal application. Because Respondent’s renewal application was timely submitted, I find that Respondent’s registration remains in effect pending the issuance of this Decision and Final Order. *See 5 U.S.C. 558(c).* Moreover, on March 17, 2010, Respondent submitted a further application for registration as a practitioner. *See GX 2.*

On January 18, 2005, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Respondent, which proposed the revocation of his registration. GX 3. The 2005 Show Cause Order alleged that Respondent had “issued numerous prescriptions for controlled substances to an addict, and that he had continued to prescribe controlled substances to patient P.H. even after he became aware that P.H. had been admitted to a hospital following an overdose. *Id.* at 2–3. This Show Cause Order further alleged that between December 2001 and July 2004, four DEA Agents made undercover visits to Respondent and that on at least ten occasions, the Agents had obtained prescriptions "without having received any type of medical exam." *Id.* at 3.

The 2005 Show Cause Order also alleged that Respondent had prescribed controlled substances in family practice, that he issued a substantially greater number of controlled-substance prescriptions than four other family practice physicians who practiced at the same medical office building, and that he had issued approval approximately 59% of the controlled substance prescriptions which were dispensed by the Oakland Medical Pharmacy, which was located in the same building. *Id.* at 1, 4–5. Finally, the Show Cause Order alleged that Respondent had prescribed Suboxone to three patients even though he did not possess a certification issued by the Michigan Center for Substance Abuse Treatment or a DEA registration to prescribe controlled substances for maintenance and detoxification treatment; the Order also alleged that he had prescribed Suboxone to three patients simultaneously with other controlled substances which were contraindicated. *Id.* at 5–6.

Respondent requested a hearing on the allegations of the 2005 Show Cause Order. Thereafter, the parties settled the matter and entered into a Memorandum of Agreement (MOA), under which the Agency agreed to renew Respondent’s registration subject to various terms as set forth in the MOA. The MOA, which became effective on May 21, 2007, was to remain in force for a period of three years. GX 5, at 2 & 5.

More specifically, Respondent agreed to limit his controlled substance activities “to prescribing only,” that he would prescibe a controlled substance only for patients with one refill, that he would issue a new controlled-substance prescription only after a patient visited with him. *Id.* at 2. Respondent also agreed that he would not prescribe controlled substances to persons who were not residents of the State of Michigan; that he would not prescribe controlled substances “to members of his immediate family”; that he would maintain a quarterly log of all controlled-substance prescriptions he issued which would be available to DEA personnel on request; and that in his patient charts, he would maintain reports from the Michigan Automated Prescriptions System (MAPS) for all patients who received controlled substances from him for “in excess of six months.” *Id.* at 2–3.

Respondent also agreed that he would not “delegate to any pharmacist authorization to dispense” a new controlled-substance prescription “or refill an existing prescription * * * prior to speaking with [him] or his designated representative * * * unless such prescription is pursuant to a lawful prescription order by [him],” *Id.* at 3. Respondent further agreed to notify DEA “in writing, within twenty days of the initiation of any proceedings which impacted [his] ability to handle controlled substances, including the initiation of any action by a state entity to restrict, deny, rescind, suspend, revoke or otherwise limit [his] authority to handle controlled substances.” *Id.* at 4. Finally, Respondent agreed that “if he violate[ ] any term or condition of [the MOA], such violation could result in [the] initiation of proceedings to revoke his” DEA registration. *Id.* at 4–5.

According to the affidavit of a DEA Diversion Investigator (DI), following Respondent’s submission of his renewal application, DIs obtained from both local pharmacies and MAPS, information pertaining to the prescriptions issued by Respondent; the DIs also met with Respondent on February 11, 2009 to review his compliance with the MOA. GX 22, at 4–5.

During the February 11, 2009 meeting, Respondent provided the DIs with his controlled-substance prescription log. *Id.* at 5. The log showed that Respondent had issued prescriptions to several patients with “as many as five refills” for Androgel, a schedule III controlled substance, as well as that he had issued prescriptions with between
three and seven refills, to multiple patients for Testim, another schedule III controlled substance. Id.; see also GXs 7, 9–11, 13. The evidence also showed that Respondent had issued a prescription for Ativan (lorazepam), a schedule IV controlled substance, with three refills, to two different patients. See GX 7.

