Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) Title *of the Form/Collection:* Fee Waiver Request.

(3) *Agency form number:* EOIR–26A (OMB #1125–0003).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: An individual submitting an appeal or motion to the Board of Immigration Appeals. Other: Attorneys or representatives representing an alien in immigration proceedings before EOIR. Abstract: The information on the fee waiver request form is used by the Board of Immigration Appeals to determine whether the requisite fee for a motion or appeal will be waived due to an individual's financial situation.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 8,614 respondents will complete each form within approximately 1 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 8,614 total annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E.405B, Washington, DC 20530.

Dated: November 13, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–27250 Filed 11–17–14; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Richard D. Vitalis, D.O.; Decision and Order

On August 12, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Richard D. Vitalis, D.O. (Applicant), of Debary, Florida. GX 1. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration on the ground that his continued ''registration would be inconsistent with the public interest.'' *Id.* at 2 (citing 21 U.S.C. 823(f)).

The Show Cause Order made numerous allegations against Applicant. First, it stated that on October 1, 2008, the Florida Department of Health (DOH) entered an emergency suspension of Applicant's medical license on the basis of his history of alcohol dependency and his failure to comply with DOH orders requiring the monitoring of his medical practice. *Id.* The Order then specifically alleged that after reinstatement of his Florida medical license on March 26, 2009, Applicant materially falsified three applications for a DEA registration when he falsely answered ''no'' on each application to the liability question which asks: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substances registration revoked, suspended, denied, restricted or place on probation?'' *Id.* at 2–3 (citing 21 U.S.C. 843(a)(4)(A)). The Order alleged that Applicant submitted these applications on October 5, 2009; May 22, 2012; and January 7, 2013. *Id.*

The Show Cause Order also alleged that on October 6, 2009, Applicant became registered as a practitioner to handle schedule II controlled substances under DEA registration number FV1682269, at the registered address of 230 Caddie Court, Debary, Florida. The Order then alleged that between July 2010 and June 3, 2011, Applicant ''issued and/or authorized prescriptions for controlled substances in Schedules 2N, 3, 3N, 4 and 5, for which [he] did not have the authority to handle, in violation of 21 U.S.C. 822(b).'' *Id.* at 3. The Show Cause Order also alleged that on June 3, 2011, Applicant's registration was modified to add all schedules. *Id.*

Next, the Show Cause Order alleged that between July 7, 2011 and March 22, 2012, three law enforcement officers made six undercover visits to Applicant at All Family Medical (hereinafter, AFM), a state-registered pain management clinic. *Id.* The Order then alleged that at the conclusion of each visit, Applicant prescribed Schedule II and IV controlled substances, including oxycodone and Xanax, to the undercover officers, for other than a legitimate medical purpose and outside the usual course of professional practice in violation of applicable federal, state and local law. *Id.* at 3–4 (citing 21 CFR 1306.04(a)).

The Show Cause Order further alleged that a medical expert reviewed the undercover visits and determined that Applicant prescribed unnecessary and excessive doses of controlled substances to the undercover officers, in deviation from the standard of care in pain medicine. *Id.* at 4–5. The Order alleged that the Expert further found that Applicant failed to comply with Florida's standards for the use of controlled substances for the treatment of pain, and that the prescriptions were issued for other than a legitimate medical purpose and outside the usual scope of professional practice. *Id.* at 5 (citing Fla. Stat. § 456.44; Fla. Admin. Code r.64B15–14.005; 21 CFR 1306.04(a)).

Finally, the Show Cause Order alleged that on January 1, 2012, D.V., a 34-year old male died as a result of an accidental overdose of controlled substances. *Id.* The Order then alleged that on December 27, 2011, Applicant issued prescriptions to D.V. for 180 tablets of oxycodone 30mg, 120 tablets of oxycodone 15mg, 40 tablets Percocet 10/325 mg, 60 tablets of alprazolam 2mg, and 90 tablets of Motrin 800mg, and that the prescriptions ''were for other than a legitimate medical purpose and outside the usual scope of professional practice.'' *Id.* (citing 21 CFR 1306.04(a)).

The Show Cause Order, which also notified Applicant of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence of failing to elect

either option, was served on Applicant by certified mail addressed to him at his proposed registered address. As evidenced by the signed return-receipt card, service was accomplished on August 27, 2013.

Since that date, more than thirty days have now passed and neither Applicant, nor anyone purporting to represent him, has requested a hearing or submitted a written statement in lieu of a hearing. Accordingly, I find that Applicant has waived his right to a hearing or to submit a written statement on the allegations of the Show Cause Order. 21 CFR 1301.43(c) & (d). I therefore issue this Decision and Order based on the investigative record submitted by the Government and make the following findings of fact.

Findings

Applicant's Licensure and Registration Status

Applicant is an osteopathic physician licensed by the Florida DOH. On October 1, 2008, the DOH ordered the emergency suspension of his medical license, on the ground that Applicant had been diagnosed with alcohol dependency and that absent monitoring by the Professional Resource Network, his continued practice of osteopathic medicine constituted an immediate and serious danger to the health, safety and welfare of the public. GX 10, at 9–10. However, on March 26, 2009, the DOH reinstated his Florida medical license. Government Request for Final Agency Action (Gov. Request), at 2.

During this period, Applicant held a DEA practitioner's registration, pursuant to which he was authorized to dispense controlled substances in schedules II though V. GX 4. However, on May 31, 2009, Applicant allowed his registration to expire and the number was subsequently retired by the Agency. *Id.* at 2.

On October 5, 2009, Applicant applied for a new DEA practitioner's registration at an address in Debary, Florida. On the application, Applicant sought authority to dispense schedule II narcotics and no other controlled substances. GX 4, at 7. Applicant was also required to answer four questions, including Question Three which asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substances registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' GX 4, at 11. Applicant answered ''no.'' *Id.* The following day, DEA issued Applicant a new registration which was limited to schedule II. *Id.* at 7. Applicant did not submit a request to add the additional drug schedules until June 6, 2011. GX 8, at 3.

On December 2, 2010, Applicant requested a change in his registered address to ''The Center for Wellness and Weight Loss D/B/A All Family Medical,'' a pain management clinic located in North Lauderdale, Florida. GX 4, at 7; GX 8, at 2 (DI Declaration). Applicant's request was approved. GX 4, at 7; GX 8, at 2.

On May 22, 2012, Applicant submitted a renewal application for his registration. *Id.* at 3. Once again, he provided a ''no'' answer to Question Three. GX 4, at 8; *see also* GX 8, at 3. The next day, DEA Agents and Task Force Officers (who had previously conducted undercover operations), along with members of the Broward County Sheriff's Office, executed a federal search warrant at AFM. GX 8, at 3.

On July 27, 2012, an Order to Show Cause and Immediate Suspension Order was personally served on Applicant. *Id.* While Applicant filed a timely hearing request, prior to the hearing date, Applicant's counsel advised the Government that he would submit a voluntary surrender in lieu of a hearing. *Id.* at 4. On December 20, 2012, the Miami Field Office received a letter which voluntarily surrendered Applicant's registration and his registration was subsequently retired from the DEA registration system. *Id.; see also* GX 4, at 7.