Based on their review of MAPS data and medical records, the DIIs further determined that on December 21, 2007, Respondent had issued a prescription for hydrocodone/acetaminophen, a schedule III controlled substance to M.L.G., a resident of Florida; that on January 8, 2008, he had issued a prescription for propoxyphene/acetaminophen, a schedule IV controlled substance, to M.S.E., a resident of Colorado; and that on July 25 and August 18, 2008, he had issued prescriptions for 60 and 90 tablets of alprazolam, a schedule IV controlled substance, to B.P., a resident of Port Orange, Florida. GX 22, at 6. The DIIs further determined that on September 24, 2007, Respondent prescribed 160 tablets of phenobarbital, a schedule IV controlled substance, to his wife, by calling in a prescription to a local pharmacy. Id. at 7; see also GX 16. Moreover, during the February 11, 2009 meeting with the DIIs, Respondent denied calling in the prescription for his wife and maintained “that he called in a refill of an earlier phenobarbital prescription issued by” another physician (Dr. C.) on September 21, 2007. GX 22, at 7. However, the prescription issued by Dr. C. was for only sixteen tablets with two refills. Id.

In addition, the DIIs compared the MAPS report showing Respondent’s prescribing with the controlled-substance log he was required to maintain. Id. at 8. This review showed that Respondent had failed to document fourteen prescriptions in the log. Id. Upon reviewing the patient charts, the DIIs also found various instances in which Respondent had prescribed controlled substances to a patient for more than six months and had not maintained a MAPS report in the patient’s chart. Id. at 9.

Finally, on November 3, 2008, the Michigan Board of Osteopathic Medicine and Surgery issued an administrative complaint to Respondent charging him with eight counts of violating state law, including five counts of “prescribing drugs without a lawful diagnostic or therapeutic purpose.” GX 18, at 5–12; 19 (citing Mich. Comp. Laws § 16221(c)(iv)). The Board also charged Respondent with negligence of competence based on his prescribing of Suboxone to treat opioid dependence without having “obtain[ed] the necessary certification.” Id. at 18–19 (citing Mich. Comp. Laws §§ 16221(a) and 16221(b)(l)). While the Board sought to impose sanctions on Respondent’s medical license, see id. at 1–3, Respondent did not notify DEA of the proceeding. 2 GX 22, at 10.

Discussion

Section 304(a) of the CSA provides that a “registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). In determining the public interest, 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.

In May of 2007, DEA exercised forbearance and allowed Respondent to settle a previous Show Cause proceeding by entering into an MOA. However, as found above, Respondent promptly proceeded to violate multiple provisions of the MOA.

First, Respondent violated the MOA’s restriction that he could only prescribe a thirty-day supply of a controlled substance with one refill, and that he could issue a new prescription only after the patient visited him. More specifically, the record shows that Respondent issued prescriptions which authorized multiple refills to multiple patients for both schedule III anabolic steroids (Androgel and Testim) and a schedule IV depressant (lorazepam).

Second, Respondent violated the MOA’s provision that he could not prescribe a controlled substance to a non-resident of Michigan. More specifically, Respondent prescribed hydrocodone/acetaminophen, a schedule III controlled substance, to


4 With respect to factor one, while the Investigative Record contains a copy of the Administrative Complaint filed by the Michigan Board, there is no evidence establishing the outcome of this proceeding. However, even assuming that Respondent retains his state authority, DEA has long held that while the possession of state authority is an essential condition for holding a Practitioner’s registration, see 21 U.S.C. 823(f), this factor is not dispositive in the public interest inquiry. Patrick Stodola, 74 FR 20727, 20730 n.16 (2009).

Likewise, there is no evidence that Respondent has been convicted of a criminal offense under either Federal or State law related to the distribution or dispensing of a controlled substance (factor three). However, because there are multiple reasons why a person may not even be charged, let alone be convicted of such an offense, DEA has long held that this factor is not dispositive. See Edmund Cheez, 72 FR 6580, 6593 n.22 (2007).
M.L.G., a resident of Florida; he prescribed propoxyphene and acetaminophen, a schedule IV controlled substance, to M.S.E., a resident of Colorado; and on two occasions, he prescribed alprazolam, a schedule IV controlled substance to B.P., a resident of Florida.

Third, Respondent violated the MOA’s prohibition against his prescribing to a member of his immediate family. More specifically, on September 24, 2007, Respondent prescribed 160 tablets of phenobarbital, a schedule IV controlled substance, to his wife. Moreover, when questioned by the DIs regarding the prescription, Respondent denied having called in the prescription and asserted that he had only called in a refill of an earlier prescription which had been written by another physician. Respondent’s statement was false because the other physician had authorized refills for only sixteen tablets, and it was materially false because the MOA prohibited him from prescribing to a family member and was thus capable of influencing the decision of the Agency as to whether to seek the revocation of his registration. See David A. Hoxie, M.D., 69 FR 51477, 51479 (2004) (considering false statements to investigators under factor five).

Fourth, Respondent violated the MOA’s requirement that he maintain a log of all controlled-substance prescriptions he issued. More specifically, Respondent failed to document fourteen controlled-substance prescriptions in the log.

Finally, Respondent violated the MOA’s requirement that he notify DEA, in writing, within twenty days, of “the initiation of any action by a state entity to * * * suspend, revoke, or otherwise limit [his] authority to handle controlled substances.” Notwithstanding that the State filed an Administrative Complaint against him, which sought to impose sanctions on his medical license and his authority to handle controlled substances, see Mich. Comp. Laws § 333.7311(6), Respondent failed to notify DEA that the proceeding had been brought.

DEA has long held that a registrant’s failure to comply with the terms of an MOA can constitute acts which render his registration inconsistent with the public interest. See Fredal Pharmacy, 55 FR 53592, 53593 (1990) (holding that pharmacy which violated MOA “had[d] engaged in conduct which threatens the public health and safety”). This is so even if the violation of the MOA does not establish a violation of the CSA or its implementing regulations. Moreover, Respondent’s various violations of the MOA, as well as his having made a false statement to the Investigators, show that he cannot be trusted to faithfully comply with the obligations of a registrant. I therefore conclude that Respondent’s registration should be revoked and his pending application should be denied.

Order
Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as by 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, AF9086415, issued to Erwin E. Feldman, D.O., be, and it hereby is, revoked. I further order that any application of Erwin E. Feldman, D.O., to renew or modify such registration, be, and it hereby is, denied. This Order is effective April 25, 2011.

Dated: March 10, 2011.

Michele M. Leonhart,
Administrator.

BILING CODE 4410-09-P

DEPARTMENT OF JUSTICE
Federal Bureau of Prisons

Finding of No Significant Impact; Notice of Availability of the Finding of No Significant Impact (FONSI) Concerning a Proposal To Award a Contract for New Low Security Beds to One Private Contractor To House Approximately 1,000 Federal, Low-Security, Adult Male, Non-US Citizen, Criminal Aliens at a Contractor-Owned, Contractor-Operated Correctional Facility

AGENCY: U.S. Department of Justice, Federal Bureau of Prisons.

ACTION: Finding of No Significant Impact.

SUMMARY: The U.S. Department of Justice, Federal Bureau of Prisons (BOP) announces the availability of the Finding of No Significant Impact (FONSI) Environmental Assessment (EA) for the proposal to award one or more contracts to house approximately, 1,000 federal, low-security, adult males, criminal aliens within one existing contractor owned, contractor operated facility.

Background Information

Growth of the federal inmate population has been substantial over the last two decades. Currently, the increased federal inmate population exceeds the combined rated capacities of the 116 BOP facilities. It is projected that this growth will continue as a result of actions and programs implemented by the U.S. Department of Justice and the U.S. Department of Homeland Security regarding sentenced and unsentenced criminal aliens.

In response, the BOP is seeking flexibility in managing its current shortage of beds by contracting for those services with non-federal facilities to house federal inmates. This approach provides the BOP with flexibility to meet population capacity needs in a timely fashion, conform to federal law, and maintain fiscal responsibility, while successfully attaining the mission of the BOP.

The BOP proposed action is to award one contract to house approximately 1,000 federal low-security, adult male, non-U.S. citizen, criminal aliens at an existing privately owned and privately operated correctional facility. Under the Proposed Action, the selected contractor would be required to operate the facility in a manner consistent with the mission and requirements of the BOP. All inmate services would be developed in a manner that complies with the BOP’s contract requirements, as well as applicable federal, state, and local laws and regulations. The contract also requires that no new construction or expansion of the existing facility occur. In addition, the facility will be within proximity, and have access to, ambulatory, fire and police protection services. The federal inmates assigned to this facility would consist primarily of inmates with sentences of 90 months or less remaining to be served. As described previously these inmates are anticipated to be low-security, adult male, non-U.S. citizen, criminal aliens, however the BOP may designate any inmate within its custody to serve their sentence in this facility. The contract awarded for this action would have one four-year base period and three, two-year option periods, for a maximum term of ten years.

Five existing privately owned and operated correctional facilities in Kentucky, Louisiana, and Texas have been offered in response to the BOP’s nationwide solicitation from which the BOP will award one contract to one of the five facilities offered. Each of the following existing facilities has been evaluated in this EA. In addition, the No Action Alternative is evaluated, to determine baseline conditions and comply with the provisions of NEPA.

- Lee Adjustment Center. Located on an approximately 90 acre parcel in Beattyville, Kentucky.
- Limestone County Detention Center. Located on a 293 acre parcel in Groesbeck, Texas.