On January 4, 2013, Applicant again applied for a registration as a practitioner in Schedules II–V, at the address of 230 Caddie Court, Debary, Florida, 32713. GX 4, at 1. Question Two asked: ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' *Id.* at 4. Applicant answered ''Yes.'' *Id.* However, in response to Question Three, Applicant again answered ''No.'' *Id.*

The DEA Investigation

Between July 7, 2011 and March 22, 2012, three law enforcement officers, acting in an undercover capacity, made a total of six visits to AFM.[1] GX 11, GX 24, GX 30. The Officers were able to see Applicant five times and were successful at obtaining controlled substance prescriptions at each of these visits.

DEA Task Force Officer M.C., using an undercover name with the same initials, visited AFM on July 7, 2011; August 11, 2011; and September 8, 2011. Declaration of M.C., at 2.

On each visit, he was equipped with a device which recorded his interactions with Applicant. The evidence includes the audio recordings, as well as a transcribed record of the portion of the visit during which M.C. met with Applicant. GX 12, 13, 15, 16, 18, 19.

During his first visit, M.C. filled out a pain management questionnaire and rated his average pain at a 5 on a scale from 1 to 10, with 10 being ''pain as bad as you can imagine.'' GX 5, at 43. He underwent a urine screening, which showed that he had no controlled substances in him. GX 11, at 2. At some point unspecified in the record, his weight, blood pressure and pulse were recorded on an ''Intake Form''; this form also stated that his CC (chief complaint) was ''chronic LBP'' and ''shoulder pain.'' GX 5, at 38. Handwritten notes under the Examination and Symptoms Findings are largely undecipherable. *Id.*

The patient record also includes a form, which is appropriately mistitled as: ''Medical Justifiction (sic) Form for Prescribing More Than a 72 Hour Dose of Controlled Substance for the Treatment of Non-Malignant Pain'' [2]; this form was signed by Applicant and dated July 7, 2011. On the form, Applicant checked the box next to the section which reads:

> I have performed an adequate physical examination of this patient this same day utilizing the standard of practice required by the Florida Board of Medicine for physicians practicing in a pain management clinic, and I find that his/her medical condition justifies the use of this medication to treat such condition.[3]

GX 5, at 19. Directly below this statement is a place for comments, which appear to be in Applicant's handwriting, but which are illegible. *Id.*

M.C.'s file also includes a form, entitled ''Pain Management Treatment Plan Medical Record'' (Treatment Plan), which appears to track the various

[1] This location is also known by an alternate address, 995 Rock Island Rd, North Lauderdale, FL 33068 as referenced by the UCs in their declarations. *See* GXs 11, 24, 30.

[2] This form states that: ''Pursuant to Florida Code Section 458.32654(2)(c) a physician who prescribes more than a 72 hour dose of a controlled substance must document in the patient's record the reason for prescribing that quantity. If it is found by the applicable regulatory agencies that this clinic qualifies as a pain clinic under such Florida Statute, I hereby document the following medical justification for prescribing the amounts prescribed to this patient.'' GX 5, at 19.

[3] An identical form is found in the medical file for each visit made by the undercovers, each indicating that ''an adequate physical exam had been performed utilizing the standards of practice required by the Florida Board of Medicine.'' Each form contains brief, illegible handwritten notes.

components of the guidelines [4] adopted by the Florida Board of Osteopathic Medicine as part of its regulations entitled ''Standards for the Use of Controlled Substances for Treatment of Pain.'' *See* Fla. Admin. R.64B15–14.005. Several of the form's sections list various line items with either a place to check ''yes'' or ''no'' or to check applicable boxes; in addition, several sections have a place for the physician to write notes. *See* GX 5, at 15–18.

With respect to the first section of this form, which pertains to the patient evaluation, the form indicates that a pain survey was completed. *Id.* at 15. While this portion of the form contains places to indicate whether therapeutic goals were discussed, whether a functional assessment was performed, whether social and drug use histories were taken, whether a medication use assessment was done and whether prior records were reviewed, Applicant checked neither the yes nor the no line and the corresponding notes section contains two indecipherable words. *Id.* So too, the medical diagnosis section appears to simply state ''as above.'' *Id.*

As for the treatment objectives, check marks are placed next to entries for ''improvement of pain without complete resolution,'' ''ability to return to some sort of employment,'' and ''return to certain level of physical activity,'' but no further notes were made. *Id.* at 16. As for non-medication treatments, which lists ten different modalities, the word ''cold'' is circled but none of the boxes are checked. *Id.* Applicant checked ''yes'' to indicate that he had discussed the risks and benefits of controlled substances with M.C. *Id.* at 17. He also indicated that drug testing had been completed, but left blank the results. *Id* at 18. Yet other evidence in M.C.'s record shows that his urine drug screen was negative.[5] *Id.* at 40.

The audio recording of the initial office visit reveals Applicant greeted M.C. and stated, ''I understand you've been having some low back pain,'' to which M.C. replied: ''yeah low back pain and, like, my shoulder's bugging me too.'' GX 12; GX 13, at 1. M.C. told Applicant he did not have an MRI of his shoulder because it was an additional charge to the MRI for his back. GX 13, at 1.

M.C. told Applicant that he controlled his pain by taking oxycodone, and that ''it's really the only thing that's helped. I've done . . . Advil and Tylenol, but it doesn't really help me.'' *Id.* Applicant stated ''so it's partially controlled with those, but you get much better pain relief when you take Roxicodone.'' *Id.* He then asked if M.C. had ''taken anything else, like hydrocodone,'' to which M.C. replied: ''No. Just the blue thirties (30's).'' *Id.*

Applicant then asked M.C. what was wrong with his shoulder. M.C. replied: ''it's just more sore. Cause right after I play it will be sore for a couple days and . . . it kinda goes away.'' *Id.* Next, Applicant asked M.C. whether he had undergone surgeries; whether he used tobacco, alcohol and either illegal or illicit drugs; and if there was a family history of various diseases. *Id.* Applicant then listened to M.C.'s breathing with a stethoscope.

After asking about M.C.'s work, Applicant stated he had ordered Roxicodone and Ibuprofen to help control his pain. *Id.* at 3. He then asked M.C., ''what, other than pain medication, seems to help with your pain; heat, cold or relaxation?'' *Id.* M.C. replied ''a little cold.'' *Id.* Applicant then repeated that he was going to prescribe Motrin and Roxicodone and told M.C. he wanted to see him back in about one month. *Id.* The visit ended, with M.C. receiving a prescription for 90 Motrin 800mg and 150 Roxicodone 30mg. GX 14; *see also* GX 11, at 3.

On August 11, 2011, M.C. returned to AFM. Upon meeting, Applicant asked M.C. ''[h]ow are you doing?'' to which M.C. replied ''[g]ood.'' GX 16, at 1. Applicant then asked M.C. if he was ''getting pain relief with [his] current medications'' and if he was ''tolerating [his] medications well''; M.C. replied ''yes'' to both questions. *Id.; see also* GX 15. After a silence which lasted approximately 3 minutes, GX 15, Applicant stated, ''Alright Michael . . . I re-ordered your Motrin and Roxicodone for you . . . and see you back in about one (1) month.'' GX 16, at 1.

Following another brief silence, M.C. asked: ''Do you want me to stand up?'' Applicant replied, ''[y]ou're fine. Take some deep breaths.'' *Id.* Applicant then told M.C., ''[s]ee you in about one (1) month,'' and the visit ended. *Id.* at 2. The total length of the visit was approximately 5 minutes, GX 15, and Applicant issued M.C. prescriptions for 150 Roxicodone 30mg and 90 Motrin 800mg. GX 17. A note for the visit lists M.C.'s weight, blood pressure, and pulse (although it is unclear if these were ever taken), and also includes Applicant's notes, which are largely indecipherable, but state that ''pt states good pain relief with current meds'' and ''tolerates meds well.'' GX 5, at 35. *Id.*

On September 8, 2011, M.C. made a third visit to AFM. GX 19; GX 5, at 32. M.C. filled out a Daily Pain Summary Form, on which he stated that he had pain on that day, that it was on average a three out of ten, and that he had ''experienced unrelieved breakthrough pain'' on three occasions on that date. GX 5, at 8.

During this appointment, Applicant asked M.C. if he was ''getting good relief with [his] current medications?'' GX 18; GX 19, at 1. M.C. answered ''[y]es,'' but added: ''I'm having a little trouble sleeping some nights . . . I didn't know if I can get any Xanax . . . Just a couple Xanax . . . I've taken it before and it helped.'' GX 19, at 1. Applicant replied, ''[s]o you're having some insomnia''; M.C. stated, ''[y]eah, not too bad, but sometimes.'' *Id.*

After placing his stethoscope on M.C.'s back and listening to him breathe, Applicant told M.C. that he had ''renewed'' both his Roxicodone and Motrin and added that he wanted to see M.C. ''back in about one (1) month.'' *Id.* The visit then concluded. *Id.* at 2. While the visit lasted approximately nine minutes, the recordings establish that M.C. and Applicant exchanged very little dialog other than that which is quoted above. In fact, after Applicant said to M.C., ''breathe normal'' and ''sounds good'' (apparently while listening with his stethoscope), approximately four and one-half minutes passed without further dialogue until Applicant told M.C. that he had ''renewed [his] Roxicodone.'' *Id., see also* GX 18 (audio recording.) Applicant again issued M.C. prescriptions for 150 Roxicodone 30mg and 90 Motrin 800mg. GX 20.

On October 11, 2011, M.C. made a fourth visit to AFM. GX 5, at 3. After Applicant greeted M.C. and made an unintelligible comment, M.C. stated: ''[y]eah, I asked you for them last time . . . I don't know if you forgot, but, you said you would, but I didn't get the script for them,'' apparently referring to the Xanax he had sought at his previous visit.[6] GX 22, at 1.

The following exchange then ensued:

[4] The form contains sections with such headings as ''Patient Evaluation/Assessment,'' ''Medical Diagnosis,'' ''Objectives of Treatment Used to Determine Treatment Success,'' ''Recommended Non-Medication Treatment Modalities,'' ''Risks and Benefits,'' ''Periodic Review,'' ''Patient Drug Testing Completed'' and ''Compliance With Controlled Substance Laws.''

[5] Applicant also checked ''no,'' indicating that he did not recommend that M.C. consult with a specialist or undergo additional evaluations or tests. Yet he made another indecipherable note in the section for listing additional evaluations and tests.

[6] The patient record includes an undated, unsigned handwritten note stating: ''pt said you were going to write some Xanax but forgot.'' GX 5, at 1.

Applicant: ''I think I said I wanted you to try and go without them.'' [7]

M.C.: ''Oh, OK.''

Applicant: ''I will go ahead and prescribe them for you this time.''

M.C.: ''OK.''

Applicant: ''Did you do ok when you didn't have them?''

M.C.: ''Um, I had taken them before and I did better with them when I was taking them. . . . And also, I work in a warehouse, and I know the holidays are coming up. So, it's a lot of heavy lifting. I didn't know if I could get a couple more of the Oxy's . . . You gave me one hundred and fifty (150) last time . . . I didn't know if you could bump it up to, like, one hundred eighty (180) maybe, if that's possible.''

Applicant: ''I'll see what I can do.''

Id.

Next, Applicant asked M.C. if he was ''doing well,'' with M.C. answering ''yes.'' *Id.* at 2. M.C. then asked if Applicant wanted him ''to stand up.'' *Id.* Applicant said ''you're fine,'' asked M.C. to ''take some deep breaths,'' and said ''sounds good.'' *Id.* Approximately four minutes of silence followed (*see* GX 21), after which Applicant told M.C. that he had ''renewed [his] scripts,'' as well as given him ''Xanax for the sleep'' and needed to see him ''back in about a month.'' GX 22, at 2. The total length of the visit was approximately eight minutes and Applicant issued M.C. prescriptions for 160 Roxicodone 15mg, 150 Roxicodone 30mg, 60 Xanax 2mg, and Motrin. GX 5, at 28.

On July 7, 2011, a second Special Agent (B.O.), made an undercover visit to AFM. GX 24, at 2; GX 26, at 1 (transcript). B.O. provided paperwork and an MRI to the clerk as a walk-in patient, and returned to AFM later in the day for his appointment. GX 26, at 1–3. He provided a urine sample, which tested negative for controlled substances. GX 24, at 2. He also completed a Pain Survey on which he reported that in the last 24 hours, his pain (on a zero to ten scale) was a five (5) at its worst, a two (2) at its least, and averaged a three (3). GX 6, at 35.

The form also asked the patient to rate the extent to which the pain interfered with various things, such as general activities, work, and sleep, with zero being no interference and ten being complete interference. B.O. circled three (3) for both his general activity and work, and five (5) for sleep. *Id.* at 36. He also wrote that he had taken non-prescription Motrin which had no effect on his pain. *Id.* at 37. Another form included in the patient file, signed by B.O. on July 7, 2011, included an oath that he ''had not been prescribed narcotic pain medication within the last 30 days, or from another physician, since my last visit to this clinic.'' *Id.* at 15.

Thereafter, B.O. was seen by Applicant, but the recording device malfunctioned and depicts only about two minutes of their interaction, during which Applicant was sitting at his desk and asked B.O. what type of work he did and how many hours a week he worked before ending. GX 26, at 5–6; GX 25. However, the Special Agent submitted a sworn declaration stating that he told Applicant he was experiencing back problems due to work, and that he had taken oxycodone from a friend which relieved the pain. GX 24, at 2. The Special Agent further stated that following this, Applicant ''placed a stethoscope on my back and printed prescriptions for 180 tablets of oxycodone 30mg and 90 tablets of Motrin 800mg.'' *Id.; see also* GX 27.

B.O.'s patient file includes an intake form which purports to document his chief complaint, his symptoms, and exam findings. GX 6, at 27. Again, most of the handwritten notes for the exam findings are illegible. The Pain Management Treatment Plan form notes a diagnosis of ''chronic lbp''; it also includes the words ''work out, stretching, chiropractic'' in the notes section under objectives of treatment. *Id.* at 6–7. In addition, the ''yes'' box is checked indicating that a pain survey was done, that the risks and benefits were discussed, that a follow-up appointment was scheduled and that a drug test was done; the ''no'' box is checked indicating that specialist consultations or additional tests were not being scheduled. *Id.* at 6–9. However, the rest of the form is blank. *Id.*

On August 4, 2011, B.O. returned to AFM. GX 29; *see also* GX 24, at 2. During the visit he was required to submit a urine sample, which registered negative for controlled substances. GX 29, at 2. He was then informed by the office clerk that he was dismissed from the practice. *Id.* at 3; *see also* GX 6, at 1–2.

On March 22, 2012, a local sheriff's deputy, using an alias with the initials T.B., went to AFM. GX 30, at 1. T.B. was initially told by the office staff that his MRI was too old because it was over two years old; he then obtained a new MRI for his neck and returned to AFM that same day. *Id.; see also* GX 31 (audiovisual recording).

T.B. completed two forms regarding his pain, a Daily Pain Summary and a Pain Management Questionnaire. On the former, he placed an x on his upper back to indicate the area where he had pain. GX 7, at 2. On the latter, he noted that in the last twenty-four hours, his pain was a four (4) at its worst, a three (3) at its least, and on average a three (3). GX 7, at 20. He also wrote that the onset of his pain was in 2005, and that ''oxycodone—helps.'' *Id.* at 22.

While the audio-video recording of T.B.'s visit depicts his interactions with the office staff regarding his MRI and his urine sample (which was negative for controlled substances), the recording in the evidentiary record ends before T.B. actually met with Applicant.[8] *See generally* GX 31. However, the undercover officer submitted a declaration summarizing his visit with Applicant. Therein, the Officer stated that Applicant said to him, '' 'I understand you are having some chronic low back pain,' despite the MRI I provided of my neck.'' GX 30, at 2. The Officer further stated that Applicant then asked if he ''had any success with pain relief in the past''; the Officer ''told [Applicant] that [he had] taken oxycodone, and that worked.'' *Id.* According to the Officer, Applicant ''then placed a stethoscope on [his] chest and back,'' after which Applicant wrote him prescriptions for 120 Roxicodone 15mg, 180 Roxicodone 30mg, as well as Motrin. *Id., see also* GX 33.

T.B.'s patient file includes both an intake form and a pain management treatment plan. While the first form includes entries for T.B.'s chief complaint and ''examination and symptom findings,'' here again, most of the entries are illegible. GX 7, at 15. As for the second form, it contains a ''yes'' checkmark next to the entries indicating that a pain survey was taken, that non-medication treatment of heat/cold was recommended, that risks and benefits were discussed, that a patient drug test was completed, and a ''no'' checkmark indicating that neither specialist consultations nor additional evaluations or tests were recommended; there are also two two-word long handwritten notes under the medical diagnosis and dates of appointment which are illegible. *Id.* at 3–6. However, nearly every other line and entry is blank. *Id.*

The record also includes the medical file of D.V., a thirty-four year old male, who was under Applicant's care for approximately thirteen months. On January 1, 2012, D.V., who had received several controlled substance prescriptions from Applicant only days

[7] There is, however, no evidence that Applicant ever made this Statement to M.C. during his September 8, 2011 visit. *See* GX 19, at 1–2; *see also* GX 18.

[8] The record also contains an exhibit which purports to be a transcript of the meeting between TB and Applicant. The record, however, contains no statement establishing that the transcript is reliable and accurate.

before, died of ''acute combined drug toxicity.'' *See generally* GX 37 (Patient File), GX 38 (Medical Examiner's Cause of Death Report), GX 39 (Autopsy).

D.V.'s patient file included medical records from his initial visit in June 2010 to AFM (then called the ''Center for Wellness and Weight Loss'') through his final visit on December 27, 2012. GX 37. D.V. was initially seen by a different physician who recorded ''low back pain and left lower extremity radiculopathy'' as D.V.'s chief complaint. GX 37, at 113. His patient file included two MRI reports from March 2006, and a prescription record from Holiday CVS dated January 2010 through June 14, 2010. *Id.* at 115–121.

D.V. first saw Applicant on November 9, 2010. *Id.* at 102. According to the records for this date, Applicant issued D.V. prescriptions for 210 Roxicodone 30mg, 90 Roxicodone 15mg, and 30 Xanax 2mg.[9] *Id.* at 103. While most of the notes on the intake form for the visit are illegible, the notes state that D.V.'s ''CC'' (chief complaint) was ''chronic LBP'' (chronic lower back pain). Under ''Examination and Symptom Findings,'' the notes list D.V.'s weight as ''265 lbs'' and blood pressure as ''162/90.'' The findings further state: ''he also notes good pain relief with current meds . . . overall feels well.'' *Id.* at 102.

On December 8, 2010, D.V. again saw Applicant as a follow-up for ''chronic LBP.'' *Id.* at 99. The Intake Form notes which are legible read: ''overall feels well . . . tolerating pain meds'' and ''Back full ROM [symbol] tenderness. . . .'' *Id.* Applicant wrote that the treatment plan was to ''continue meds,'' which were listed as 210 Roxicodone 30mg, 80 Roxicodone 15mg and 80 Xanax 2mg. GX 37, at 100. However, the file does not contain copies of the prescriptions or a discharge summary for this visit. *Id.*

On December 28, 2010, D.V. again saw Applicant, who documented a diagnosis of chronic LBP and anxiety. GX 37, at 98. The physician's handwritten notes state: ''Overall feels well . . . good pain relief with current meds . . . does report running out of 15mg Roxicodone.'' *Id.* The notes also list D.V.'s weight at ''278 lbs'' and blood pressure as ''180/116.'' *Id.* The Discharge Summary lists the prescriptions issued that date as 210 Roxicodone 30mg, 120 Roxicodone 15mg, 90 Xanax 2mg, and Motrin. *Id.* at 97.

D.V. returned to AFM on a monthly basis for his ''chronic LBP'' throughout 2011. *Id.* at 49–96. Throughout this period, Applicant repeatedly issued D.V. prescriptions on a monthly basis providing 210 Roxicodone 30mg, 90 or 120 Roxicodone 15mg, and 60 or 90 Xanax 2mg. Also, on multiple dates, Applicant provided additional prescriptions or early refills.

For example, on August 30, 2011, Applicant issued D.V. prescriptions for 210 Roxicodone 30mg, 120 Roxicodone 15mg, and 60 Xanax 2mg. *Id.* at 69. Yet on September 6, Applicant wrote D.V. a script for an additional 180 Roxicodone 30mg, followed by a script on September 13 for 180 Percocet 10/325, a schedule II drug combining oxycodone and acetaminophen. *Id.* at 67–68. Yet only three days later, Applicant issued D.V. a further script for 180 Roxicodone 30mg. *Id.* at 66.

Indeed, during the 63-day period between D.V.'s August 30, 2011 visit and his next appointment on November 1, 2011, the record shows that Applicant issued D.V. prescriptions totaling 738 tablets of Roxicodone 30mg, 390 tablets of Roxicodone 15mg, 300 Percocet 10/325 mg, and 180 Xanax 2mg. *Id.* at 62–69. Per Applicant's dosing instruction of one Roxicodone 30mg tablet every 4–6 hours, even if D.V. took one tablet every 4 hours, he still would have used only 378 tablets in that 63 day period, leaving 360 tablets unaccounted for. As for the Xanax, based on the dosing instruction of one tablet every twelve hours, D.V. would have had 60 tablets remaining. Yet, at D.V.'s November 1st visit, Applicant provided him with prescriptions for 180 Roxicodone 30mg, 120 Roxicodone 15mg, 60 Percocet 10/325, and 60 Xanax. *Id.* at 59.

Regarding Applicant's prescribing to D.V. during this period, the Government's Expert found that ''[t]here is no documentation in the history as to why the additional prescriptions had been provided to the patient between that visit of 11/01/2011 and the previous visit of 8/30/2011.'' GX 35, at 12. There is, however, a Sheriff's Office Event Report which establishes that on September 30th, D.V. was a passenger in a car which was followed by the Sheriff's Office as it left Applicant's clinic and was stopped after its driver ran a stop sign. GX 37, at 9. During the traffic stop, the Officers learned that D.V. was on probation; D.V. consented to a search of his person, during which the Officers found a clear orange pill bottle which contained twenty-seven tablets of oxycodone 30mg; the vial's label was partially torn off and the remaining information ''was unreadable.'' *Id.* The Officers also seized D.V.'s prescriptions for oxycodone 15mg, alprazolam 2mg, and Motrin. *Id.* D.V. ''was released and given a case number for the pills and prescriptions.'' *Id.*

There is also a one-page document in the file, which is titled: ''[D.V.] Medication Report.'' *Id.* at 6. The document lists the dates of the various oxycodone prescriptions Applicant wrote between August 2 and October 6 and contains various notations as to why several of the prescriptions were issued. *Id.* For example, the document states that D.V. could not fill the August 30 prescription for 210 oxycodone 30mg and that he turned in the prescription, thus suggesting the reason why Applicant issued him a prescription for 180 oxycodone 30mg on September 6. *Id.* Yet the document also includes a notation that the reason Applicant issued D.V. a prescription for 120 oxycodone 15mg on September 29 was because the police had taken D.V.'s prescription (dated September 27) for 138 oxycodone 30mg. *Id.* The reliable evidence shows, however, that the police did not take this prescription but rather the September 29 prescription for 120 oxycodone 15mg. *Id.* Moreover, the handwriting is markedly more legible than that on the various intake forms, thus suggesting that Applicant did not create the document.

On November 29, D.V. again saw Applicant, who noted on the Intake Form: ''pt reports good pain relief with current meds . . . tolerates meds well overall feels well . . . Back full ROM.'' *Id.* at 57. According to a Discharge Summary, which was printed at 12:16 p.m., Applicant prescribed 180 Roxicodone 30mg, 120 Roxicodone 15mg, 60 Xanax 2mg, and Motrin.[10] GX 37, at 56.

On December 9, 2011, Applicant issued D.V. a prescription for 100 tablets of Roxicodone 15mg. *Id.* at 55. There are, however, no notes in D.V.'s file bearing this date.[11]

On December 27, D.V. made his next and last visit. On the Intake Form, Applicant wrote: ''pt states good pain relief with current meds . . . tolerates meds well . . . overall feels well.'' *Id.* at 51. An unsigned, undated, handwritten note in the file states ''Due for urine.'' *Id.* at 50. Applicant issued D.V. prescriptions for 180 Roxicodone 30mg, 120 Roxicodone 15mg, 40

[9] The record does not include copies of DV's actual prescriptions, but does contain Discharge Summaries which correspond to office visit records and list medications prescribed by Applicant.

[10] The file contain a second discharge summary for the same date which was printed at 3:08:57 p.m., and which documents that Applicant issued DV prescriptions for 180 Roxicodone 30mg, 120 Percocet 10/325mg, 60 Xanax 2mg, and Motrin. It is unclear, however, whether these were additional prescriptions beyond those listed in the first discharge summary. GX 37, at 54.

[11] An undated, unsigned handwritten note in the file states ''trade in 50 30's and get 100 15s.'' *Id.* at 53.

Percocet 10/325mg, 60 Xanax 2mg, and Motrin. *Id.* at 49.

As found above, on January 1, 2012, D.V. ''died as a result of acute combined drug toxicity.'' GX 39, at 1. The medical examiner's toxicology report found that D.V.'s blood was positive for alprazolam, cocaine, diazepam, methadone, and oxycodone. *Id.* at 5. The Medical Examiner's Cause of Death Report states that D.V.'s family reported that he was ''currently taking Xanax and Oxycodone . . . and had been addicted to pain medications for a number of years for treatment of back pain and a shoulder injury, but all incidents were remote and full recovery was reached.'' GX 38, at 1. On the date of his death, D.V. ''was drinking alcohol throughout the day while continuing to take his daily Xanax and Oxycodone regimen [that] he was prescribed.'' *Id.* at 2.

The Expert's Report

The medical files of the three undercover officers and patient D.V. were reviewed by the Government's Expert, Mark Rubenstein, M.D. Dr. Rubenstein, who is licensed in Florida, Maryland, and Virginia, is a diplomate of the American Board of Physical Medicine and Rehabilitation with a subspecialty certificate in Pain Medicine; a Fellow of the American Academy of Physical Medicine and Rehabilitation; a diplomate of the American Academy of Pain Management; and has held positions with several pain and rehabilitation clinics. GX 34. He has also held various appointments, including that of clinical professor at several medical schools, and has made numerous presentations on the treatment of injuries and chronic pain. *Id.*

Using the Florida Standards for the Use of Controlled Substances for [the] Treatment of Pain, *see* Fla. Admin. Code r. 64B15–14.005, Dr. Rubenstein reviewed the patient files of the undercover officers and D.V. and evaluated Applicant's controlled substance prescribing practices. He then provided a report with his conclusions. *See* GX 35, at 1.

Regarding T.B., Dr. Rubenstein found that the patient file ''showed no objective abnormality for the chief complaint of low back pain.'' *Id.* He noted that ''the only objective abnormality contained within the file was a cervical MRI scan, but the patient's complaints as per the physician were chronic low back pain.'' *Id.* Yet there was ''no documentation of any musculoskeletal or neurologic examination germane to the neck or back region.'' *Id.* at 4.

Dr. Rubenstein further found that Applicant failed to do a ''a complete history and physical examination'' and ''therefore, there was no justification for the use of high doses of opioids, specifically high quantities of Roxicodone 15 and 30mg, with no other treatment alternatives afforded to the patient other than Motrin 800 mg.'' *Id.* Dr. Rubenstein also observed that:

> [T.B.]'s initial drug screen was negative, indicating he was either opioid naïve or clearly not using any opioid medications demonstrating any tolerance at the initial visit, therefore it would be considered inappropriate to initiate a dose of Roxicodone 30 mg every four to six hours for a patient who is not using same . . . this dose would be aggressive, excessive and place the patient at risk for drug toxicity or overdose including respiratory depression. *Id.*

Dr. Rubenstein thus concluded that Applicant's treatment ''represents a deviation from the standard of care in pain medicine.'' *Id.* He also observed that the physician's handwriting and medical records were not legible, which would ''be a deviation from the Florida statutes for the standards of adequacy of medical records, as well as a deviation from the standards for the use of controlled substances for the treatment of pain.'' *Id.*

With regard to M.C., Dr. Rubenstein found that the only objective pathology was an MRI of the lumbar spine showing only some disc bulging. *Id.* at 6. Yet, ''[t]here was no documented detailed neurologic or musculoskeletal exam, and the only follow-up visits were [sic] a neurologic exam is even referenced indicated that the neurologic exam was ''intact.'' '' *Id.* According Dr. Rubenstein, ''[t]he medical records are lacking legibility, and clearly a detailed history and physical was not performed or documented by the physician.'' *Id.*

Dr. Rubenstein observed Applicant ''offered the patient only medications with no other treatment alternatives for a complaint of chronic low back pain.'' *Id.* at 6. He further observed that while M.C.'s ''initial urine drug screen was completely negative'' and ''there was no documented history of using medications from other providers and no records of same,'' Applicant prescribed M.C. ''Roxicodone 30mg to take every four to six hours.'' *Id.*

Dr. Rubenstein explained that ''[t]his would be an inappropriate dose for an opioid naïve patient'' and ''would be considered excessive for a young male who had no significant pathology documented from an objective perspective.'' *Id.* He then noted that ''[t]here were no follow-up [sic] urine screens to ensure compliance with the medication regimen.'' *Id.*

Dr. Rubenstein further observed that there were no treatment alternatives afforded to the patient for his back pain, such as physical therapy, injection therapy, activity modification and non-opioid alternatives other than Motrin. *Id.* He also noted that on October 11, 2011, Applicant added Roxicodone 15mg to M.C.'s medications, and that M.C. ''may have been taking up to six Roxicodone 30mg tablets and six 15mg tablets for a total of 270mg of oxycodone daily if the full dose was utilized.'' *Id.* Yet there was no documentation ''as to why the Roxicodone 15mg was being added, and especially why an additional 160 of these tablets were recommended.'' *Id.* at 5.

As for the Xanax 2mg prescription which Applicant provided on M.C.'s last visit, Dr. Rubenstein observed that this would be excessive for an initial starting dose. *Id.* at 6. He further noted that ''[t]here was no mental health consultation or other documented abnormal mental status exam to have even warranted such a dose.'' *Id.*

Next, Dr. Rubenstein noted that Applicant violated the standards for the adequacy of medical records by not keeping legible medical records. *Id.* Finally, he concluded that Applicant violated the Florida standards for the use of controlled substances in treating pain, because he did not perform a detailed history and physical, use appropriate consultations for treatment objectives, keep accurate and complete medical records, or individualize treatment. *Id.* As such, this represented a deviation from the standard of care in pain medicine. *Id.*

As for B.O., Dr. Rubinstein found that he presented with low level back pain and an MRI showing only some disc bulging and facet hypertrophy. *Id.* at 8. Yet Applicant did not perform a ''detailed physical examination'' to include a musculoskeletal or neurologic exam. *Id.*

Dr. Rubinstein also found that Applicant did not take a detailed history of B.O.'s pain. *Id.* While Dr. Rubenstein acknowledged that the file included a completed pain questionnaire, ''it was not even specific to low back pain.'' *Id.* Moreover, while the MRI listed a referring physician of Robert Green, there were no records in the chart from prior physicians and there was ''no information in the chart'' that Applicant ''attempt[ed] to discern what had been done by [Dr. Green] or any other providers in the past.'' *Id.* According to Dr. Rubenstein, ''[t]here was not nearly enough documentation on physical exam to support any diagnosis other

than 'chronic low back pain,' which is a generic diagnosis and not specific for a neurologic or musculoskeletal abnormality.'' *Id.* There was also no documentation that Applicant had considered alternative treatments ''such as physical therapy, referral to a spine specialist, non-opioid alternatives such as medications or other agents, injection therapy, [or] exercise specifically for lumbar stabilization.'' *Id.*

Dr. Rubenstein further noted that B.O.'s initial urine drug screen was negative and thus ''there was clearly no basis to initiate a dose of Roxicodone 30mg every four to six hours.'' *Id.* Dr. Rubenstein then observed that ''[t]his dose would be considered excessive, aggressive, and placed the patient at risk for drug overdose or drug toxicity.'' *Id.* Based on his conclusion that Applicant had failed to perform an adequate history and physical examination, Dr. Rubenstein concluded that Applicant breached the standard of care for pain medicine and violated Florida rule 64B8–9.013 when he prescribed Roxicodone 30mg at B.O.'s first visit. *Id.* at 9.

Dr. Rubenstein also noted that Applicant's physical exam notes were illegible and lacked ''sufficient detail to document why the course of treatment was undertaken.'' *Id.* Thus, he concluded that Applicant violated Florida's regulation governing the ''Standards of Adequacy of Medical Records.'' *Id.*

Dr. Rubenstein reviewed D.V.'s patient file and the medical examiner's report. He described D.V.'s file as ''[d]isconcerting.'' *Id.* at 15. He found that the only imaging study was a 2006 MRI and there was ''no attempt to obtain previous medical records for his pain management.'' *Id.* at 16. He then noted that

> The young male with a history of chronic low back pain and no focal neurologic abnormality [was] given high doses of Roxicodone, oxycodone, and alprazolam. There was never any documented mental status examination, referral for treatment of anxiety, specialist referral for evaluation of back pain, etc. There were no consults with other specialists, no consideration of treating drug dependence or addiction, and no treatment alternatives [were] afforded to the patient. There was no documentation as to any history of shoulder pain or evaluation of same despite the . . . medical examiner's report indicating presence of same that initiated [D.V.'s] drug dependence and drug addiction. There was no attempt to recognize [D.V.'s] drug addiction . . . and no serial drug monitoring to ensure the prescriptions were being utilized appropriately. No attempts were made . . . to reliably reduce the risk of drug diversion, such as urine drug screens to ensure compliance. . . . Had drug screens been performed . . . then a proper treatment protocol may have been afforded to the individual.

Id. at 15–16.

Dr. Rubinstein further observed that while Applicant documented on the ''Pain Management Treatment Plan'' form that drug testing had been completed at several of D.V.'s visits, there were no drug test results in the file. *Id.* at 13–14. Dr. Rubinstein thus explained that Applicant's documenting that monitoring had been performed when there were no test results in D.V.'s file ''represents improprieties in the medical records themselves.'' *Id.* at 16.

Dr. Rubinstein also observed that D.V.'s weight rendered him obese and yet Applicant never addressed this issue or his intermittent hypertension with him. *Id.* Moreover, D.V. ''was clearly either drug dependent, drug addicted, or drug diverting and no attempts were made to address those issues'' with him. *Id.*

Dr. Rubenstein thus concluded that Applicant did not meet ''the standard of care for pain medicine in prescribing such high doses of medications with the frequency performed to this individual.'' *Id.* He further found that Applicant deviated ''from the Standards for the Use of Controlled Substances for the Treatment of Pain by failing to perform periodic reviews, ensure compliance, obtain consultations for the evaluation of ongoing back pain, and by fail[ing] to provide any treatment alternatives to opioid medications and high-dose benzodiazepines.'' *Id.*

Dr. Rubinstein thus found that Applicant deviated from the standard of care in pain medicine with respect to each of the undercover officers and D.V. He further concluded that the prescriptions Applicant issued ''for these individuals were issued for other than a legitimate medical purpose and would be considered outside the usual course of professional practice.'' GX 35, at 1.

Other Evidence

In preparation for the previous Order to Show Cause proceeding, Investigators reviewed prescription data from the Florida Prescription Monitoring Program (PDMP), as well as pharmacy records from various states, including Florida. GX 8, at 3–4 (Declaration of Diversion Investigator). They also obtained from several pharmacies some of the prescriptions which Applicant had authorized between July 2010 and June 3, 2011. *Id.* at 3. As found above, when Applicant applied for a new registration in October 2009, he sought authority to dispense only schedule II narcotics. Accordingly, the Agency issued him a registration which authorized him to dispense schedule II narcotics but no other controlled substances. Thus, Applicant did not have authority to dispense non-narcotic schedule II controlled substances or any controlled substances in schedules III, IV, and V.

According to the declaration of an Agency Investigator, various records show that during this period, Applicant issued approximately 1,116 prescriptions, which authorized the dispensing of approximately 85,432 dosage units of controlled substances in drug schedules 2N (non-narcotic), 3, 4, and 5. *Id.* at 3–4.

Included in the evidentiary record are fifteen prescriptions for Xanax, a schedule IV controlled substance, five prescriptions for Adderall, a schedule 2N controlled substance, and two prescriptions for Valium, a schedule IV controlled substance, which Applicant issued between November 30, 2010 and May 24, 2011. GX 9.

The record also includes a computer-generated sixteen (16) page document, which lists various prescriptions for drugs such as alprazolam, diazepam, phentermine, zolpidem, and amphetamine salts issued by Applicant between July 2, 2010 and June 3, 2011, along with the names of the patients (and their city of residence) and the dispensing pharmacy (and city where located). *See* GX 40. While in the record's Table of Contents, the Government refers to this document as ''Chart and PDMP Report for Respondent's Prescribing Outside Registration (19 pages),'' GX Table of Contents, the document bears no label identifying it as such. Moreover, while an Investigator stated that she had had reviewed Florida PDMP records, her affidavit does not identify this document as being part of the PDMP records she reviewed. *See generally* GX 8.

Discussion

Section 303(f) of the Controlled Substances Act provides that an application for a practitioner's registration may be denied upon a determination ''that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the CSA requires the consideration of the following factors:

> (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.

Id.

''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.* Moreover, it is well established that I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Kevin Dennis, M.D.,* 78 FR 52787, 52974 (2013); *MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011).

Furthermore, under Section 304(a)(1), a registration may be revoked or suspended ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1). DEA has long held that the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See Anthony D. Funches,* 64 FR 14267, 14268 (1999); *Alan R. Schankman,* 63 FR 45260 (1998); *Kuen H. Chen,* 58 FR 65401, 65402 (1993). Thus, the allegation that Respondent materially falsified his application is properly considered in this proceeding. *See Samuel S. Jackson,* 72 FR 23848, 23852 (2007). The Government bears the burden of proof in showing that the issuance of a registration is inconsistent with the public interest. 21 CFR 1301.44(d).

The Material Falsification Allegation

As found above, on October 1, 2008, the Florida Department of Health entered an emergency suspension of Applicant's Florida medical license, on the basis of his history of alcohol dependency and his failure to comply with the DOH's orders which required the monitoring of his medical practice. GX 10, at 10. In March 2009, the DOH re-instated his medical license. Applicant, however, allowed his DEA registration to expire on May 31, 2009.

On October 5, 2009, Applicant applied for a new DEA registration and provided a ''no'' answer to the third liability question, which asked whether he had previously had a state professional license revoked or suspended. GX 4, at 10. Applicant's answer was clearly false, and knowingly so, as the DOH had suspended his medical license on October 1, 2008 and Applicant's license was not reinstated until March 26, 2009. Moreover, Applicant also provided a ''no'' answer to question three on the applications he filed on May 22, 2012 and January 4, 2013. Thus, Applicant has submitted three applications in which he provided a false answer to question three.

Congress did not, however, grant the Agency authority to revoke an existing registration or deny an application based on any falsification, but rather, only those which are material. *See* 21 U.S.C. 824(a)(1). As the Supreme Court has explained, ''[t]he most common formulation'' of the concept of materiality ''is that a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed.'' *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); *see also United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770). The Supreme Court has further explained that ''[i]t has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, *or even that it would more likely than not have triggered an investigation.*'' *Kungys,* 485 U.S. at 771 (emphasis added). Rather, the test is ''whether the misrepresentation or concealment was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.'' *Id.* '' '[T]he ultimate finding of materiality turns on an interpretation of substantive law,' '' *id.* at 772 (int. quotations and other citation omitted), and must be met ''by evidence that is clear, unequivocal, and convincing.'' [12] *Id.*

As the above makes clear, the relevant decision for assessing whether a false statement is material is the Agency's decision as to whether an applicant is entitled to be registered (or in the case of a current registrant, remain registered). Thus, because possessing authority to dispense controlled substances under the laws of the State in which a physician practices medicine is a requirement for holding a DEA registration, *see* 21 U.S.C. 802(21) & 823(f), a false answer to question three is material where an applicant no longer holds authority to practice medicine (regardless of the reason for the State's action) or authority to dispense controlled substances, as well as where the State has placed restrictions on a practitioner's authority to prescribe controlled substances. So too, because in determining whether an application should be granted, Congress directed the Agency to consider the five public interest factors, even where an applicant currently holds unrestricted state authority to dispense controlled substances, the failure to disclose state action against his medical license may be material if the action was based on conduct (or on the status arising from such conduct, *i.e.,* a conviction for a controlled substance offense or mandatory exclusion from federal health care programs) which is actionable under either the public interest factors or the grounds for denial, suspension, and revocation set forth in section 824. *See Scott C. Bickman,* 76 FR 17694, 17701 (2011) (holding that failure to disclose state probation was not material where probation was based on an act of medical malpractice and did not involve controlled substances).

Here, citing *Bickman,* the Government contends that Applicant's falsification is material because the Florida DOH concluded that as a result of his dependency on alcohol, ''his 'continued practice as an osteopathic physician constitute[d] an immediate serious danger to the health, safety, and welfare of the public' '' and that '' '[n]othing short of suspending [his] license will adequately protect the public.' '' Req. for Final Agency Action, at 14. Had Applicant's state license been suspended at the time he filed any of his DEA applications, his answer to question three would have been materially false because he would have lacked authority to dispense controlled substances and would not have been entitled to be registered.[13] But it wasn't.

[12] While *Kungys* involved a denaturalization proceeding, in other civil proceedings, courts have required that a party establish that a falsification is material by ''clear, unequivocal, and convincing evidence'' and not simply by a ''preponderance of the evidence.'' *Driscoll* v. *Cebalo,* 731 F.2d 878, 884 (Fed. Cir. 1984). In any event, the Government has produced no evidence as to why the statement is material.

[13] Citing *Bickman,* the Government argues that ''[a] falsification is material if the state medical board 'concluded that Respondent's conduct posed such a risk to patients as to warrant the suspension or revocation of his medical license (and authority to prescribe controlled substances under [s]tate law).'' Gov. Req. for Final Agency Action, at 14. The quoted language, however, does not support the Government's contention as it served only to distinguish Bickman's circumstance of having been placed on probation by his state board from that which would have existed had his state license been suspended or revoked at the time he submitted his application. As explained above, because

Moreover, the Government makes no argument that had Applicant truthfully disclosed the State's suspension, it would have uncovered information that he had committed actionable misconduct under the public interest standard or the other grounds provided in 21 U.S.C. 824(a). Indeed, the State's suspension order made no allegation that Applicant engaged in misconduct actionable under the public interest standard (whether resulting in a criminal conviction or not) or that he was convicted of an offense subjecting him to mandatory exclusion from federal health care programs. *See id.* Rather, the DOH's Order was based on its conclusion that Applicant is an alcoholic. Notably, the DOH made no allegation that Applicant was also a drug abuser and the Government cites no decision in which this Agency has denied the application of a physician, who was then duly authorized by the State in which he/she practiced to dispense controlled substances, on the sole ground that the physician was an alcoholic. Accordingly, I reject the allegation. *Hoi Y Kam,* 78 FR 62694, at 62696 (2013); *see also* Scott C. Bickman, 76 FR 17694, 17701 (2011).

The Public Interest Allegations

The Government alleges that granting Applicant's registration would be inconsistent with the public interest based on his conduct which is relevant in assessing his experience as a dispenser of controlled substances (Factor Two) and his compliance with applicable laws related to controlled substances (Factor Four).[14] More specifically, the Government contends that Applicant violated the CSA in two respects. First, he issued prescriptions to three undercover officers and D.V. which lacked a legitimate medical purpose in violation of the CSA's prescription regulation. Second, he issued controlled substances prescriptions for drugs he was not authorized to prescribe under his registration. I agree.

Factors Two and Four

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of the closed regulatory system, a controlled substance may only be dispensed upon a lawful prescription issued by a practitioner. *Carlos Gonzalez, M.D.,* 76 FR 63118, 63141 (2011).

Fundamental to the CSA's scheme is the Agency's longstanding regulation, which provides that ''[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.*

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 drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (*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) (stating that the prescription requirement likewise 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.'' *Ralph J. Chambers,* 79 FR 4962 at 4970 (2014) (citing *Paul H. Volkman,* 73 FR 30629, 30642 (2008), *pet. for rev. denied Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009)); *see also Moore,* 423 U.S. at 142–43 (noting that evidence established that the 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''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Volkman,* 73 FR 30642.

Pursuant to Florida Stat. § 456.44(3)(a), a ''complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record.'' Moreover, ''the medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse.'' *Id.* This section also requires a physician to develop a written plan for assessing ''each patient's risk for of aberrant drug-related behavior, and monitor that risk on an ongoing basis in accordance with the plan.'' *Id.; see also* Fla. Admin. Code r. 64B15–14.005(3)(a).

The Government also cites to the Florida Standards for the Use of Controlled Substances for Treatment of Pain. One of the Standards states that ''osteopathic physicians should be diligent in preventing the diversion of drugs for illegitimate purposes,'' and that ''all such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.'' Fla. Admin. Code r. 64B15–14.005(1)(d) & (e).

possessing state authority is a requirement for obtaining a DEA registration, failing to disclose a continuing state suspension (or a revocation order which remains in effect) is always material. *See* 21 U.S.C. 802(21) & 823(f)). By contrast, whether the failure to disclose a suspension which has since terminated is material depends upon the basis of the State's action.

[14] As for factor one—the recommendation of the state licensing board—it is undisputed that Applicant holds a current license as an osteopathic physician in the State of Florida and possesses state authority to dispense controlled substances. While Respondent therefore meets an essential prerequisite for obtaining a registration under the CSA, 21 U.S.C. 823(f), DEA has held repeatedly that a practitioner's possession of State authority is not dispositive of the public interest determination. DEA maintains a separate oversight responsibility with respect to the handling of controlled substances and has a statutory obligation to make its independent determination as to whether the granting of such privileges would be in the public interest. *Mortimer Levin,* 57 FR 8680, 8681 (1992). Thus, neither a State's failure to take action against a registrant's medical license, nor a State's restoration of a practitioner's prescribing authority, is dispositive in determining whether or not an application should be granted. *See Jayam Krishna-Iyer,* 74 FR 459, 461 (2009); *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As for factor three, there is no evidence that Respondent has been convicted of an offense ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

As found above, upon reviewing the patient files of the undercover officers as well as D.V., the Government's Expert found that Applicant issued controlled substances for other than a legitimate medical purpose and outside the usual course of professional practice. As support for his conclusion, the Expert observed that Applicant failed to perform detailed histories and adequate physical examinations, failed to develop any treatment plan other than to prescribe controlled substances, prescribed large and excessive doses of controlled substances, failed to properly monitor patients, and failed to keep legible and complete medical records. I agree with the Expert's analysis and conclude that Applicant knowingly diverted controlled substances including oxycodone (schedule II) and alprazolam (schedule IV) to the undercover officers and D.V. and thus violated federal law. 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a). I further find that Applicant's misconduct was egregious. This finding provides reason alone to deny Applicant's application.

However, the record also supports the conclusion that Applicant exceeded the authority of his registration by prescribing controlled substances in schedules which were outside the scope of his registration. Pursuant to 21 U.S.C. 822(b), ''[p]ersons registered by the Attorney General . . . to . . . dispense controlled substances . . . are authorized to possess . . . or dispense such substances . . . *to the extent authorized by their registration.*'' (emphasis added).

As found above, on October 5, 2009, Applicant applied for a new registration as a practitioner. Notwithstanding that the application form clearly instructed him to check all drug schedules for which he sought authority, Applicant checked the box for only schedule II narcotics. Accordingly, the Agency granted him a registration which was limited to schedule II narcotics. Applicant did not seek authority to dispense controlled substances in the additional schedules until June 6, 2011.

Thus, between October 6, 2009 (the date the application was granted) and June 6, 2011, Applicant could not lawfully prescribe any controlled substances outside of those narcotics in schedule II. The record, however, contains fifteen prescriptions for Xanax (alprazolam) and two prescriptions for Valium (diazepam), both of which are schedule IV controlled substances, as well as five prescriptions for Adderall (amphetamine), a schedule II non-narcotic, which Applicant issued without authority to do so. Even though Applicant eventually obtained a registration for the remaining drug schedules, Applicant was responsible for ensuring that he had obtained the necessary authority for each schedule of controlled substances he intended to dispense. I thus conclude that Applicant violated federal law by dispensing controlled substances for which he lacked authorization. 21 U.S.C. 822(b) & 841(a)(1).

Accordingly, I find that the Government's evidence with respect to factor two and four establishes a *prima facie* case that granting Applicant's application ''would be inconsistent with the public interest.'' *Id.* § 823(f). Because Applicant failed to respond to the Show Cause Order, whether by requesting a hearing or submitting a written statement, and thus has failed to offer any evidence to the contrary, I will order that his application be denied.

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 application of Richard D. Vitalis, D.O., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: November 10, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014–27206 Filed 11–17–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 10:30 a.m., Friday, November 21, 2014.

PLACE: U.S. Parole Commission, 90 K Street NE., 3rd Floor, Washington, DC

STATUS: Closed.

MATTERS TO BE CONSIDERED: Determination on seven original jurisdiction cases.

CONTACT PERSON FOR MORE INFORMATION: Jacqueline Graham, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street NE., 3rd Floor, Washington, DC 20530, (202) 346–7001.

Dated: November 14, 2014.

Isaac Fulwood,

Chairman, U.S. Parole Commission.

[FR Doc. 2014–27444 Filed 11–14–14; 4:15 pm]

BILLING CODE 4410–31–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Certificate of Medical Necessity

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, ''Certificate of Medical Necessity,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 18, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201410-1240-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).